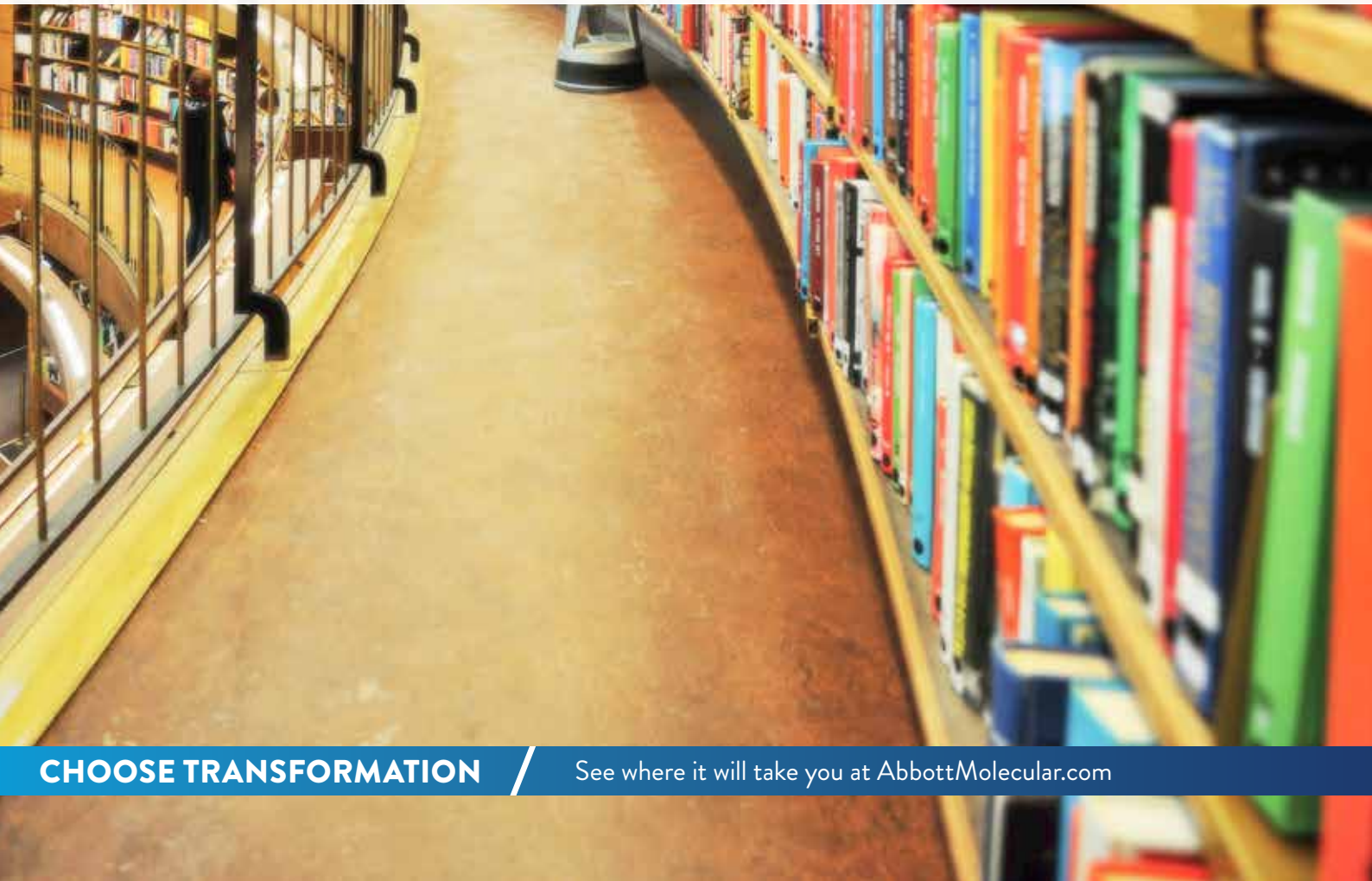
Abbott

# ABBOTT MOLECULAR ONCOLOGY AND GENETICS

2015-2016
Product Catalog



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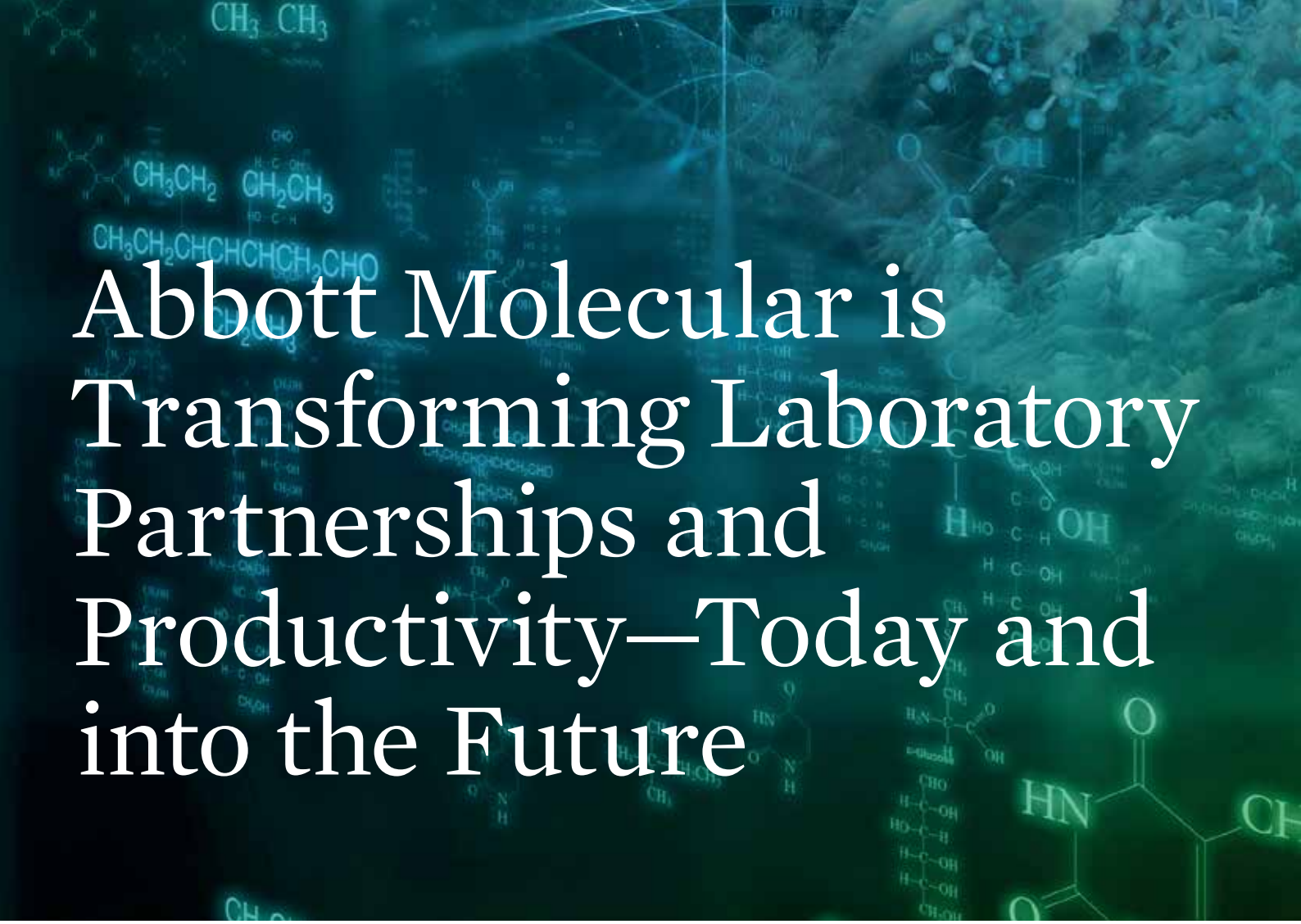
Please note some products may not be for sale in all markets. Contact your local representative for availability.

| | |
|---|---|
| **ASR (Analyte Specific Reagent)** | *Analytical and performance characteristics are not established* |
| **CE (CE Marked)** | *Conformité Européenne* |
| **GPR (General Purpose Reagent)** | *For Laboratory use* |
| **RUO (Research Use Only)** | *Not for use in diagnostic procedures* |

All products manufactured and/or distributed by Abbott Molecular should be used in accordance with the products' labeled intended use. Products labeled "Research Use Only" should be used for research applications, and are not for use in diagnostic procedures.



# Abbott Molecular is Transforming Laboratory Partnerships and Productivity—Today and into the Future

As a leader in molecular diagnostics, Abbott is committed to providing solution-oriented offerings built on FISH and PCR. Building on a proven track record of service to the worldwide community of researchers and clinicians, Abbott Molecular continues to deliver patented Vysis FISH technology and real-time PCR assays that enable your laboratory to partner with health care providers.

Our commitment to exploring new clinical frontiers is evident in the development and delivery of innovative systems and assay solutions that aid physicians in the diagnosis of disease, selection of therapies and monitoring of disease.

The new product offerings in this catalog and those coming throughout the remainder of 2015 have been designed in partnership with laboratories, directly incorporating the feedback we've gathered from you. These options expand the Vysis FISH portfolio and increase productivity by driving improvements in laboratory efficiency and enabling customization of solutions on a lab by lab basis.

### EXPERIENCE A FASTER, MORE COMPREHENSIVE CHROMOSOME SEARCH.

The Chromosome Search Tool at abbottmolecular.com has been transformed to provide faster access to the most up-to-date Vysis FISH probe information.

Clear guidance for laboratory professionals.

The Chromosome Search is a web-based tool that organizes all Vysis DNA FISH probes according to their chromosome and specific locus. Each of the 24 human chromosomes are listed by chromosome number and represented by a

chromosome ideogram (diagrammatic representation of a chromosome, as described in ISCN 19951). Each ideogram is illustrated at the 550 band level. Some ideogram bands may be further subdivided in order to provide greater resolution for purposes of graphic representation.

Chromosomes 1-22, X and Y are displayed at the top of the Chromosome Search web page. Each chromosome can be accesed by clicking on the corresponding chromosome number of interest. The web page will update to the chromosome selected and the following information will be displayed from left to right:

- Chromosome number and ideogram
- Locus designation
- Product name
- Fluorophore designation

"Mousing" over the probe produces a highlight on the ideogram corresponding to the specific product locus and fluorophore.

Additional quick links are embedded within each probe description and provide single click, direct access to:

- Associated FISH product page
- FISH hybridization images
- Product specific ideograms
- Direct on-line purchase (limited to countries where e-commerce is enabled)

*Visit the Apple iTunes store to download your copy!*

## FUNCTIONALITY AT THE TIP OF YOUR FINGERS.

Check out the Vysis FISH Chromosome Search iPad Application. Get fast and mobile access to the most up-to-date Vysis FISH probe information, organized according to their chromosome and specific locus. Each of the 24 human chromosomes are listed by chromosome number and represented by a chromosome ideogram illustrated at the 550 band level. This patented, interactive tool provides access from FISH probe descriptions directly to the following:

- FISH Probe Maps
- FISH Hybridization Images
- Associated product page and ordering information through links to this website

## DOWNLOAD A DIGITAL COPY OF THE ABBOTT MOLECULAR ONCOLOGY AND GENETICS CATALOG AT :

**www.AbbottMolecularOncologyCatalog.com**

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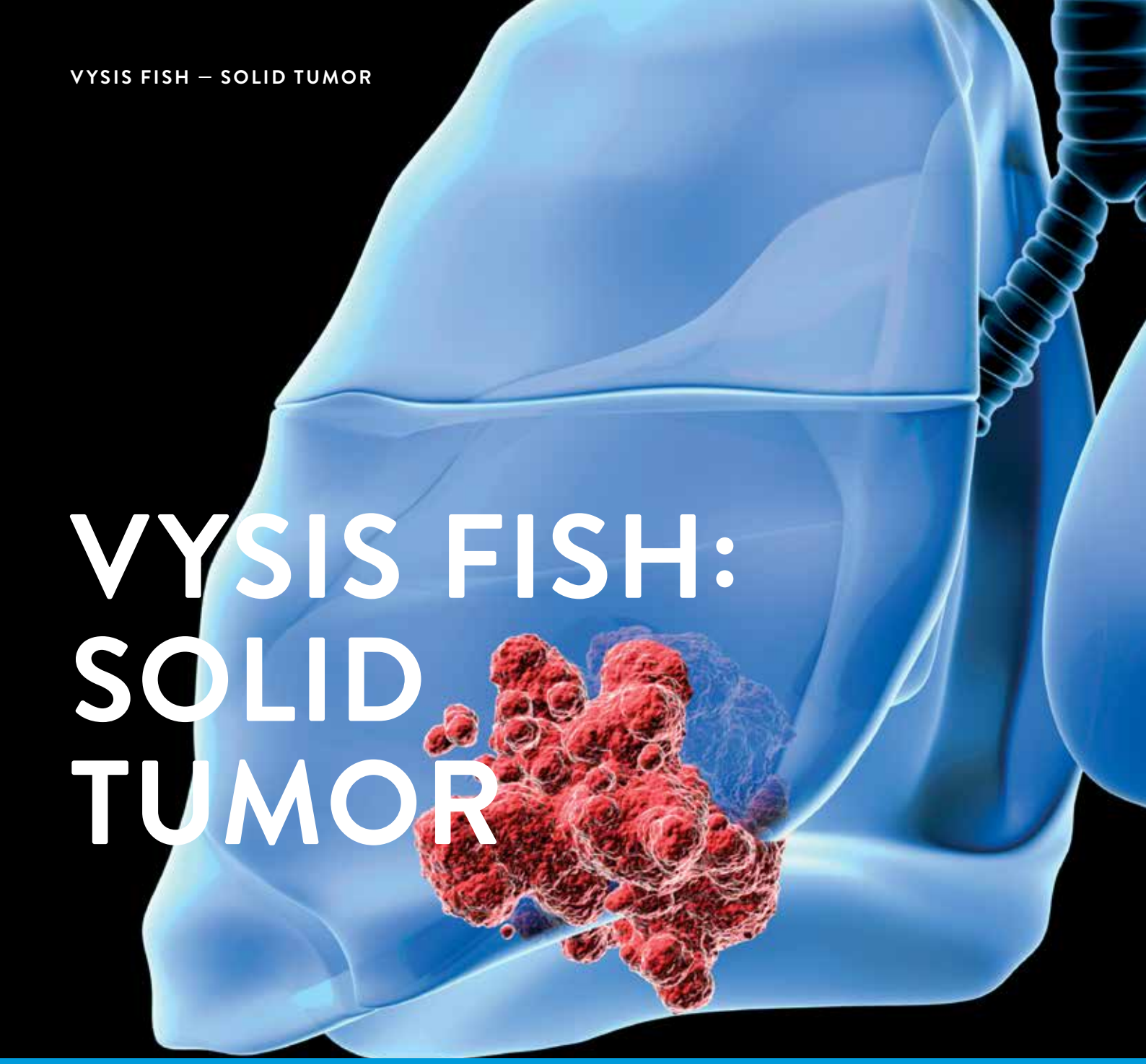
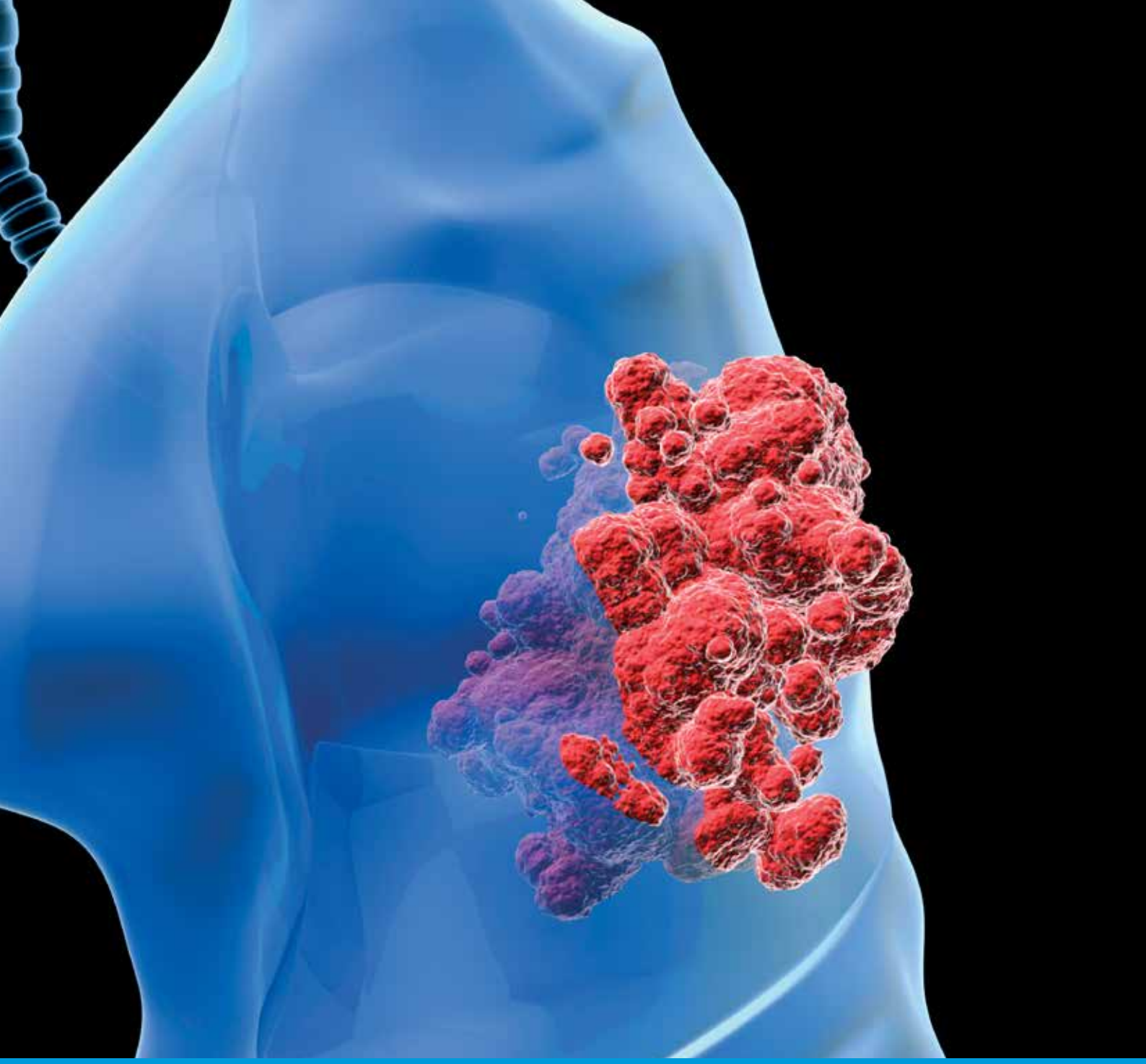


# VYSIS FISH: SOLID TUMOR

Accurate and reliable detection of genetic aberrations in solid tumors with DNA fluorescence in *situ* Hybridization (FISH) probe technology is a powerful means to aid in diagnoses and treatment decisions. Abbott Molecular offers a comprehensive line of direct-labeled Vysis DNA probes for solid tumor assessment. Single- and multi-color probe sets offer researchers and clinicians a variety of ways to identify chromosome or locus deletions, gains, or translocations that have been associated with specific types of solid tumors. These probes can be applied to a variety of sample types prepared for metaphase or interphase analysis.



## VYSIS FISH TECHNOLOGY FOR ONCOLOGY, CYTOLOGY, AND PATHOLOGY PROVIDES THE FOLLOWING ADVANTAGES:

- Specific high-intensity signals with direct-labelled probes.
- Low background for easy analysis.
- Rapid, convenient, and easy-to-use assays.
- Many probes designed for gene amplification detection include internal control probes.
- Protocols that offer hybridization as quickly as four hours on the HYBrite and ThermoBrite Denaturation and Hybridization System.
- Solid tumor probes have been optimized for paraffin-embedded tissues.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **BLADDER CANCER** | | | | |
| ProbeChek Control Slides for UroVysion Bladder Cancer Kit **(CE)** | 3 Slides | 02J27-010 | 00884999002111 | 14 |
| UroVysion Bladder Cancer Kit **(CE)** | 20 Assays | 02J27-020 | 00884999002135 | 14 |
| UroVysion Bladder Cancer Kit **(CE)** | 100 Assays | 02J27-099 | 00884999002197 | 14 |
| Vysis AURKA SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 05N93-020 | 00884999015470 | 17 |
| Vysis CDKN2A / CEP 9 FISH Probe Kit **(CE)** | 20 µL | 04N61-020 | 00884999009295 | 19 |
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 | 20 |
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 | 21 |
| **BREAST CANCER** | | | | |
| PathVysion **(FDA IVD)** | 20 Assays | 2J01-030 | 00884999001732 | 22 |
| PathVysion **(IVD Japan Only)** | 20 Tests | 2J01-031 | 00884999001749 | 25 |
| PathVysion **(FDA IVD)** | 50 Assays | 2J01-035 | 00884999001756 | 22 |
| PathVysion **(FDA IVD)** | 100 Assays | 2J01-036 | 00884999001763 | 22 |
| PathVysion HER-2 DNA Probe Kit II **(CE)** | 20 Assays | 06N46-030 | 00884999035867 | 25 |
| PathVysion HER-2 DNA Probe Kit II **(CE)** | 50 Assays | 06N46-035 | 00884999035874 | 25 |
| PathVysion HER-2 DNA Probe Kit II **(CE)** | 100 Assays | 06N46-036 | 00884999035881 | 25 |
| ProbeChek Control Slides for PathVysion HER-2 DNA Probe Kit - Cut-off Control Slides **(CE)** | 5 Slides | 02J04-030 | 00884999001831 | - |
| ProbeChek Control Slides for PathVysion HER-2 DNA Probe Kit - Normal Control Slides **(CE)** | 5 Slides | 02J05-030 | 00884999001855 | - |
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 | 27 |
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 200 µL | 01N35-020 | 00884999000773 | 29 |
| Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12-q24.13) **(CE)** | 20 µL | 03N87-020 | 00884999006256 | 30 |
| Vysis TOP2A / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N89-020 | 00884999006270 | 31 |
| Vysis TOP2A / HER-2 / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N90-020 | 00884999006287 | 32 |
| Vysis ZNF217 SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 05N15-020 | 00884999014602 | 34 |
| Vysis ZNF217 SpectrumOrange FISH Probe Kit **(CE)** | 20 µL | 03N91-020 | 00884999006294 | 34 |
| Vysis ZNF217 SpectrumRed FISH Probe Kit **(CE)** | 10µL | 05N16-010 | 00884999014619 | 34 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **GLIOMAS** | | | | |
| Vysis CDKN2A / CEP 9 FISH Probe Kit **(CE)** | 20 µL | 04N61-020 | 00884999009295 | 36 |
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 200 µL | 01N35-020 | 00884999000773 | 37 |
| Vysis LSI 1p36 / LSI 1q25 and LSI 19q13/19p13 Dual-Color Probe **(CE)** | 2 vials, 200 µL each | 04N60-020 | 00884999009288 | 38 |
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 | 41 |
| Vysis PTEN / CEP 10 FISH Probe Kit **(CE)** | 20 µL | 04N62-020 | 00884999009301 | 42 |
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 | 44 |
| **LUNG CANCER** | | | | |
| 10q26 FGFR2 SpectrumOrange/CEP 10 SpectrumGreen FISH Probe Kit **(RUO)** | 20 µL | 08N42-060 | 00884999042582 | 45 |
| ProbeChek ALK Negative Control Slides **(CE)** | 5 slides | 06N38-005 | 00884999025721 | 46 |
| ProbeChek ALK Positive Control Slides **(CE)** | 5 slides | 06N38-010 | 00884999025738 | 46 |
| Vysis ALK Break Apart FISH Kit **(IVD Japan Only)** | 20 Assays | 06N38-021 | 00884999035836 | 46 |
| Vysis ALK Break Apart FISH Probe Kit **(CE)** | 20 Assays | 06N38-020 | 00884999025745 | 46 |
| Vysis ALK Break Apart FISH Probe Kit (automation protocol) **(CE)** | 50 Assays | 06N38-50 | 00884999037205 | 46 |
| Vysis BRAF SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 06N09-020 | 00884999025028 | 48 |
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 200 µL | 01N35-020 | 00884999000773 | 49 |
| Vysis LSI EGFR SpectrumRed Probe **(ASR)** | 20 µL | 04N31-020 | 00884999008281 | 50 |
| Vysis LSI MYC SpectrumGold Probe **(ASR)** | 20 µL | 04N35-020 | 00884999008342 | 51 |
| Vysis LSI MYC SpectrumGreen Probe **(ASR)** | 20 µL | 04N36-020 | 00884999008359 | 52 |
| Vysis LSI NTRK1 Break Apart FISH Probe Kit **(RUO)** | 20 µL | 08N43-60 | 00884999042612 | 53 |
| Vysis LSI NTRK1 (Cen) SpectrumGreen Probe **(ASR)** | 20 µL | 08N43-030 | 00884999042605 | 54 |
| Vysis LSI NTRK1 (Tel) SpectrumRed Probe **(ASR)** | 20 µL | 08N43-020 | 00884999042599 | 55 |
| Vysis MET SpectrumRed FISH Probe Kit **(CE)** | 20 µL | 06N05-020 | 00884999024984 | 56 |
| Vysis PIK3CA SpectrumGreen FISH Probe Kit **(CE)** | 20 µL | 06N10-020 | 00884999034907 | 57 |
| Vysis ProbeChek ALK Negative Control II (only use with 06N38-50) **(CE)** | 5 slides | 06N38-006 | 00884999038196 | 46 |

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **MELANOMA** | | | | |
| Vysis Melanoma FISH Probe Kit **(CE)** | 200 µL | 01N89-020 | 00884999001312 | 58 |
| **OTHER CANCERS** | | | | |
| Vysis 6q22 ROS1 Break Apart FISH Probe **(RUO)** | 20 µL | 08N29-020 | 00884999037892 | 60 |
| Vysis 8p12 FGFR1 SpectrumRed/CEP 8 SpectrumAqua FISH **(RUO)** | 20 µL | 08N21-060 | 00884999038059 | 61 |
| Vysis 10q11 RET Break-Apart FISH Probe **(RUO)** | 20 µL | 08N31-060 | 00884999038097 | 62 |
| Vysis AURKA SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 05N93-020 | 00884999015470 | 63 |
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 | 65 |
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 200 µL | 01N35-020 | 00884999000773 | 67 |
| Vysis Esophageal FISH Probe Kit **(CE)** | 20 µL | 04N19-020 | 00884999008021 | 68 |
| Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe **(CE)** | 20 µL | 08L65-020 | 00884999031555 | 70 |
| Vysis LSI 22 (BCR) SpectrumGreen Probe **(ASR)** | 20 µL | 05J17-024 | 00884999011236 | 71 |
| Vysis LSI D5S23, D5S721 SpectrumGreen Probe **(ASR)** | 20 µL | 04N30-020 | 00884999008274 | 72 |
| Vysis LSI EGFR SpectrumRed Probe **(ASR)** | 20 µL | 04N31-020 | 00884999008281 | 73 |
| Vysis LSI LPL SpectrumOrange Probe **(ASR)** | 20 µL | 04N34-020 | 00884999008335 | 74 |
| Vysis LSI MDM2 SpectrumOrange Probe **(ASR)** | 20 µL | 01N15-020 | 00884999000513 | 75 |
| Vysis LSI MYC SpectrumGold Probe **(ASR)** | 20 µL | 04N35-020 | 00884999008342 | 76 |
| Vysis LSI MYC SpectrumGreen Probe **(ASR)** | 20 µL | 04N36-020 | 00884999008359 | 77 |
| Vysis LSI N-MYC (2p24) SpectrumGreen/Vysis CEP 2 SpectrumOrange Probe **(ASR)** | 20µL | 07J72-001 | 00884999029156 | 78 |
| Vysis LSI N-MYC (2p24.1) SpectrumOrange Probe **(ASR)** | 20 µL | 05J50-001 | 00884999011984 | 79 |
| Vysis LSI ROS1 (Cen) SpectrumGreen Probe **(ASR)** | 20 µL | 08N07-020 | 00884999037120 | 80 |
| Vysis LSI ROS1 (Tel) SpectrumOrange Probe **(ASR)** | 20 µL | 08N05-020 | 00884999037458 | 81 |
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 | 82 |
| Vysis MDM2/CEP 12 FISH Probe Kit **(CE)** | 10 µL | 01N15-010 | 00884999035362 | 83 |
| Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12-q24.13) **(CE)** | 20 µL | 03N87-020 | 00884999006256 | 84 |



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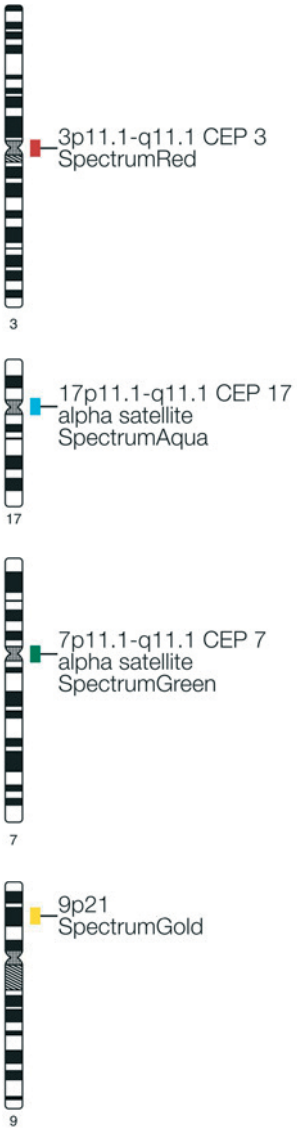
| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Vysis TOP2A / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N89-020 | 00884999006270 | 85 |
| Vysis TOP2A / HER-2 / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N90-020 | 00884999006287 | 86 |
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 | 88 |
| Vysis ZNF217 SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 05N15-020 | 00884999014602 | 89 |
| Vysis ZNF217 SpectrumOrange FISH Probe Kit **(CE)** | 20 µL | 03N91-020 | 00884999006294 | 89 |
| Vysis ZNF217 SpectrumRed FISH Probe Kit **(CE)** | 10 µL | 05N16-010 | 00884999014619 | 89 |
| **PROSTATE CANCER** | | | | |
| Vysis LSI Androgen Receptor Gene (Xq12) SpectrumOrange Probe **(ASR)** | 20 µL | 05J44-001 | 00884999011793 | 91 |
| Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12-q24.13) **(CE)** | 20 µL | 03N87-020 | 00884999006256 | 92 |
| **SARCOMAS** | | | | |
| Vysis DDIT3 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N57-020 | 00884999005778 | 93 |
| Vysis EWSR1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N59-020 | 00884999005792 | 95 |
| Vysis FOXO1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N60-020 | 00884999005808 | 97 |
| Vysis FUS Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N58-020 | 00884999005785 | 98 |
| Vysis LSI MDM2 SpectrumOrange Probe **(ASR)** | 20 µL | 01N15-020 | 00884999000513 | 99 |
| Vysis MDM2/CEP 12 FISH Probe Kit **(CE)** | 10 µL | 01N15-010 | 00884999035362 | 100 |
| Vysis SS18 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N61-020 | 00884999005815 | 101 |

BLADDER CANCER

# UroVysion Bladder Cancer Kit

## UROVYSION
## BLADDER CANCER KIT




### PRODUCT DESCRIPTION

The UroVysion Bladder Cancer Kit (UroVysion Kit) is FDA approved and designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer. Results from the UroVysion Kit are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

The UroVysion Bladder Cancer Kit probes are directly labeled with one of the Vysis fluorophores; SpectrumRed, SpectrumGreen, SpectrumAqua or SpectrumGold. The UroVysion Bladder Cancer Kit consists of three alpha-satellite repeat sequence probes; CEP 3 SpectrumRed, CEP 7 SpectrumGreen, and CEP 17 SpectrumAqua that hybridize to the centromere regions of chromosomes 3, 7, and 17, respectively. In addition, a unique sequence probe, LSI p16 (9p21) SpectrumGold, is included that hybridizes to the p16 gene at 9p21. This probe set is premixed in Hybridization Buffer.

### VYSIS MICROSCOPE FILTER RECOMMENDATIONS

UroVysion probe signals and DAPI counterstain should be viewed with the following Vysis filter sets:

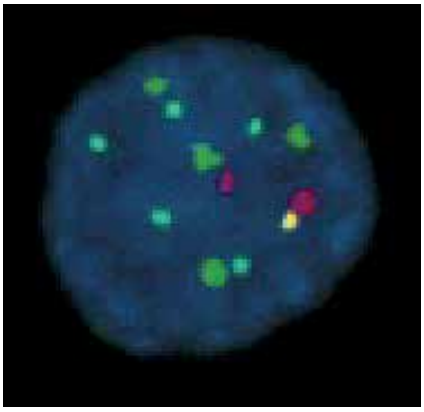
- DAPI single bandpass (DAPI counterstain)
- Aqua single bandpass (chromosome 17)
- Yellow single bandpass (p16 gene)
- Red/Green dual bandpass (chromosomes 3 and 7)

An epi-fluorescence microscope equipped with a 100-watt mercury lamp is strongly recommended. An epi-fluorescence microscope enables a light source to transmit light through the viewing path, replacing the illuminator and condenser of the conventional wide field microscope. For this mode to function, the structures of interest are labeled with a fluorophore. Light from the source is collimated and directed into the tube of the microscope to a 45-degree mirror with an interference coating that lets in light at particular wavelengths and is transparent at other wavelengths (a dichroic mirror). This light is directed to the back of the objective and is focused into the sample. The objective functions

as a condenser. Exciting light is absorbed by the fluorophore in the sample. The energy of the absorbed photon causes an electron in the dye molecule to jump to a higher energy orbital state. The electron rapidly jumps back to its ground orbital state, with the energy released becoming a photon of less energy compared to the exciting photon. The emitted photon has a color shifted toward red. The eyepiece collects the image in an identical manner as is transmitted in wide field microscopy.

## RESULTS OF HYBRIDIZATION

Determination of results is conducted by enumeration of CEP 3, 7 and 17, and LSI p16 (9p21) signals through microscopic examination of the nucleus.Hybridization is viewed using a fluorescence microscope equipped with appropriate excitation and emission filters allowing visualization of the red, green, aqua, and gold fluorescent signals. Samples hybridized with the UroVysion Bladder Cancer Kit will exhibit signals indicative of the copy number of chromosomes 3, 7, and 17 and of the p16 gene. Processing The UroVysion Bladder Cancer Kit can be used with the Vysis VP2000TM Processor for specimen pretreatment and the ThermoBriteTM Denaturation/ Hybridization unit for modular automation.



**Normal hybridization:** Aneusomic interphase cell obtained from a sample showing two copies of chromosome 3 (red), four copies of chromosome 7 (green), five copies of chromosome 17 (aqua) and one copy of p16 gene (gold) after the UroVysion Bladder Cancer Kit (UroVysion Kit) hybridization.

## INTENDED USE

The UroVysion Bladder Cancer Kit (UroVysion Kit) is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer. Results from the UroVysion Kit are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

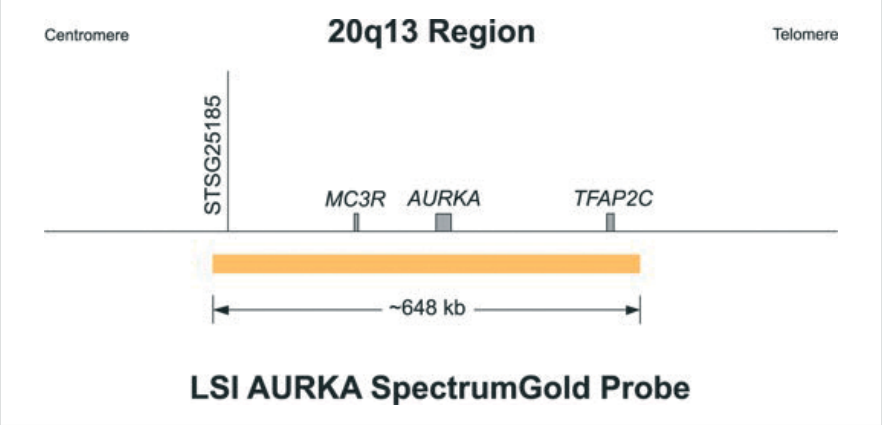
## LIMITATIONS

1. The UroVysion Kit has been optimized for identifying and quantitating chromosomes 3, 7, and 17, and locus 9p21 in human urine specimens.
2. The performance of the UroVysion Kit was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the assay.
3. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
4. UroVysion assay results may not be informative if the specimen quality and/ or specimen slide preparation is inadequate, e.g., the presence of excessive granulocytes or massive bacteruria.
5. Technologists performing the UroVysion signal enumeration must be capable of visually distinguishing between the red and green signals.
6. Positive UroVysion results in the absence of other signs or symptoms of bladder cancer recurrence may be evidence of other urinary tract related cancers, e.g., ureter, urethra, renal, and/or prostate in males, and further patient follow-up is justified. In a study conducted on patients with hematuria (see "Symptomatic Patients: Performance vs. Standard of Care" for details on this clinical study) 3 patients, whose initial bladder cystoscopy was negative, were subsequently diagnosed with renal cancer within 6 months of this initial study visit. All 3 of these cases were positive by UroVysion.

7. If UroVysion results are negative but standard clinical or diagnostic tests (e.g., cytology, cystoscopy) are positive, the standard procedures take precedence over the UroVysion test. Although the UroVysion Kit was designed to detect genetic changes associated with most bladder cancers, there will be some bladder cancers whose genetic changes cannot be detected by the UroVysion test.
8. Ta stage solitary tumors smaller than 5mm could not be detected by UroVysion FISH.23 UroVysion FISH results are dependent on the amount of tumor cells that are deposited on the slide.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| UroVysion Bladder Cancer Kit **(CE)** | 20 Assays<br>100 Assays | 02J27-020<br>02J27-099 | 00884999002135<br>00884999002197 |
| ProbeChek Control Slides for UroVysion Bladder Cancer Kit **(CE)** | 3 Slides | 02J27-010 | 00884999002111 |

# Vysis AURKA SpectrumGold FISH Probe Kit

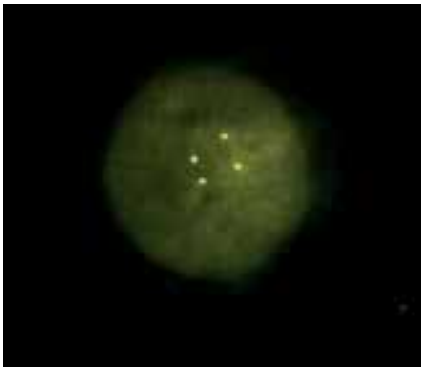




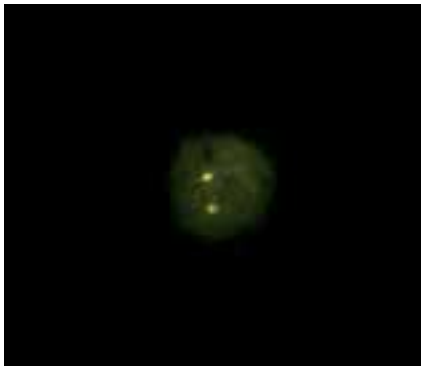
## PRODUCT DESCRIPTION

The Vysis AURKA SpectrumGold FISH Probe Kit is designed to detect the copy number of Aurora Kinase A (AURKA) locus localized in chromosome 20 at the 20q13.2 band via fluorescence in situ hybridization (FISH) in human urine specimens.

The Vysis AURKA SpectrumGold FISH assay is based on the ability of the Aurora Kinase A Locus-Specific Identifier (LSI) probe to identify copy number changes of the 20q13.2 chromosomal locus using a FISH test. Experimental data suggest that inappropriately high or low levels of Aurora Kinase activity are linked to genetic instability and that a high level of expression of Aurora Kinase A is often associated with amplification of the region of chromosome 20 encoding AURKA, indicating that deregulated expression of at least one gene in the amplified region provides a survival/proliferation advantage to a tumor cell and is therefore linked directly to neoplasia. Over-expression of the Aurora Kinase A gene has also been shown to be associated with aneuploidy, chromosome instability and promotion of tumorigenic transformation and progression in mammalian cells and in several human tumors, including urothelial carcinoma. AURKA amplification has been demonstrated in breast, colon, brain, bladder, head/neck and endometrium cancers, and its expression in tumors is often associated with genetic instability and poor prognosis. FISH data on voided urine samples from patients with bladder cancer indicate that amplification of AURKA is frequent in bladder cancer and can be detected in urothelialcells. Further, amplification of chromosome 20q has been associated with clinically aggressive variants of several common malignancies, including bladder cancer.



**Abnormal hybridization:** Abnormal copy number of the AURKA gene is indicated by more than two copies of the gold probe signal. Disregard nuclei with less than 2 copies of the gold probe signal.

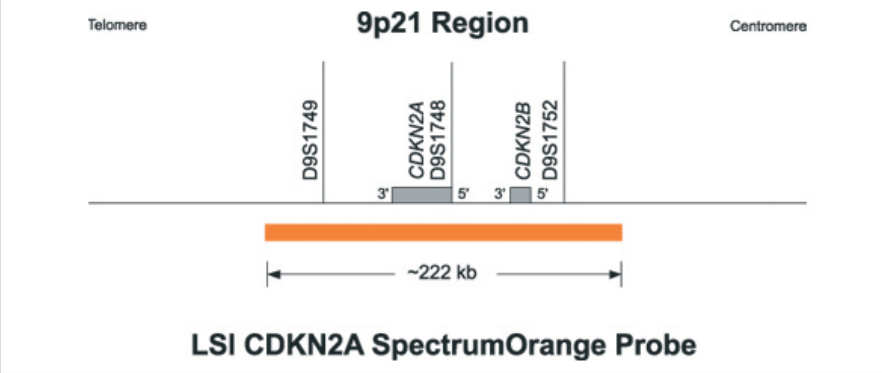


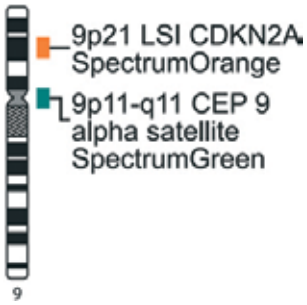
**Normal hybridization:** In a nucleus with a normal copy number of the AURKA gene, two gold signals will be observed.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis AURKA SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 05N93-020 | 00884999015470 |

BLADDER CANCER

# Vysis CDKN2A/CEP 9 FISH Probe Kit




## PRODUCT DESCRIPTION

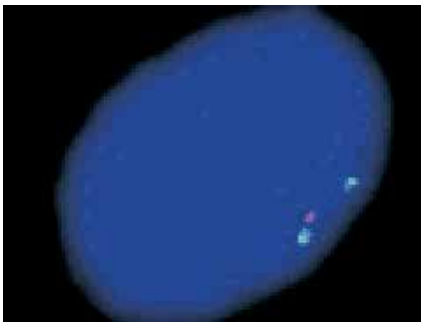
Alterations of the 9p21 locus including the tumor suppressor gene CDKN2A (p16) are implicated in different Meningiomas and Gliomas. Studies support the association of CDKN2A homozygous deletion with malignant progression and suggest that it is a marker of worse prognosis in anaplastic oligodendrogliomas.

The Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes have been used in several cytogenetic studies to detect losses of the CDKN2A gene. Using this probe set as well as other relevant markers (e.g. p53, RB1, 1p36, 19q13, all Vysis FISH probes), Kramar et al. investigated 82 samples from 81 patients with histolgically confirmed glial tumors. In a study using the Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes on 189 confirmed glioblastoma patients less than 50 years old, Korshunov et al. found 9p21 deletion to be correlated with an unfavorable prognosis.

Vysis LSI CDKN2A/CEP 9 Probes are provided in one vial as a mixture of the LSI CDKN2A (p16) probe labeled with SpectrumOrange and the CEP 9 probe labeled with SpectrumGreen. The LSI CDKN2A probe spans approximately222 kb and contains a number of genetic loci including D9S1749, DS1747, p16 (INK4B), p14 (ARF), D9S1748, p15(INK4B), and D9S1752. The CEP 9 SpectrumGreen probe hybridizes to alpha satellite sequences specific to chromosome 9.

## RESULTS OF HYBRIDIZATION

In a normal sample, the expected pattern for a nucleus hybridized with the Vysis LSI CDKN2A / CEP 9 Probe is the two orange, two green (2O2G) signal pattern. If a deletion at the 190 kb region covered by the LSI p16 probe occurs on one chromosome 9 homolog and both centromeres from chromosome 9 are retained, the one orange, two green (1O2G) signal pattern is expected.Very small deletions may occur that do not delete the entire LSI p16 probe target and therefore will not be detected.

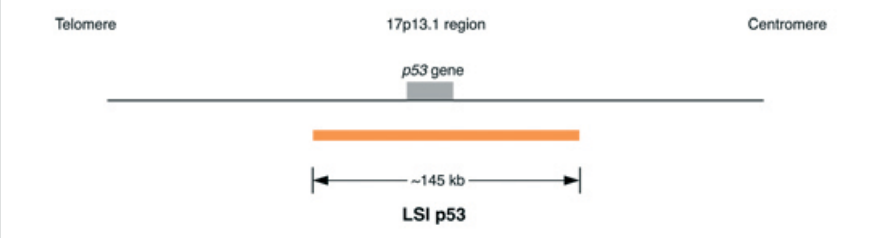


**Abormal hybridization:** Vysis LSI CDKN2A / CEP 9 Probe hybridized to a nucleus exhibiting the one orange and two green signal (1O2G) pattern. One p16 gene locus is deleted and both chromosome 9 homologs are present as indicated by one orange and two green signals, respectively.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CDKN2A / CEP 9 FISH Probe Kit **(CE)** | 20 µL | 04N61-020 | 00884999009295 |

BLADDER CANCER

# Vysis LSI TP53 (17p13.1) SpectrumOrange Probe



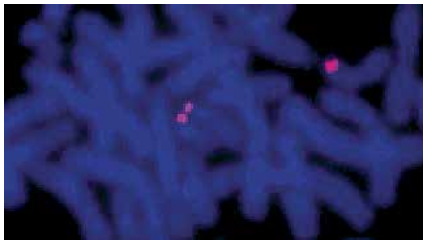


## PRODUCT DESCRIPTION

The LSI TP53 (previously designated as p53) Probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene. The ability to use FISH probes such as the LSI p53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the p53 locus.The LSI p53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.

## RESULTS OF HYBRIDIZATION

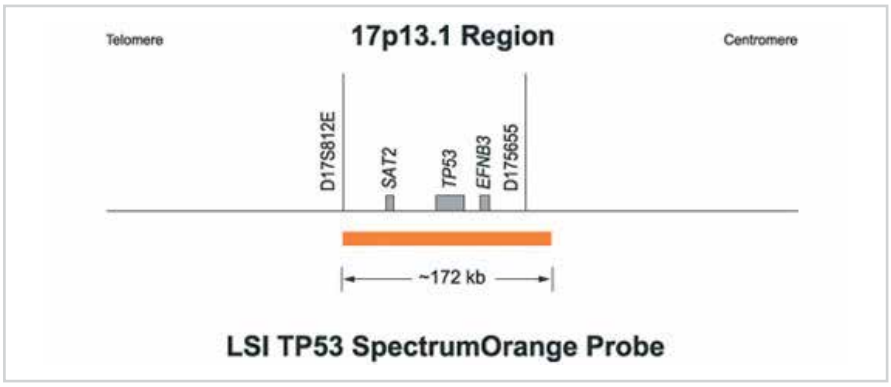
In a cell containing a deletion of the LSI p53 locus, one orange LSI p53 signal will be observed (1O signal pattern). In a cell harboring amplification of the p53 locus multiple copies of the orange signal will be observed. In a normal cell the two orange (2O) signal pattern is observed.



**Normal hybridization:** LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 |

# Vysis TP53 / CEP 17 FISH Probe Kit

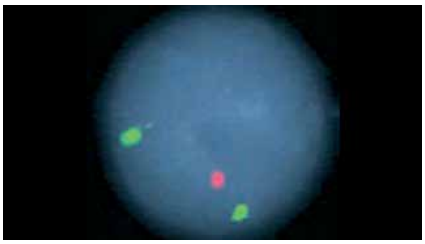




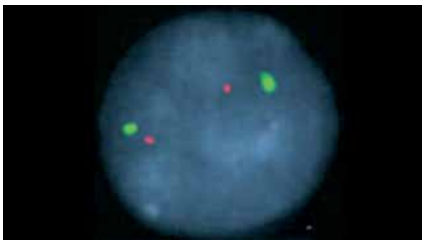
## PRODUCT DESCRIPTION

The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma. The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.



**Abnormal hybridization:** Nucleus showing the two green and one orange signal.

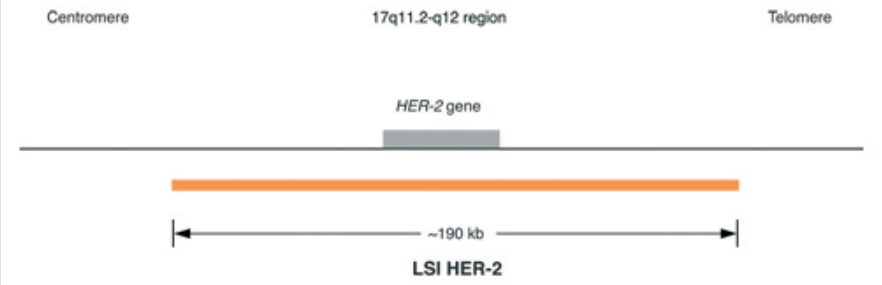


**Normal hybridization:** Nucleus showing the two green and two orange signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 |

BREAST CANCER

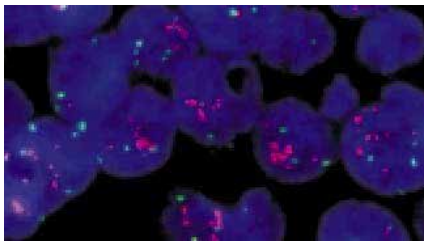
# PathVysion HER-2 DNA Probe Kit





## RESULTS OF HYBRIDIZATION

Results on enumeration of 20 interphase nuclei from tumor cells per target are reported as the ratio of average HER-2/neu copy number to that of CEP 17. Our clinical study found that specimens with amplification showed a LSI HER-2/neu and CEP 17 signal ratio of greater than or equal to 2.0; normal specimens showed a ratio of less than 2.0. Results at or near the cut-off point (1.8-2.2) should be interpreted with caution.



PathVysion HER-2 DNA Probe Kit hybridized to breast tissue showing multiple copies of the HER-2 gene as represented by multiple orange signals. The ratio of orange to green probe signals is greater than 2.0 indicating HER-2 amplification.

## INTENDED USE

The PathVysion HER-2 DNA Probe Kit (PathVysion Kit) which is FDA approved is designed to detect amplification of the HER-2/neu gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Results from the PathVysion Kit are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer patients. The PathVysion Kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin, and 5-fluorouracil (CAF) chemotherapy.

The PathVysion Kit is indicated as an aid in the assessment of patients for whom HERCEPTIN (Trastuzumab) treatment is being considered (see HERCEPTIN package insert).

HER-2/neu, also known as c-erbB2 or HER-2, is a gene that has been shown to play a key role in the regulation of cell growth. The gene codes for a 185 kd transmembrane cell surface receptor that is a member of the tyrosine kinase family. HER-2 has been shown to be amplified in human breast, ovarian, and other cancers. PathVysion 02J01 is available in some countries and does not contain the gastric indication.

## INTENDED USE

The PathVysion HER-2 DNA Probe Kit (PathVysion Kit) is designed to detect amplification of the HER-2/neu gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Results from the PathVysion Kit are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer patients. The PathVysion Kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node-positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin and 5-fluorouracil (CAF) chemotherapy.

The PathVysion Kit is indicated as an aid in the assessment of patients for whom HERCEPTIN (Trastuzumab) treatment is being considered (see HERCEPTIN package insert).

## WARNING

The Vysis PathVysion Kit is not intended for use to screen for or diagnose breast cancer. It is intended to be used as an adjunct to other prognostic factors currently used to predict disease-free and overall survival in stage II, node-positive breast cancer patients. In making decisions regarding adjuvant CAF treatment, all other available clinical information should also be taken into consideration, such as tumor size, number of involved lymph nodes, and steroid receptor status.No treatment decision for stage II, node-positive breast cancer patients should be based on HER-2/neu gene amplification status alone.

The PathVysion HER-2 DNA Probe Kit consists of two labeled DNA probes. The LSI HER-2 probe that spans the entire HER-2 gene is labeled in SpectrumOrange. The CEP 17 probe is labeled in SpectrumGreen and hybridizes to the alpha satellite DNA located at the centromere of chromosome 17 (17p11.1-q11.1). Inclusion of the CEP 17 probe allows for the relative copy number of the HER-2 gene to be determined.

## WARNING

*HERCEPTIN therapy selection*

NOTE: All of the patients in the HERCEPTIN clinical trials were selected using an investigational immunohistochemical assay (CTA). None of the patients in those trials were selected using the PathVysion assay. The PathVysion assay was compared to the CTA on a subset of clinical trial samples and found to provide acceptably concordant results. The actual correlation of the PathVysion assay to HERCEPTIN clinical outcome in prospective clinical trials has not been established.

*Adjuvant therapy selection*

The PathVysion Kit is not intended for use to screen for or diagnose breast cancer. It is intended to be used as an adjunct to other prognostic factors currently used to predict disease-free and overall survival in stage II, node-positive breast cancer patients and no treatment decision for stage II, node-positive breast cancer patients should be based on HER-2/neu gene amplification status alone. Selected patients with breast cancers shown to lack amplification of HER-2/neu may still benefit from CAF (cyclophosphamide, doxorubicin, 5-fluorouracil) adjuvant therapy on the basis of other prognostic factors that predict poor outcome (e.g. tumor size, number of involved lymph nodes, and hormone receptor status). Conversely, selected patients with breast cancers shown to contain gene amplification may not be candidates for CAF therapy due to preexisting or intercurrent medical illnesses. Required Training

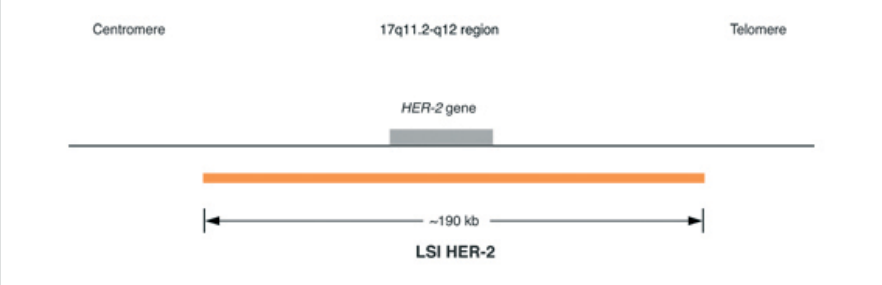
Abbott Molecular will provide training in specimen preparation, assay procedure, and interpretation of FISH testing of the Her-2 gene for inexperienced users. It is also recommended that a laboratory that has previously received training but now has new personnel performing the assay request training for the new users.

## LIMITATIONS

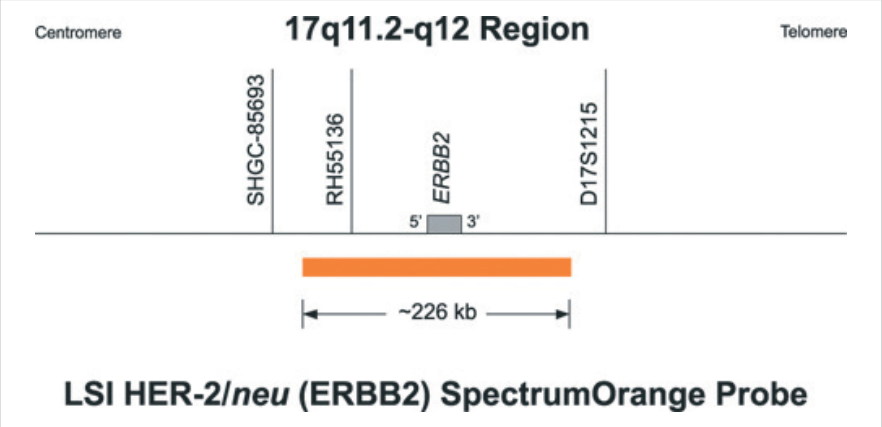
1. The PathVysion Kit has been optimized only for identifying and quantifying chromosome 17 and the HER-2/neu gene in interphase nuclei from formalin-fixed, paraffin-embedded human breast tissue specimens. Other types of specimens or fixatives should not be used.
2. The performance of the PathVysion Kit was validated using the procedures provided in the package insert only. Modifications to these procedures may alter the performance of the assay.
3. Performance characteristics of the PathVysion Kit have been established only for node positive patients receiving the designated regimens of CAF and for metastatic breast cancer patients being considered for HERCEPTIN therapy. Performance with other treatment regimens has not been established.
4. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
5. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate. Technologists performing the FISH signal enumeration must be capable of visually distinguishing between the orange and green signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| PathVysion **(FDA IVD)** | 20 Assays | 2J01-030 | 00884999001732 |
| | 50 Assays | 2J01-035 | 00884999001756 |
| | 100 Assays | 2J01-036 | 00884999001763 |

# PathVysion HER-2 DNA Probe Kit II



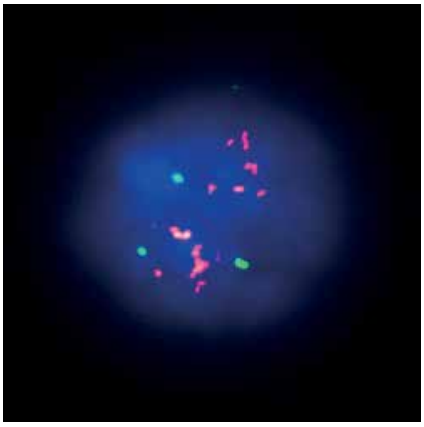




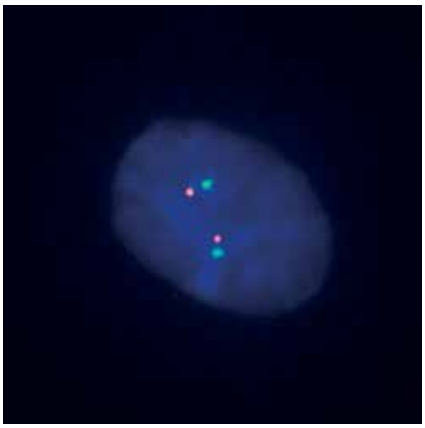

## INTENDED USE

The PathVysion HER-2 DNA Probe Kit II (PathVysion Kit II) is designed to detect amplification of the HER-2/neu gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast and gastric cancer tissue specimens.

For breast cancer indication, results from the PathVysion Kit II are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer patients. The PathVysion Kit II is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node-positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin and 5-fluorouracil (CAF) chemotherapy. The PathVysion Kit II is indicated as an aid in the assessment of breast cancer patients for whom HERCEPTIN (trastuzumab) treatment is being considered (see HERCEPTIN package insert). PathVysion 02J01 is available in some countries and does not contain the gastric indication.



**Abnormal hybridization**



**Normal hybridization**

## INTENDED USE

The PathVysion HER-2 DNA Probe Kit II (PathVysion Kit II) is designed to detect amplification of the HER-2/neu gene via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded human breast and gastric cancer tissue specimens

For breast cancer indication, results from the PathVysion Kit II are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-positive breast cancer patients. The PathVysion Kit II is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node-positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin and 5-fluorouracil (CAF) chemotherapy. The PathVysion Kit II is indicated as an aid in the assessment of breast cancer patients for whom HERCEPTIN (trastuzumab) treatment is being considered (see HERCEPTIN package insert).

**Warning:** *The following warning pertains to the PathVysion Kit II breast cancer indication only.*

*HERCEPTIN Therapy Selection*

**NOTE:** All of the patients in the HERCEPTIN clinical trials were selected using an investigational immunohistochemical assay (clinical trial assay [CTA]). None of the patients in those trials were selected using the PathVysion assay. The PathVysion assay was compared to the CTA on a subset of clinical trial samples and found to provide acceptably concordant results. The actual correlation of the PathVysion assay to HERCEPTIN clinical outcome in prospective clinical trials has not been established.

*Adjuvant Therapy Selection*

The PathVysion assay is not intended for use to screen for or diagnose breast cancer. It is intended to be used as an adjunct to other prognostic factors currently used to predict disease-free and overall survival in stage II, node-positive breast cancer patients and no treatment decision for stage II, node-positive breast cancer patients should be based on HER-2/neu gene amplification status alone. Selected patients with breast cancers shown to lack amplificationof the HER-2/neu gene may still benefit from cyclophosphamide, doxorubicin, 5-fluorouracil (CAF) adjuvant therapy on the basis of other prognostic factors that predict poor outcome (eg, tumor size, number of involved lymph nodes, and hormone receptor status). Conversely, selected patients with breast cancers shown to contain gene amplification may not be candidates for CAF therapy due to pre-existing or intercurrent medical illnesses.

*Required Training*

Abbott Molecular will provide training in specimen preparation, assay procedure, and interpretation of FISH testing of the HER-2/neu gene for inexperienced users. It is also recommended that a laboratorythat has previously received training, but now has new personnel performing the assay, request training for the new users.

## LIMITATIONS

1. The PathVysion Kit II gastric cancer assay has only been optimized for identifying and quantifying chromosome 17 and the HER-2/neu gene in interphase nuclei from formalin-fixed, paraffin-embedded human gastric tissue specimens. Other types of specimens or fixatives should not be used.
2. The performance of the PathVysion Kit II was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the assay.
3. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
4. Technologists performing the FISH signal enumeration must be capable of visually distinguishing between the orange and green signals.

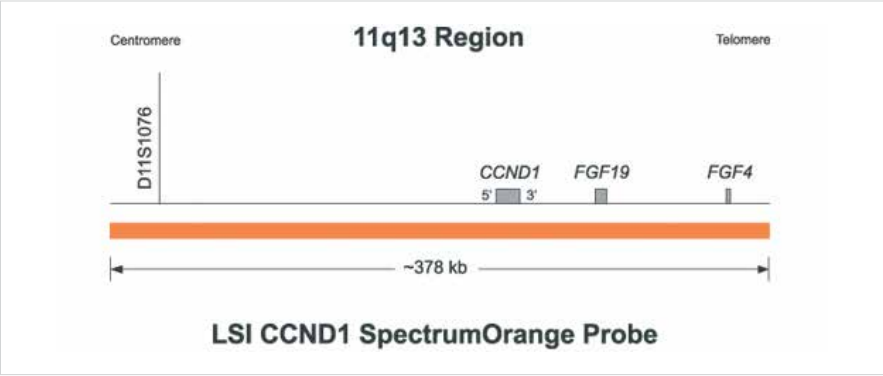
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| PathVysion **(FDA IVD)** | 20 Assays<br>50 Assays<br>100 Assays | 2J01-030<br>2J01-035<br>2J01-036 | 00884999001732<br>00884999001756<br>00884999001763 |
| PathVysion **(IVD Japan Only)** | 20 Tests | 2J01-031 | 00884999001749 |
| PathVysion HER-2 DNA Probe Kit II **(CE)** | 20 Assays<br>50 Assays<br>100 Assays | 06N46-030<br>06N46-035<br>06N46-036 | 00884999035867<br>00884999035874<br>00884999035881 |
| Protease IV **(CE)** | 75 mg x 5<br>750 mg x 5 | 06N46-001<br>06N46-002 | 00884999035843<br>00884999035850 |

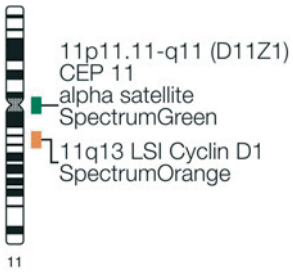


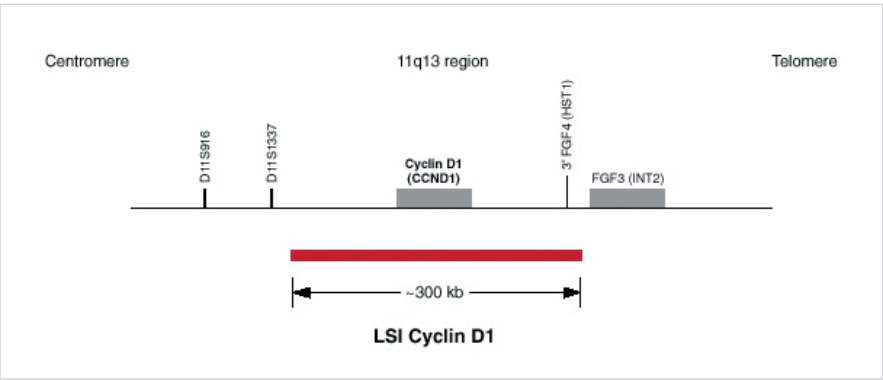
Please note some products may not be for sale in all markets. Contact your local representative for availability.

BREAST CANCER

# Vysis CCND1/CEP 11 FISH Probe Kit




## PRODUCT DESCRIPTION

Amplification of the chromosome 11q13 region, which harbors the Cyclin D1 (CCND1, PRAD1) oncogene, has been reported to occur in up to 15% of breast cancers. CCND1 amplification has been reported to be a prognostic marker.

Several studies used the Vysis CCND1/CEP 11 FISH Probe Kit to detect CCND1 amplification in breast cancer samples. Al-Karaya et al. analyzed a tissue microarray of 2197 breast cancer samples using the probe kit and found CCND1 amplification in 20.1% of cases. CCND1 amplification was associated with high tumor grade and a tendency toward shortened survival. Jirstrom et al. analyzed a tissue microarray of 500 breast cancer specimens from patients treated and not treated with adjuvant tamoxifen. The study found CCND1 amplification to be agonistic to tamoxifen with amplified patients having a significantly higher risk of recurrence.

The Vysis LSI CCND1 SpectrumOrange/CEP11 SpectrumGreen Probes have been applied to cancers other than breast cancer. For example, Katz et al. found elevated CCND1 copy number to be sensitive indicator of mantle cell lymphoma, and could distinguish mantle cell lymphoma from most other B-cell non Hodgkins lymphoma specimens.

The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/ CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

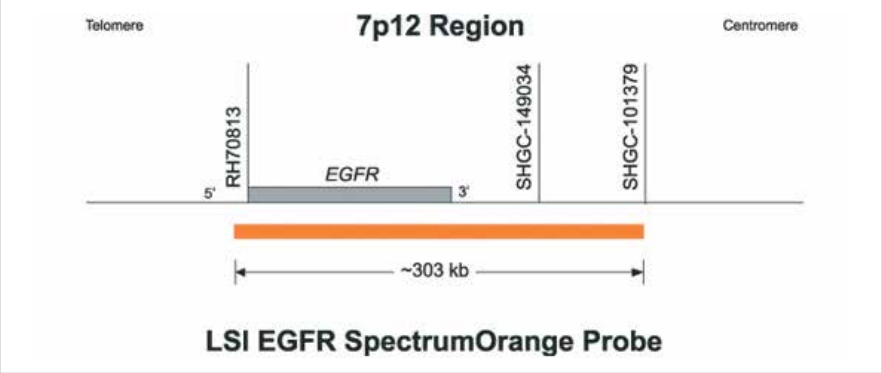
## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange orange signals. Other patterns may be observed if additional genetic alterations are present.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 |

BREAST CANCER

# Vysis EGFR/CEP 7 FISH Probe Kit





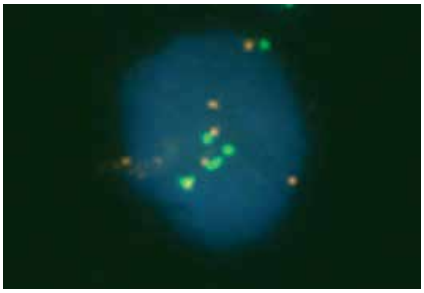
## PRODUCT DESCRIPTION

EGFR abnormalities including increased copy number and amplification have been correlated with the development of many solid tumors, including non-small cell lung cancer (NSCLC) which is the leading cause of cancer death worldwide.

NSCLC has a 5-year survival rate of approximately 15%. There is a pressing need for improvement in identifying patients most likely to respond to specific treatments for NSCLC. Inhibition of EGFR by agents that block its tyrosine kinase domain has been demonstrated to reduce proliferation of lung cancer cells, resulting in suppression of tumor growth.

## RESULTS OF HYBRIDIZATION

In a cell with normal copy number of the EGFR gene and chromosome 7, two orange signals (EGFR), and two green signals (chromosome 7) will be observed. Simultaneously, the copy number of chromosome 7 can be quantified by enumeration of the green signals observed within the same cell. Therefore, enumeration of both the orange EGFR and green CEP 7 signals provide a mechanism for determining EGFR copy number relative to total chromosome 7 copy number.

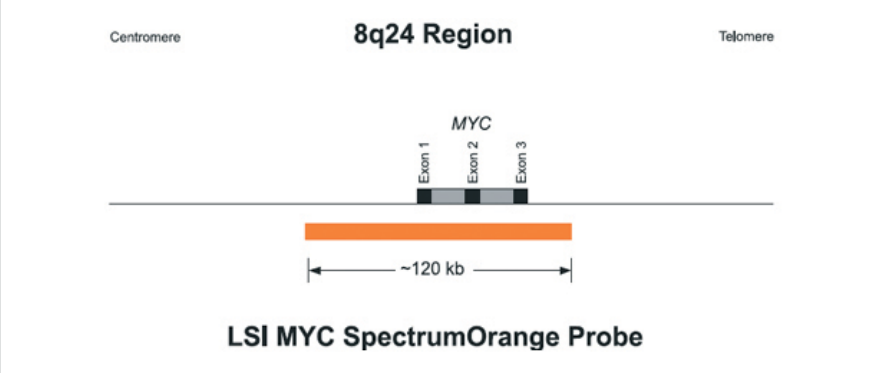


**Abnormal hybridization:** An abnormal cell hybridized with the Vysis LSI EGFR SpectrumOrange /CEP 7 SpectrumGreen Probes. The cell contains multiple EGFR (orange) signals and chromosome 7 (green signals).

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 20 µL | 01N35-020 | 00884999000773 |

BREAST CANCER

# Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12-q24.13)





## PRODUCT DESCRIPTION

The MYC (C-MYC) oncogene has been reported to be amplified in >20% of breast carcinoma and various other malignancies and is a prognostic factor for breast cancer. FISH is a rapid and reproducible method that allows the accurate measurement of the level of oncogene amplification within interphase nuclei in human tumors. This probe may be used to determine the MYC copy number or as a general purpose probe for the 8q24 region.

The Vysis LSI MYC SpectrumOrange Probe was employed in a number of studies. Park et al. used the Vysis LSI MYC Probe to investigate co-amplification of the MYC and HER2 genes in 214 consecutive breast cancers. For detecting lung cancer, Sokolava et al. compared a FISH-based assay, that included Vysis LSI MYC, to conventional cytology in 74 bronchial washing specimens, and achieved significantly higher sensitivity with the FISH assay (82% vers. 54%). In a recent study, Rygiel et al. used the Vysis LSI MYC (8q24.12-q24.13) SpectrumOrange Probe to evaluate amplification of MYC as a diagnostic marker to identify patients with Barrett's esophagus with high-grade dysplasia or esophageal adenocarcinoma.

The LSI C-MYC (8q24.12-q24.13) Probe is an approximately 120 kb SpectrumOrange labeled probe.

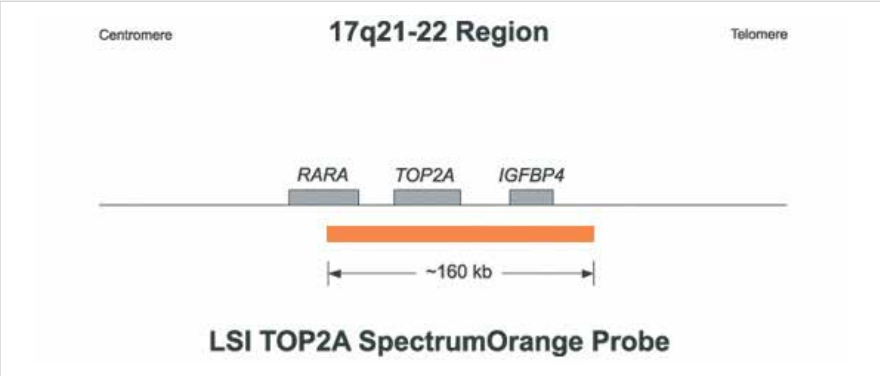
## RESULTS OF HYBRIDIZATION

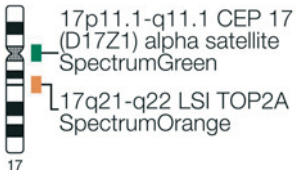
In a cell with amplification of the C-MYC locus,multiple copies of the orange signal may be seen when hybridized with the C-MYC probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12-q24.13) **(CE)** | 20 µL | 03N87-020 | 00884999006256 |

BREAST CANCER

# Vysis TOP2A/CEP 17 FISH Probe Kit




## PRODUCT DESCRIPTION

The TOP2A gene, located at 17q21-q22, encodes topoisomerase II- a key enzyme in DNA replication, cell cycle progression, and chromosome segregations. As a key enzyme in DNA replication, TOP2A protein is the molecular target for many inhibitors. The TOP2A gene is located telomeric to the HER-2 oncogene, which is located in the 17q11.2-q12 region. HER-2 is one member of a family of transmembrane protein receptors. The close proximity of HER-2, TOP2A, and other genes in the 17q region, suggest a potential relationship between these genes. This probe set is premixed in Hybridization Buffer.

LSI TOP2A is a single ~160kb unique sequence probe that hybridizes to the 17q21-22 region containing the TOP2A gene and is directly labeled with SpectrumOrange. The CEP 17 probe, which hybridizes to alpha satellite DNA at 17p11.1-q11.1, is directly labeled with SpectrumGreen.

In a cell with the normal quantity (two copies) of the TOP2A gene, two orange signals will be observed. If amplification or deletion of the TOP2A gene has occured, more or less than two signals will be present. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi-color probe.

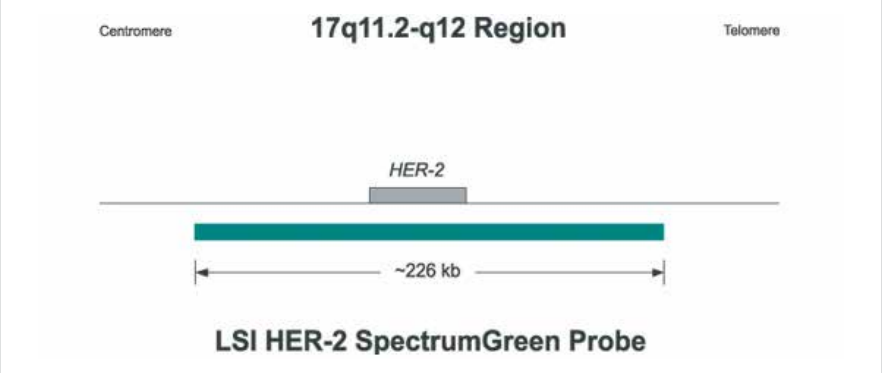
## RESULTS OF HYBRIDIZATION

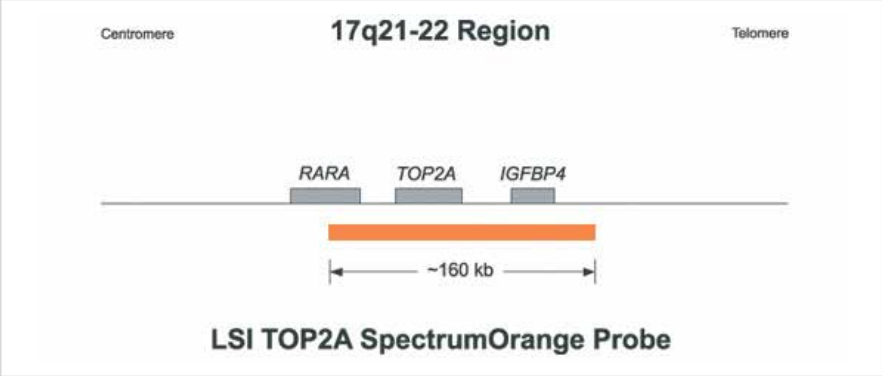
In a cell with the normal quantity (two copies) of the TOP2A gene, two orange signals will be observed. If amplification or deletion of the TOP2A gene has occured, more or less than two signals will be present.

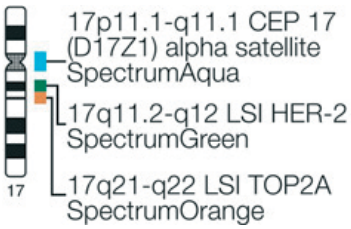
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TOP2A / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N89-020 | 00884999006270 |

BREAST CANCER

# Vysis TOP2A/HER-2/CEP 17 FISH Probe Kit




## PRODUCT DESCRIPTION

The TOP2A gene, located at 17q21-q22 encodes topoisomerase II-α, a key enzyme in DNA replication, cell cycle progression, and chromosome segregation. As a key enzyme in DNA replication, TOP2A protein is the molecular target for many inhibitors. The TOP2A gene is located telomeric to the HER-2 oncogene, which is located in the 17q11.2-q12 region. HER-2 is one member of a family of transmembrane protein receptors. The close proximity of HER-2, TOP2A, and other genes in the 17q region, suggest a potential relationship between these genes. The TOP2A gene has also been shown to be co-amplified with HER-2 in cell lines and in human breast cancers.

The Vysis Locus Specific Identifier (LSI) TOP2A SpectrumOrange/HER-2 SpectrumGreen/CEP17 SpectrumAqua Probe Set utilizes locus specific probes for TOP2A and HER-2 as well as chromosome 17 centromeric probe. Each probe is labeled with a different fluorophore to allow accurate enumeration of each locus within individual nuclei. Simultaneous enumeration of all three probes reveals the copy number gains or losses of HER-2 and TOP2A relative to the copy number of chromosome 17. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi color probe.

TOP2A and HER-2 gene status is of interest since topoisomerase II-α is a molecular target of anthracycline drugs and HER-2 is targeted by several small molecule tyrosine kinase inhibitors as well as antibodies against the HER-2 receptor protein. Beser et al. used the Vysis TOP2A/HER-2/CEP17 FISH Probe Kit to examine the frequency of TOP2A amplification and deletion relative to the HER-2 gene status and chromosome 17 aneusomy in a series of 50 breast tumors. Hicks et al. used the same probe set to similarly document the relationship between TOP2A and HER-2 genomic alterations and chromosome 17 aneusomy in 138 breast cancers.

LSI TOP2A is a single ~160 kb unique sequence probe that hybridizes to the 17q21-22 region containing the TOP2A gene. In both products, the probe is directly labeled with SpectrumOrange. The HER-2 probe that spans the entire HER-2 gene at 17q11.2-q12 is an an ~190 kb unique sequence probe. In the LSI TOP2A/HER-2/CEP 17 product, this probe is directly labeled with SpectrumGreen. The The CEP 17 probe, which hybridizes to alpha satellite DNA at 17p11.1-q11.1, is directly labeled with SpectrumGreen or SpectrumAqua SpectrumAqua in the LSI TOP2A/CEP 17 and LSI TOP2A/HER-2/ CEP 17 products, respectively.

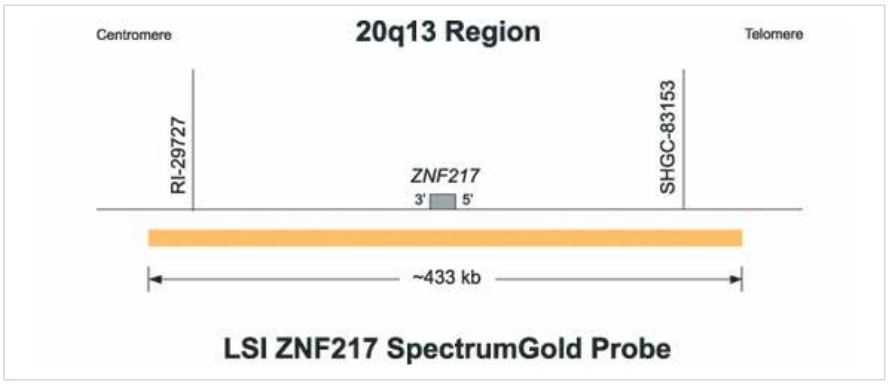
## RESULTS OF HYBRIDIZATION

LSI TOP2A/HER-2/CEP 17 Multi-color Probe: As with TOP2A and chromosome 17, a nucleus with a normal quantity (two copies) of HER-2 will appear with two green signals. Simultaneous enumeration of all three probes will reveal the copy number of each as well well as the amplification or deletion status of TOP2A and HER-2 relative to chromosome 17 copy number. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi-color probe.

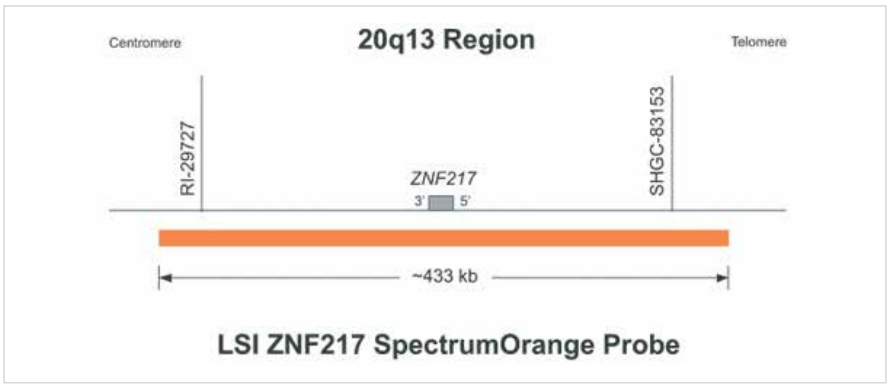
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TOP2A / HER-2 / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N90-020 | 00884999006287 |

BREAST CANCER

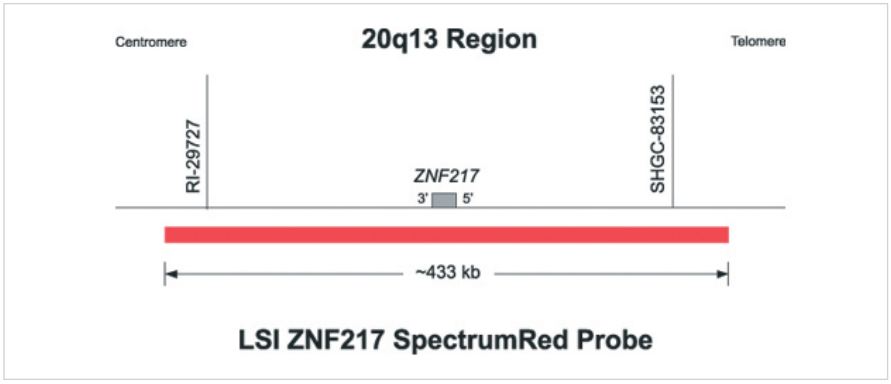
# Vysis LSI ZNF217 SpectrumGold, SpectrumOrange, Spectrum Red












## PRODUCT DESCRIPTION

The ZNF217 gene is a candidate oncogene suggested to play a key role during neoplastic transformation. ZNF217 is located at 20q13, which is a region that is frequently amplified in a variety of tumor types. Amplification of ZNF217 in breast cancer is associated with aggressive tumor behaviour and poor clinical prognosis.

The Vysis LSI ZNF217 SpectrumOrange** Probe was used in a study that indicated distinct differences in the role of genes known to be amplified in female breast cancer and their relevance for the pathogenesis of male breast cancer. In another study, fluorescence in situ hybridization was performed on 128 male breast tumors using the Vysis LSI ZNF217 SpectrumOrange Probe**in addition to other Vysis probes including LSI HER-2, LSI CCND1, LSI MYC, and the corresponding centromeric probes to evaluate the frequency of amplification of the genes in MBC. A third study used the Vysis LSI ZNF217 SpectrumOrange** Probe to identify gain of ZNF217 as an important abnormality and prognostic factor in larynx tumorigenesis. For this study a tissue microarray consisting of 863 larynx carcinomas was analysed.

The LSI ZNF217 (20q13.2) Probe hybridizes within an approximately 1 Mb amplified segment within the 20q13.2 region. The LSI ZNF217 Probe contains the ZNF217 gene centrally located within this region of amplification. The ZNF217 gene is a candidate oncogene. Using the LSI ZNF217 probe, copy number or amplification of this region can be detected.

The LSI ZNF217 is an approximately 433 kb SpectrumOrange labeled probe.

The Vysis ZNF217 SpectrumGold Probe Kit consists of a single probe direct labeled with SpectrumGold. The probe covers approximately a 433kb region that encompasses the entire 17.5-kb ZNF217 gene on chromosome 20 as well as adjacent regions.

The Vysis LSI ZNF217 SpectrumRed Probe is a single approximately 433 kb unique sequence probe direct labeled in SpectrumRed, that hybridizes to the 20q13.2 region of chromosome 20 and includes the 17.5 kb ZNF217 gene.

**The Vysis LSI ZNF217 SpectrumOrange Probe was used in studies, which are referenced above. Vysis LSI ZNF217 SpectrumGold Probe hybridizes to the same sequence as the Vysis LSI ZNF217 SpectrumOrange Probe, but is labeled with SpectrumGold Fluorophore.

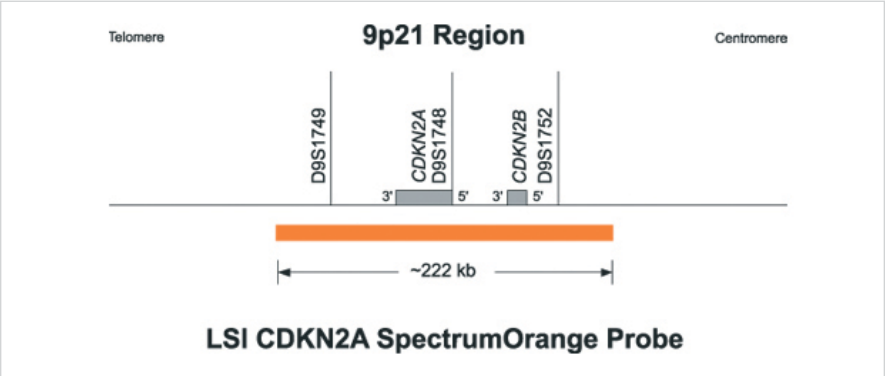
## RESULTS OF HYBRIDIZATION

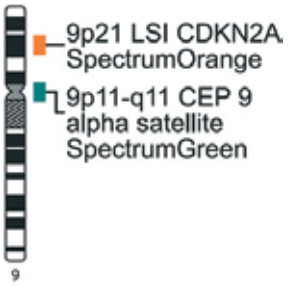
When hybridized with the LSI ZNF217 Probe, a normal cell containing two copies of the 20q13.2 region will exhibit two gold signals. signals. In a cell harboring amplification of the ZNF217 gene or 20q13.2 region, multiple copies of the gold signal will be observed.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ZNF217 SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 05N15-020 | 00884999014602 |
| Vysis ZNF217 SpectrumOrange FISH Probe Kit **(CE)** | 20 µL | 03N91-020 | 00884999006294 |
| Vysis ZNF217 SpectrumRed FISH Probe Kit **(CE)** | 10 µL | 05N16-010 | 00884999014619 |

GLIOMAS

# Vysis CDKN2A/CEP 9 FISH Probe Kit




## PRODUCT DESCRIPTION

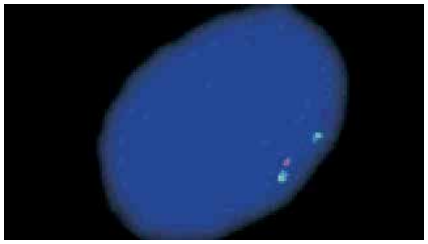
Alterations of the 9p21 locus including the tumor suppressor gene CDKN2A (p16) are implicated in different Meningiomas and Gliomas. Studies support the association of CDKN2A homozygous deletion with malignant progression and suggest that it is a marker of worse prognosis in anaplastic oligodendrogliomas.

The Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes have been used in several cytogenetic studies to detect losses of the CDKN2A gene. Using this probe set as well as other relevant markers (e.g. p53, RB1, 1p36, 19q13, all Vysis FISH probes), Kramar et al. investigated 82 samples from 81 patients with histolgically confirmed glial tumors. In a study using the Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes on 189 confirmed glioblastoma patients less than 50 years old, Korshunov et al. found 9p21 deletion to be correlated with an unfavorable prognosis.

Vysis LSI CDKN2A/CEP 9 Probes are provided in one vial as a mixture of the LSI CDKN2A (p16) probe labeled with SpectrumOrange and the CEP 9 probe labeled with SpectrumGreen. The LSI CDKN2A probe spans approximately222 kb and contains a number of genetic loci including D9S1749, DS1747, p16 (INK4B), p14 (ARF), D9S1748, p15(INK4B), and D9S1752. The CEP 9 SpectrumGreen probe hybridizes to alpha satellite sequences specific to chromosome 9

## RESULTS OF HYBRIDIZATION

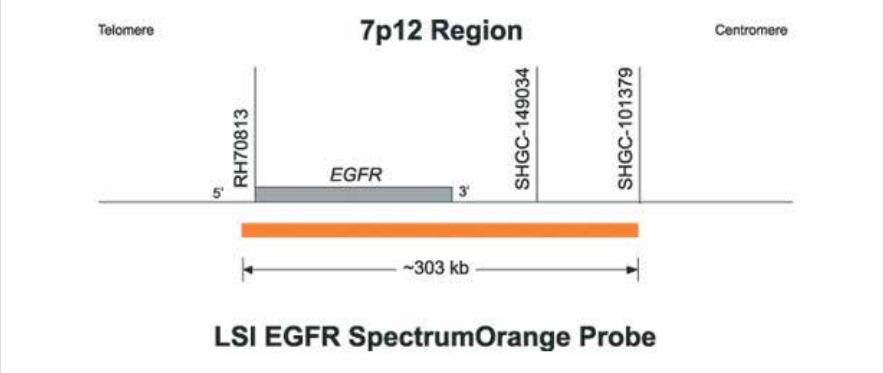
In a normal sample, the expected pattern for a nucleus hybridized with the Vysis LSI CDKN2A / CEP 9 Probe is the two orange, two green (2O2G) signal pattern. If a deletion at the 190 kb region covered by the LSI p16 probe occurs on one chromosome 9 homolog and both centromeres from chromosome 9 are retained, the one orange, two green (1O2G) signal pattern is expected.Very small deletions may occur that do not delete the entire LSI p16 probe target and therefore will not be detected.



**Abnormal hybridization:** Vysis LSI CDKN2A / CEP 9 Probe hybridized to a nucleus exhibiting the one orange and two green signal (1O2G) pattern. One p16 gene locus is deleted and both chromosome 9 homologs are present as indicated by one orange and two green signals, respectively.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CDKN2A / CEP 9 FISH Probe Kit **(CE)** | 20 µL | 04N61-020 | 00884999009295 |

# Vysis EGFR/CEP 7 FISH Probe Kit





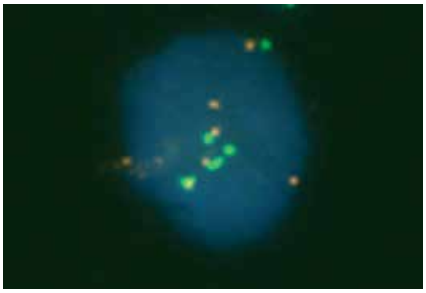
## PRODUCT DESCRIPTION

EGFR abnormalities including increased copy number and amplification have been correlated with the development of many solid tumors, including non-small cell lung cancer (NSCLC) which is the leading cause of cancer death worldwide.

NSCLC has a 5-year survival rate of approximately 15%. There is a pressing need for improvement in identifying patients most likely to respond to specific treatments for NSCLC. Inhibition of EGFR by agents that block its tyrosine kinase domain has been demonstrated to reduce proliferation of lung cancer cells, resulting in suppression of tumor growth.

## RESULTS OF HYBRIDIZATION

In a cell with normal copy number of the EGFR gene and chromosome 7, two orange signals (EGFR), and two green signals (chromosome 7) will be observed. Simultaneously, the copy number of chromosome 7 can be quantified by enumeration of the green signals observed within the same cell. Therefore, enumeration of both the orange EGFR and green CEP 7 signals provide a mechanism for determining EGFR copy number relative to total chromosome 7 copy number.

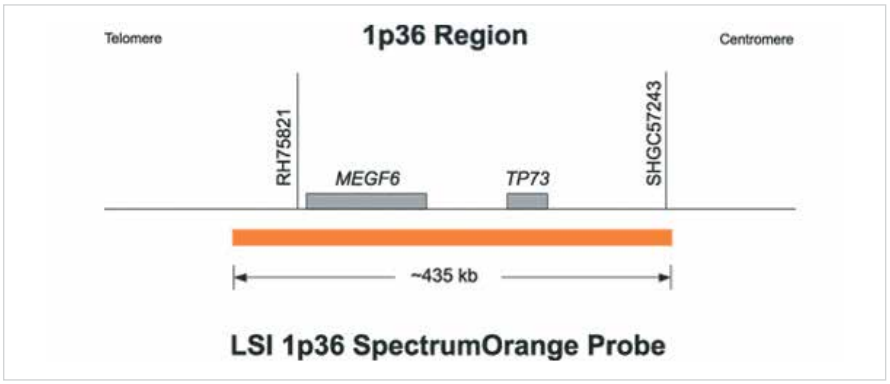


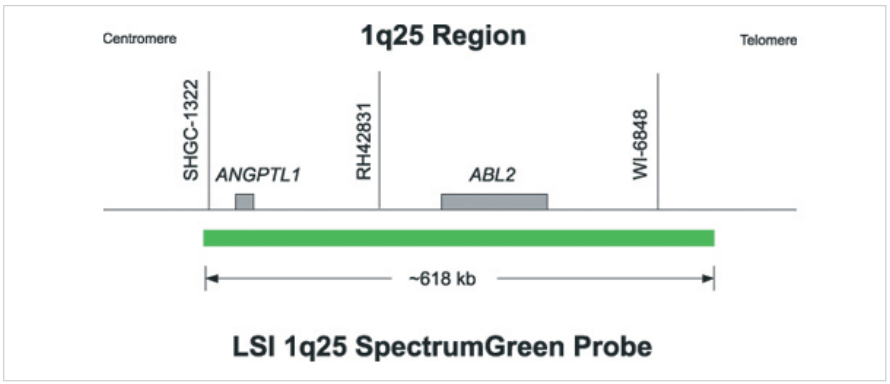
**Abnormal hybridization:** An abnormal cell hybridized with the Vysis LSI EGFR SpectrumOrange /CEP 7 SpectrumGreen Probes. The cell contains multiple EGFR (orange) signals and chromosome 7 (green signals).

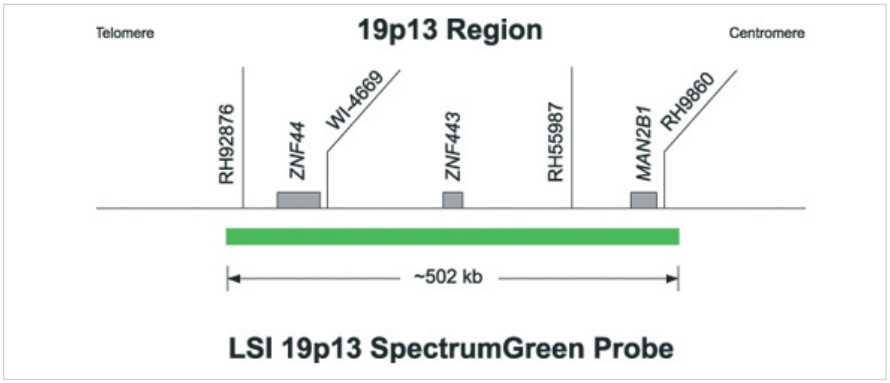
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 200 µL | 01N35-020 | 00884999000773 |

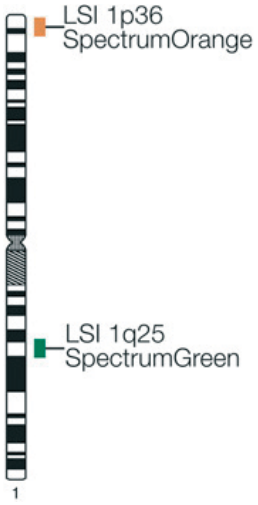
GLIOMAS

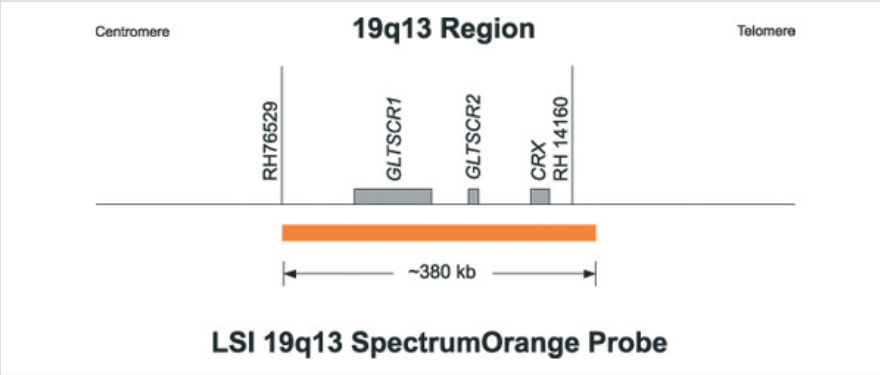
# Vysis LSI 1p36/LSI 1q25 and LSI 19q13/19p13 Dual-Color Probe



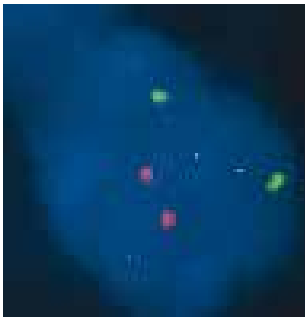

## PRODUCT DESCRIPTION

Diffuse gliomas of the central nervous system are classified based on their histological appearance as astrocytomas, oligodendrogliomas and mixed oligoastrocytomas. Fluorescence in situ hybridization using 1p36 and 19q13 LSI FISH probes showed that the oligodendroglial phenotype was also associated with the 1p deletion and that allelic loss of 1p was a powerful predictor of chemotherapeutic response. Combined 1p36-19q13 deletions were highly associated with classic oligodendroglioma histology and a longer survival rate.1-5

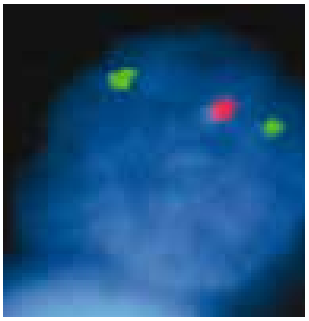
The Vysis LSI 1p36/1q25 and 19q13/19p13 probes performed successfully in several studies to detect losses in 1p36 and 19q13.6-7 FISH testing using this probe set in an analysis of 81 histologically confirmed patient samples (glial tumors, WHO grade I-IV) supported previous study findings that loss of 1p36 and 19q13 is highly correlated with tumors with oligodendroglial component.6 Wharton et al. detected 1p and 19q deletions in the majority of samples graded as oligodendrogliomas, WHO grade II and III.7

These and other studies established FISH analysis using LSI 1p36/LSI 19q13 as a useful tool to complement morphological diagnosis of malignant tumors with a oligodendroglial component.

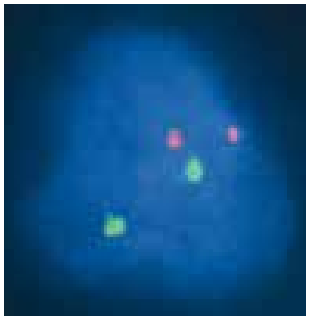
The Vysis LSI 1p36 SpectrumOrange/1q25 SpectrumGreen Probes are provided in one vial as a mixture of a ~435 kb SpectrumOrange-labeled 1p36 probe and a ~618 kb SpectrumGreen-labeled 1q25 probe premixed in hybridization buffer. The LSI 1p36 probe contains sequences that extend from near SHGC 57243 locus, through the TP73 and MEGF6 genes, and ends at a point telomeric to the MEGF6 locus. The LSI 1q25 probe contains sequences that extend from a point telomeric to the ABL2 gene, through the ABL2 and ANGPTL1 genes, and ends proximally near the SHGC-1322 locus.



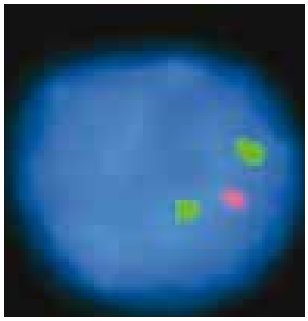
**Normal hybridization:** Result of the hybridization of the LSI 1p36 / LSI 1q25 Dual-Color Probe vial 1 as observed in normal interphase cells.



**Abnormal hybridization:** An abnormal cell hybridized with the LSI 1p36 / LSI 1q25 Dual-Color Probe vial 1. The cell in this image shows the one orange, two green signal pattern indicative of the 1p36 deletion.



**Normal hybridization:** Result of the hybridization of the LSI 19p13 / LSI 19q13 Dual-Color Probe vial 2 as observed in normal interphase cells.



**Abnormal hybridization:** An abnormal cell hybridized with the LSI 19p13 / LSI 19q13 Dual-Color Probe vial 2. The cell in this image shows the one orange, two green signal pattern indicative of the 19q13 deletion.

The Vysis LSI 19q13 SpectrumOrange/19p13 SpectrumGreen Probes are provided in one vial as a mixture of a ~380 kb SpectrumOrange-labeled 19q13 probe and a ~502 kb SpectrumGreen-labeled 19p13 probe premixed in hybridization buffer. The LSI 19p13 probe contains sequences that extend from a point centromeric to the MAN2B1 locus, through MAN2B1, ZNF443 and ZNF44 genes, and ends at a point telomeric to the ZNF44 locus. The LSI 19q13 probe contains sequences that extend from a point telomeric to the CRX locus, through the CRX, GLTSCR2 and GLTSCR1 genes, and ends proximally at a point centromeric to the GLTSCR1 locus.

## RESULTS OF HYBRIDIZATION

### VIAL 1

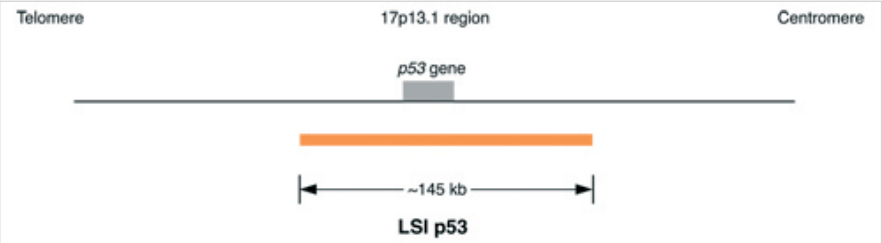
This probe allows status assessment of the following two chromosome regions: 1p36 and 1q25. In a normal cell hybridized with the LSI 1p36 and LSI 1q25, two orange and two green signals will be observed indicative of two intact copies of chromosome 1. In an abnormal cell with a deletion in the 1p36 region fewer than two orange signals will be observed.

### VIAL 2

This probe allows status assessment of the following two chromosome regions: 19q13 and 19p13. In a normal cell with two intact copies of chromosome 19, two orange and two green signals will be observed. In an an abnormal cell with a deletion in the 19q13 region fewer than two orange orange signals will be observed.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 1p36 / LSI 1q25 and LSI 19q13/19p13 Dual-Color Probe **(CE)** | 2 vials, 200 µL each | 04N60-020 | 00884999009288 |

# Vysis LSI TP53 (17p13.1) SpectrumOrange Probe



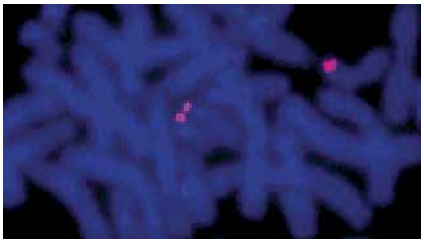


## PRODUCT DESCRIPTION

The LSI TP53 (previously designated as p53) Probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene. The ability to use FISH probes such as the LSI p53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the p53 locus.The LSI p53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.

## RESULTS OF HYBRIDIZATION

In a cell containing a deletion of the LSI p53 locus, one orange LSI p53 signal will be observed (1O signal pattern). In a cell harboring amplification of the p53 locus multiple copies of the orange signal will be observed. In a normal cell the two orange (2O) signal pattern is observed.

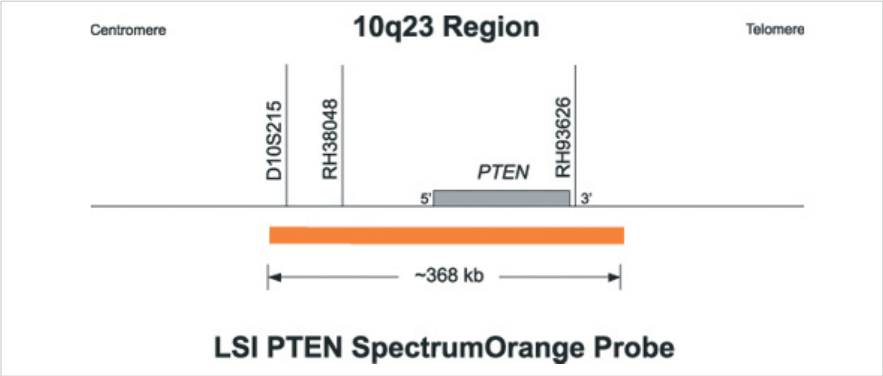


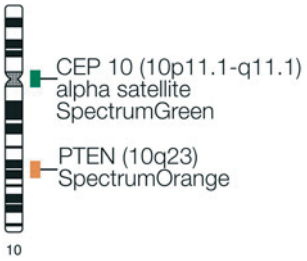
**Normal hybridization:** LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 |

GLIOMAS

# Vysis PTEN/CEP 10 FISH Probe Kit




## PRODUCT DESCRIPTION

The gene for the phosphatase and tensin homolog (PTEN) on chromosome 10q23 is mutated in a wide range of human cancers with comparable frequency to the gene for p53. The PTEN tumor suppressor gene is mutated in multiple cancers that undergo 10q loss. The PTEN gene encodes a lipid phosphatase that negatively regulates the phosphoinositol-3-kinase/Akt pathway. Allelic loss of chromosome 10q is one of the most common events in gliomas.

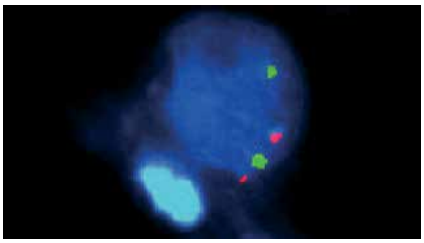
The Vysis LSI PTEN SpectrumOrange/CEP 10 SpectrumGreen Probes performed successfully in several cytogenetic studies to detect losses of the PTEN gene. Evaluation of this probe set in a study using diffusely infiltrating astrocytoma samples from 159 patients correlated significantly with histological grade. The clinical findings emphasized the utility of combining histological interpretation and molecular testing. Korshunov et al. successfully used the Vysis PTEN SpectrumOrange/CEP 10 SpectrumGreen Probes and Vysis FISH probes for other relevant markers (EGFR, CDKN2A, 1p/19q) to obtain clinically useful information for 114 morphologically ambiguous high-grade gliomas composed small cells. Another study using the Vysis FISH probes for PTEN and EGFR, including biopsy-proved tissue samples from 63 anaplastic astrocytoma and 111 glioblastoma multiforme cases, demonstrated the clinical significance of both markers.

Vysis LSI PTEN SpectrumOrange/CEP 10 SpectrumGreen Probes are provided in one vial as a mixture of LSI PTEN (10q23) probe, labeled with SpectrumOrange, and the CEP 10 probe, labeled with SpectrumGreen. The LSI PTEN (10q23) SpectrumOrange Probe is a ~ 368 kb probe that hybridizes to the 10q23 region on chromosome 10 and contains sequences that flank both the 5' and 3' ends of the PTEN gene. The CEP 10 SpectrumGreen probe hybridizes to alpha satellite sequences specific to chromosome 10.

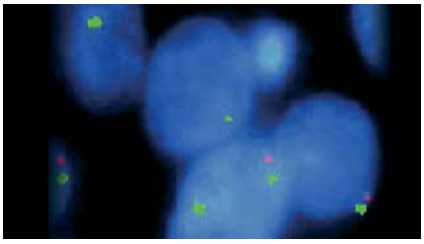
## RESULTS OF HYBRIDIZATION

In a normal cell with two intact copies of chromosome 10, two green and two orange signals will be observed.

In an abnormal cell with a deletion of the PTEN (10q23) gene region, fewer than two orange signals will be observed.



**Normal hybridization:** Result of the hybridization of the Vysis LSI PTEN / CEP 10 Probes as observed in normal interphase cells. (Photo courtesy of Dr. Arie Perry, Washington University.)

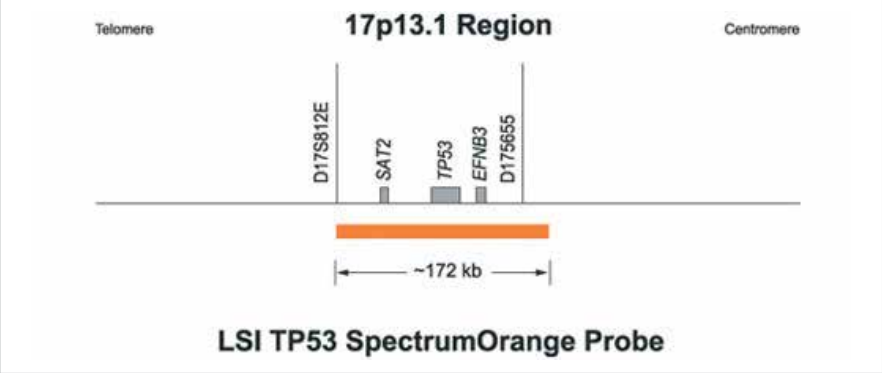


**Abnormal hybridization:** An abnormal cell hybridized with the Vysis LSI PTEN / CEP 10 Probes. The cell in this image shows the one orange, two green signal pattern indicative of a PTEN (10q23) deletion. (Photo courtesy of Dr. Arie Perry, Washington University.)

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis PTEN / CEP 10 FISH Probe Kit **(CE)** | 20 µL | 04N62-020 | 00884999009301 |

GLIOMAS

# Vysis TP53/CEP 17 FISH Probe Kit

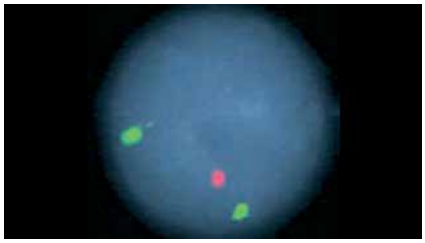




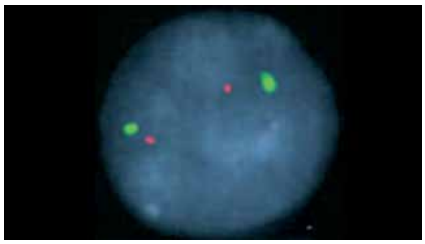
## PRODUCT DESCRIPTION

The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma. The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.



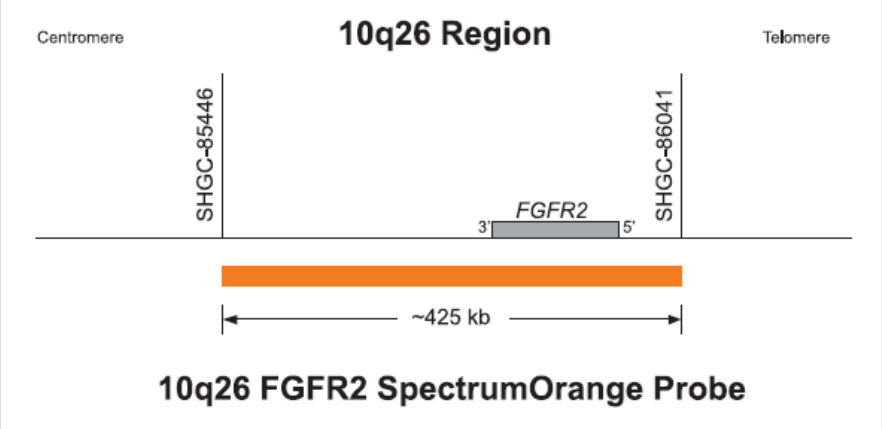
**Abnormal hybridization:** Nucleus showing the two green and one orange signal.

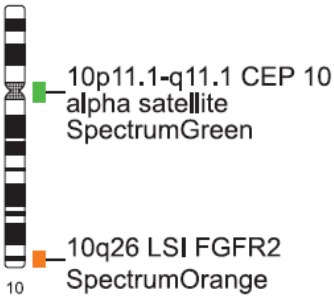


**Normal hybridization:** Nucleus showing the two green and two orange signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 |

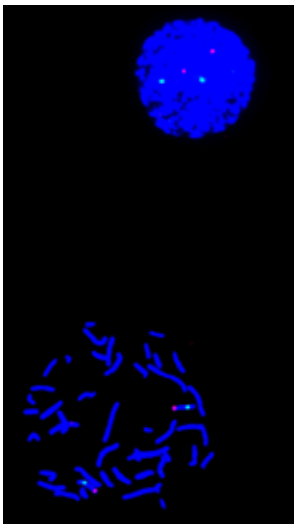
# 10q26 FGFR2 SpectrumOrange/ CEP 10 SpectrumGreen FISH Probe Kit




## PRODUCT DESCRIPTION

The 10q26 FGFR2 SpectrumOrange probe is approximately 425 kb in size and contains the entire FGFR2 gene. The CEP 10 SpectrumGreen probe hybridizes to the alpha satellite DNA located at the centromere of chromosome 10 (10p11.1-q11.1).



Metaphase and Interphase images of hybridized cell using the 10q26 FGFR2 SpectrumOrange/CEP 10 SpectrumGreen FISH Probe Kit

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| 10q26 FGFR2 SpectrumOrange/CEP 10 SpectrumGreen FISH Probe Kit **(RUO)** | 20 µL | 08N42-060 | 00884999042582 |

LUNG CANCER

# Vysis ALK Break Apart FISH Probe Kit




## NCCN GUIDELINES VERSION 2.2013 FOR NON-SMALL CELL LUNG CANCER

- Recommend ALK testing concurrently with EGFR mutation testing for diagnosing the following NSCLC histological subtypes: adenocarcinomas, large cell carcinomas, and NOS (not otherwise specified)
- States that a molecular diagnostic test that uses fluorescence in situ hybridization (FISH) is approved by the FDA to determine which patients with NSCLS are positive for ALK rearrangements

## EARLY FISH TESTING AT DIAGNOSIS CAN DETERMINE APPROPRIATE ALK-DIRECTED THERAPY

- Unlike IHC which is highly subjective and RT/PCR which misses variants, the Vysis ALK test using break-apart FISH technology offers the benefits of:
- Identifying ALK gene rearrangements with fusion partners, including but not restricted to: EML4, TFG, and KIF5B

- Reducing false negative results, which provides confidence that patients are correctly identified and aiding pathologists and oncologists in their goal to diagnose and appropriately manage their NSCLC patients

## PERSONALIZED MEDICINE ADVANCES

- The first companion diagnostic for a novel subclass of non-small cell lung cancer patients.
- Detection of ALK-positive NSCLC is necessary for selection of patients for treatment with XALKORI (crizotinib).
- Abbott announced the simultaneous approval of Pfizer's XALKORI (crizotinib) and Abbott's Vysis ALK FISH Probe Kit

## INTENDED USE

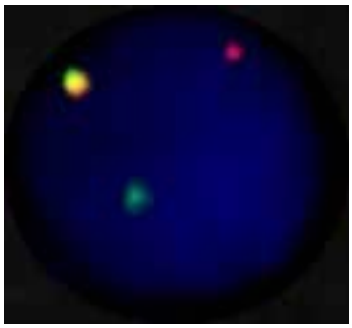
The Vysis ALK Break Apart FISH Probe Kit is a qualitative test to detect rearrangements involving the ALK gene via fluorescence in situ hybridization (FISH) in formalin-fixed paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) tissue specimens to aid in identifying those patients eligible for treatment with Xalkori® (Crizotinib).

## WARNINGS AND LIMITATIONS

1. The Vysis ALK Break Apart FISH Probe Kit has been optimized only for identifying and quantifying rearrangements of the ALK gene from formalin-fixed, paraffin-embedded human NSCLC tissue specimens. The assay should be only on 10% neutral buffered FFPE human lung tumor tissue. Other types of specimens or fixatives should not be used.
2. The performance of the Vysis ALK Break Apart FISH Probe Kit was established using the procedures provided in the package insert only. Modifications to these procedures may alter the performance of the assay.
3. The clinical interpretation of any test results should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
4. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
5. Technologists performing the FISH signal enumeration must be capable of visually distinguishing between the orange, green and yellow signals.`

## RESULTS OF HYBRIDIZATION

When hybridized with the LSI ALK Dual Color, Break Apart Rearrangement Probe, the 2p23 ALK region in its native state will be seen as two immediately adjacent or fused orange/green (yellow) signals (2F). However, if a t(2;5) or other chromosome rearrangement at the 2p23 ALK breakpoint region has occurred, one orange and one green signal will be seen, while the native ALK region will remain as an orange/green fusion signal (1O1G1F). The hybridization result of the LSI ALK Dual Color, Break Apart Rearrangement Probe containing the t(2;5) translocation will be the centromeric green probe remaining at 2p23, while the telomeric orange signal that covers the region is translocated to 5q35 on the derivative chromosome.

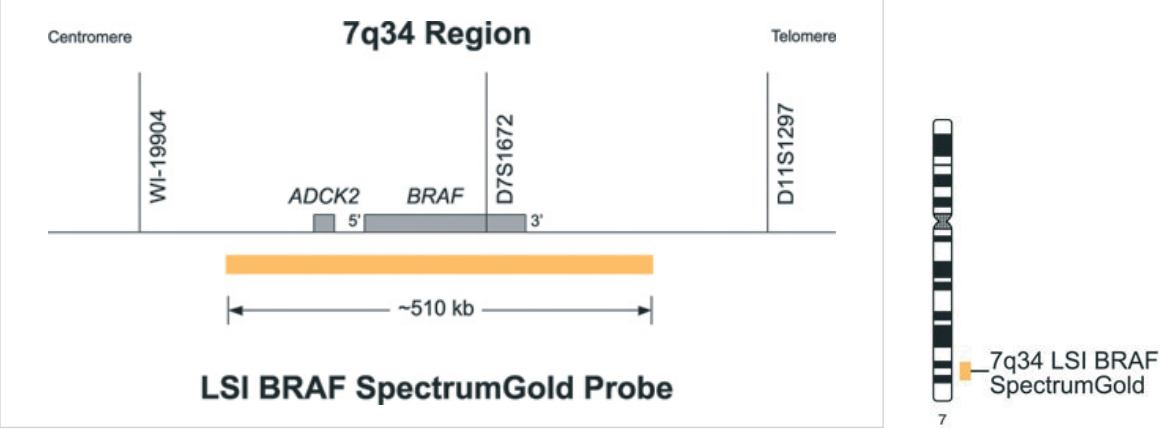


| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| ProbeChek ALK Negative Control Slides **(CE)** | 5 slides | 06N38-005 | 00884999025721 |
| ProbeChek ALK Positive Control Slides **(CE)** | 5 slides | 06N38-010 | 00884999025738 |
| Vysis ALK Break Apart FISH Kit **(IVD Japan Only)*** | 20 Assays | 06N38-021 | 00884999035836 |
| Vysis ALK Break Apart FISH Probe Kit **(CE)*** | 20 Assays | 06N38-020 | 00884999025745 |
| Vysis ALK Break Apart FISH Probe Kit (automation protocol) **(CE)*** | 50 Assays | 06N38-50 | 00884999037205 |
| Vysis Paraffin Pretreatment IV & Post-Hybridization Wash Buffer Kit **(CE)** | 1 Kit | 01N31-005 | 00884999000735 |
| Vysis ProbeChek ALK Negative Control II (only use with 06N38-50) **(CE)** | 5 Slides | 06N38-006 | 00884999038196 |

** Product availability varies by country. Contact your local sales representative for specific ordering information.*

LUNG CANCER

# Vysis BRAF SpectrumGold FISH Probe Kit

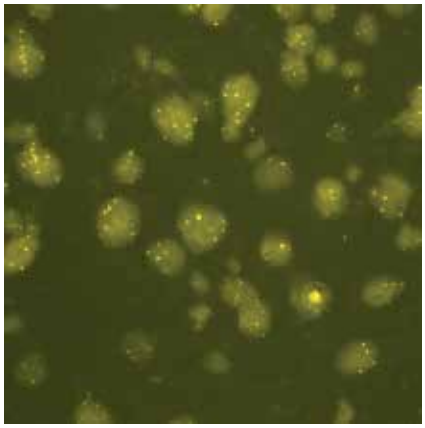



## PRODUCT DESCRIPTION

The Vysis BRAF FISH assay is based on the ability of BRAF locus specific identifier (LSI) probe to identify copy number changes of 7q34 chromosomal locus, using a FISH test.

BRAF is one of three serine/threonine RAF-regulated kinases that have an important role in cellular proliferation, differentiation, and programmed cell death. It alsoparticipates in the RAS-RAF-MEK-ERK-BRAF in promoting tumorigenesis (malignant transformation of kinase BRAFs).

Mutationally activated BRAF-V600E is detected in melanoma (70%), colorectal (15%), papillary thyroid (40%), ovarian (30%), and non-small-cell lung cancers (NSCLCs) (3%). Melanoma with activating mutation of BRAF is more likely tohave copy gains at the BRAF locus. BRAF copy number gains have been identified in both follicular thyroid cancer and malignant melanoma, and may occur through either gene amplification or chromosome 7 polysomy. The BRAF copy number gains are expected in lung cancer, where chromosome 7 is also amplified.

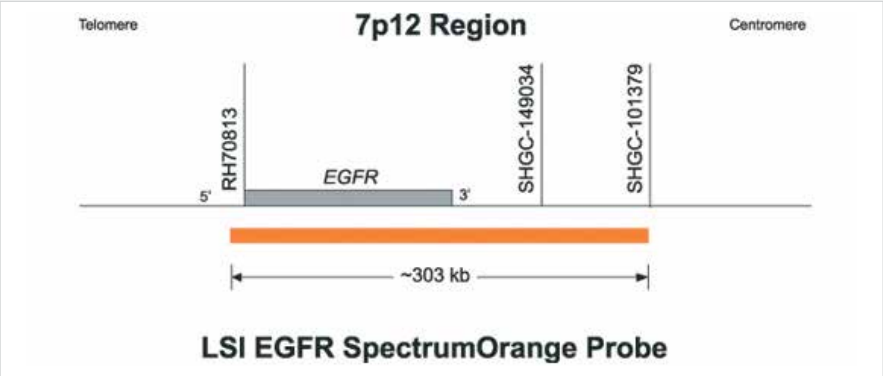


## RESULTS OF HYBRIDIZATION

Normal diploid nuclei or metaphase chromosome sets are expected to exhibit two gold fluorescent BRAF signals, which correspond to two target loci on chromosome homologues to which the BRAF fluorescent probe is bound: 7q34. A chromosome set that has an extra copy (copies) of BRAF (7q34) will exhibit more than two gold fluorescent signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis BRAF SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 06N09-020 | 00884999025028 |

# Vysis EGFR/CEP 7 FISH Probe Kit





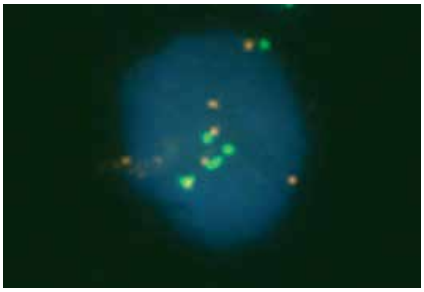
## PRODUCT DESCRIPTION

EGFR abnormalities including increased copy number and amplification have been correlated with the development of many solid tumors, including non-small cell lung cancer (NSCLC) which is the leading cause of cancer death worldwide.

NSCLC has a 5-year survival rate of approximately 15%. There is a pressing need for improvement in identifying patients most likely to respond to specific treatments for NSCLC. Inhibition of EGFR by agents that block its tyrosine kinase domain has been demonstrated to reduce proliferation of lung cancer cells, resulting in suppression of tumor growth.

## RESULTS OF HYBRIDIZATION

In a cell with normal copy number of the EGFR gene and chromosome 7, two orange signals (EGFR), and two green signals (chromosome 7) will be observed. Simultaneously, the copy number of chromosome 7 can be quantified by enumeration of the green signals observed within the same cell. Therefore, enumeration of both the orange EGFR and green CEP 7 signals provide a mechanism for determining EGFR copy number relative to total chromosome 7 copy number.

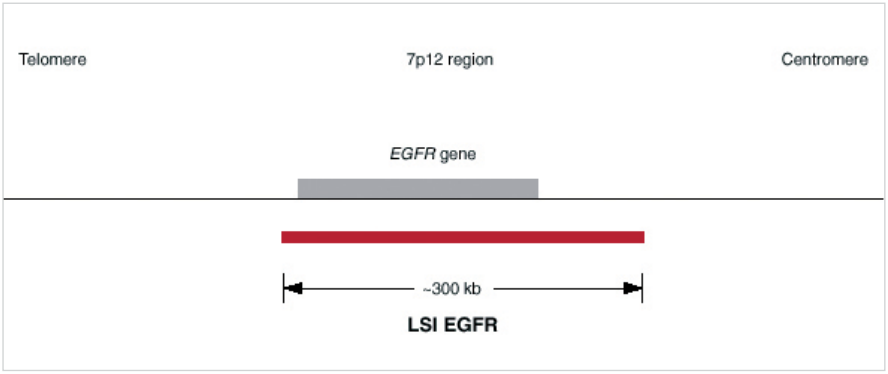


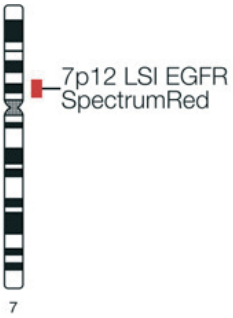
**Abnormal hybridization:** An abnormal cell hybridized with the Vysis LSI EGFR SpectrumOrange /CEP 7 SpectrumGreen Probes. The cell contains multiple EGFR (orange) signals and chromosome 7 (green signals).

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 200 µL | 01N35-020 | 00884999000773 |

LUNG CANCER

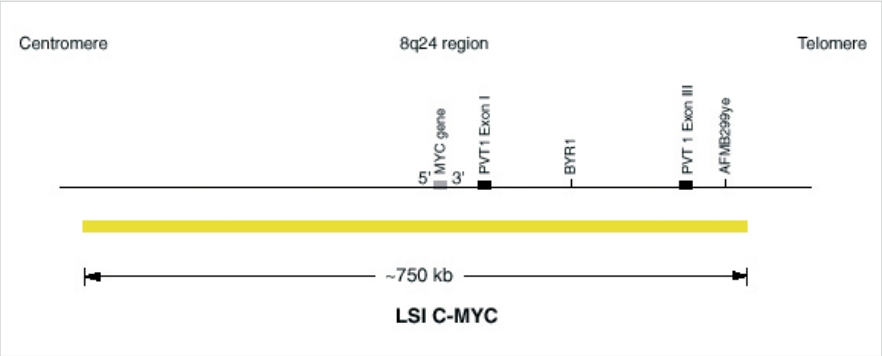
# LSI EGFR SpectrumRed Probe

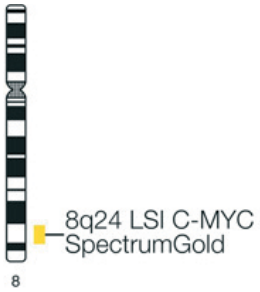



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI EGFR SpectrumRed Probe **(ASR)** | 20 µL | 04N31-020 | 00884999008281 |

# Vysis LSI MYC SpectrumGold Probe

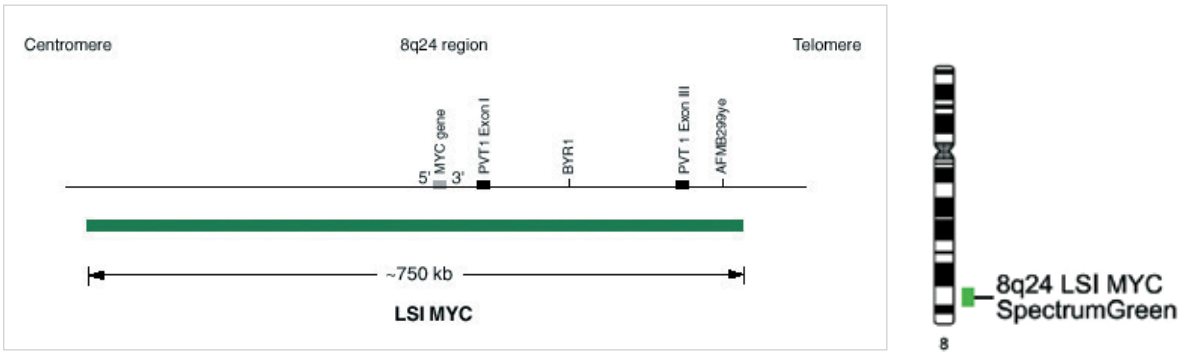



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYC SpectrumGold Probe **(ASR)** | 20 µL | 04N35-020 | 00884999008342 |

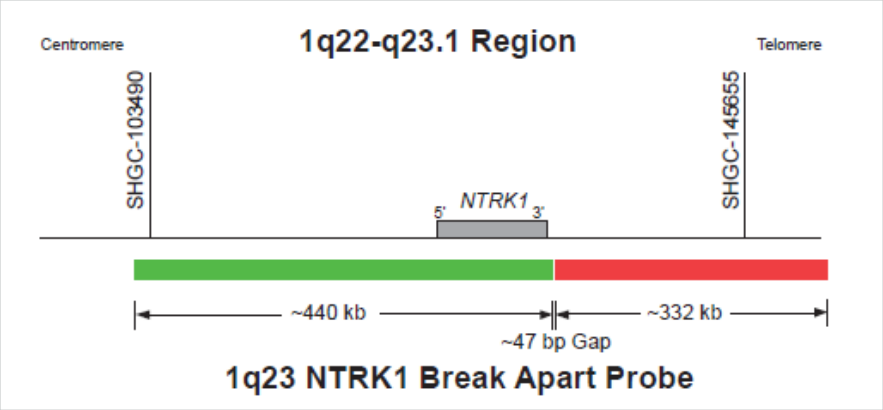
LUNG CANCER

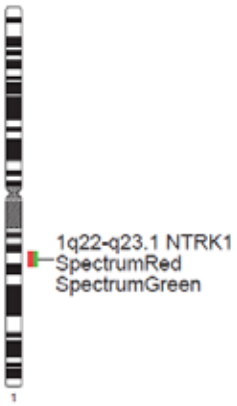
# Vysis LSI MYC SpectrumGreen Probe




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYC SpectrumGreen Probe **(ASR)** | 20 µL | 04N36-020 | 00884999008359 |

# Vysis LSI NTRK1 Break Apart FISH Probe Kit

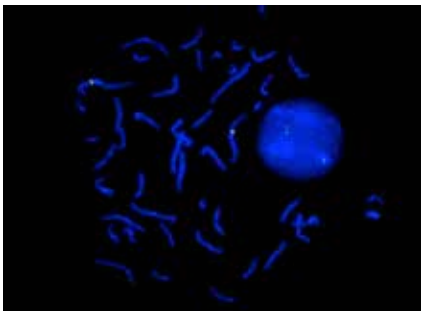



## PRODUCT DESCRIPTION

The 1q23 NTRK1 (Tel) SpectrumRed probe is approximately 332 kb in size and is positioned telomeric of the NTRK1 gene.

The 1q23 NTRK1 (Cen) SpectrumGreen probe is approximately 440 kb in size and contains the entire NTRK1 gene.



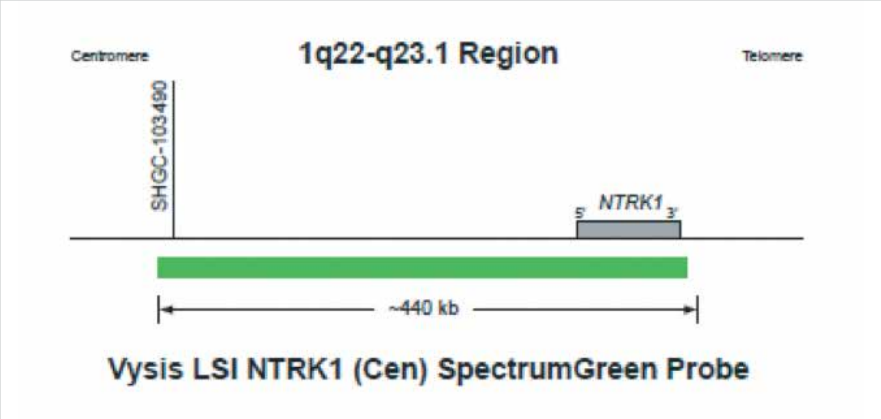
## RESULTS OF HYBRIDIZATION

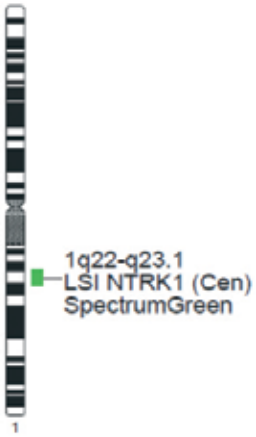
The signal pattern observed in cells containing the NTRK1 rearrangement is the expected pattern of at least one green/red (yellow) fusion signal. In addition, a single green (1G) and a single red (1R) may also be also visible.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI NTRK1 Break Apart FISH Probe Kit **(RUO)** | 20 µL | 08N43-60 | 00884999042612 |

LUNG CANCER

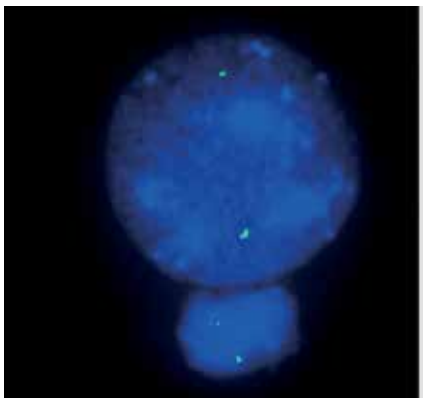
# Vysis LSI NTRK1 (Cen) SpectrumGreen Probe



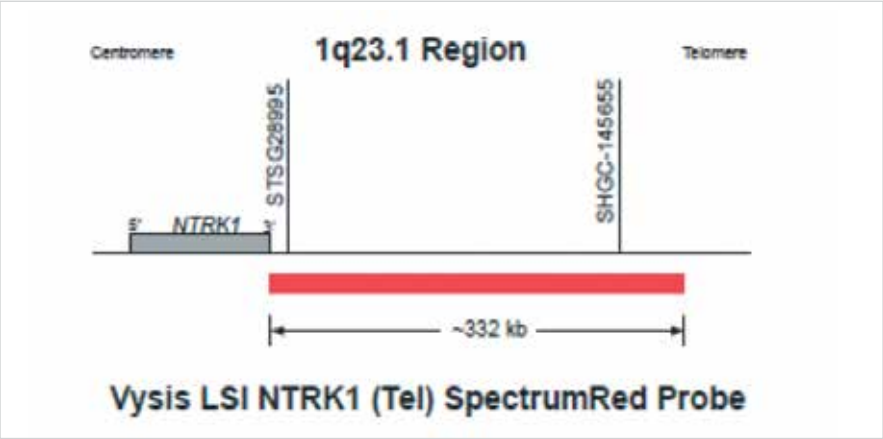

## PRODUCT DESCRIPTION

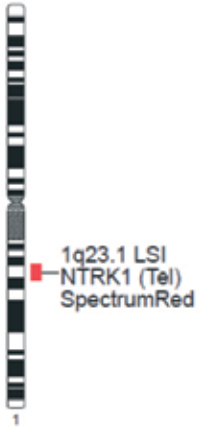
The 1q23 NTRK1 (Cen) SpectrumGreen probe is approximately 440 kb in size and contains the entire NTRK1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI NTRK1 (Cen) SpectrumGreen Probe **(ASR)** | 20 µL | 08N43-030 | 00884999042605 |

# Vysis LSI NTRK1 (Tel) SpectrumRed Probe



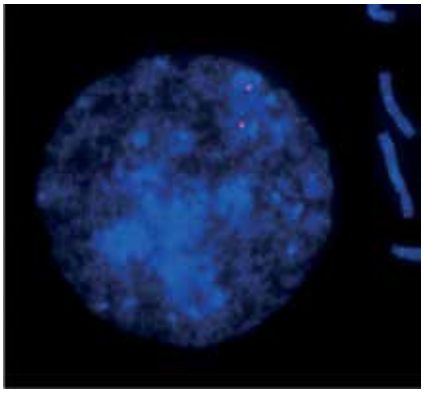




## PRODUCT DESCRIPTION

The 1q23 NTRK1 (Tel) SpectrumRed probe is approximately 332 kb in size and is positioned telomeric of the NTRK1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.

## RESULTS OF HYBRIDIZATION

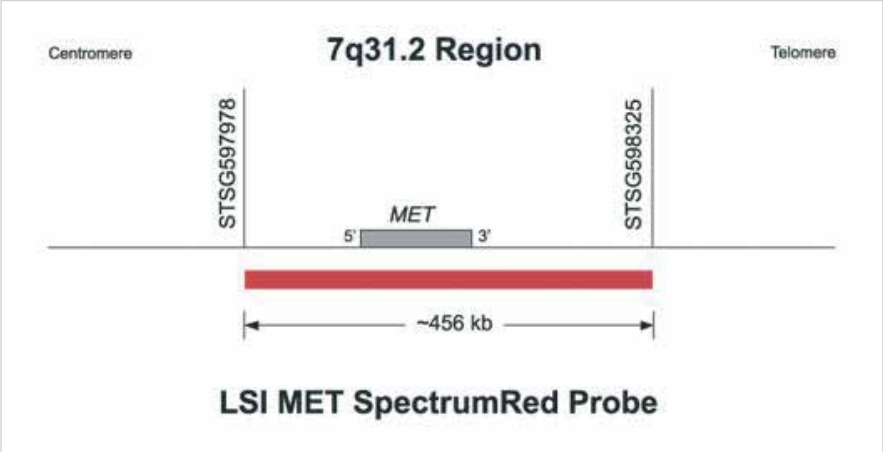
The 1q23 NTRK1 (Tel) SpectrumRed probe is approximately 332 kb in size and is positioned telomeric of the NTRK1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.

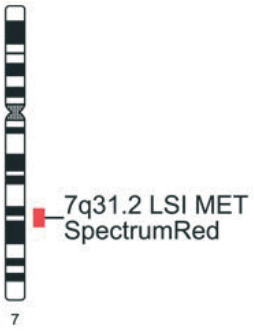


| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI NTRK1 (Tel) SpectrumRed Probe **(ASR)** | 20 µL | 08N43-020 | 00884999042599 |

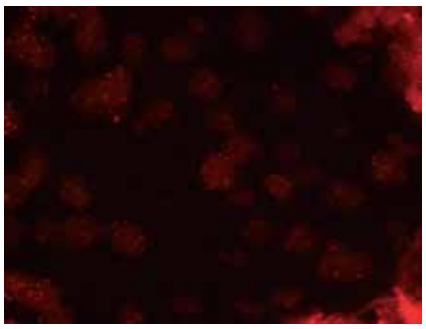
LUNG CANCER

# Vysis MET SpectrumRed FISH Probe Kit




## PRODUCT DESCRIPTION



The Vysis MET SpectrumRed FISH Probe Kit is based on the ability of MET locus-specific identifier (LSI) probe to identify copy number changes of 7q31.2 chromosomal locus, using a FISH test.

MET is a Receptor Tyrosine Kinase. It binds to the ligand, Hepatocyte Growth Factor (HGF). The MET pathway regulates many cellular responses including cell proliferation, survival, motility, invasion and morphogenesis. This pathway is one of the most frequently dysregulated pathways in human cancer for both solid tumors and hematological malignancies including gastric, head and neck, liver, ovarian, non-small cell lung (NSCL) and thyroid cancers, as well as in metastases of some of these cancers.

MET has been shown to be frequently overexpressed or amplified in many cancers, including brain, colorectal, gastric, lung, head and neck and stomach cancers where it is correlated with poor clinical outcomes.

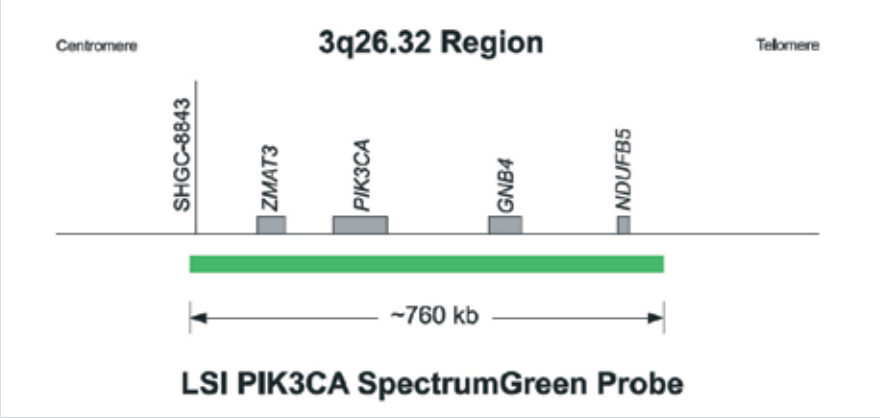
The MET locus has been found to have potential utility for the prognosis of lung cancer where FISH positive MET status predicted worse survival in patients with non-small cell lung cancer (NSCLC).

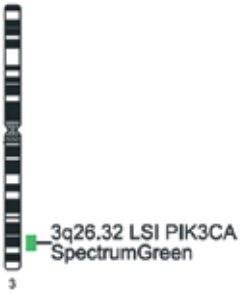
## RESULTS OF HYBRIDIZATION

In a nucleus with normal copy number of the MET gene, two red signals will be observed. Abnormal copy number of the MET gene is indicated by more than two copies of the red probe signal.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis MET SpectrumRed FISH Probe Kit **(CE)** | 20 µL | 06N05-020 | 00884999024984 |

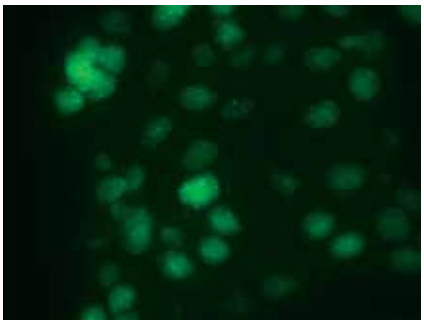
# Vysis PIK3CA SpectrumGreen FISH Probe Kit




## PRODUCT DESCRIPTION

The Vysis PIK3CA SpectrumGreen FISH Probe Kit is designed to detect copy number of 3q26.32 via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin-embedded (FFPE) lung cancer tissue. The PIK3CA gene locus has been shown to be frequently amplified in many cancers, including lung, ovarian, cervical, gastric, colorectal, breast, head and neck.



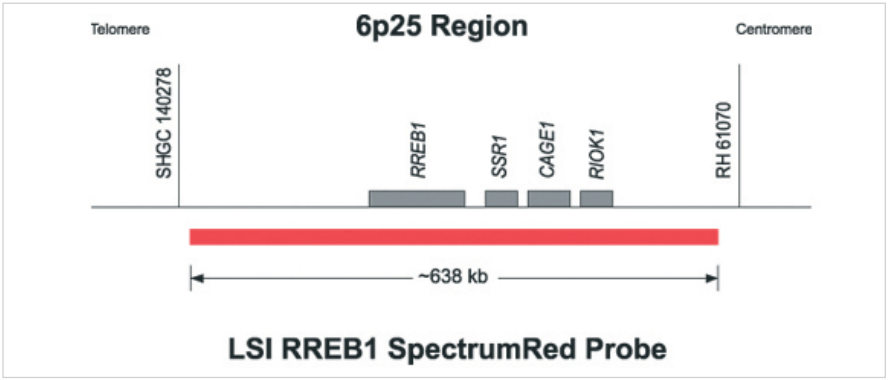
## RESULTS OF HYBRIDIZATION

Normal diploid nuclei are expected to exhibit two green fluorescent PIK3CA signals. A chromosome set that has an extra copy (copies) of PIK3CA will exhibit more than two green fluorescent signals.

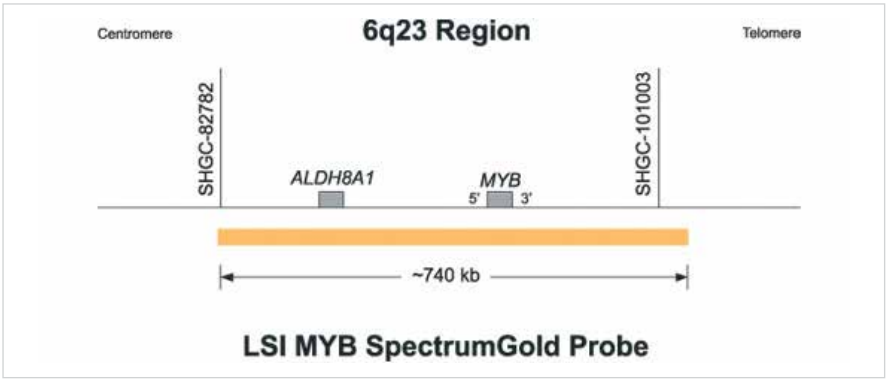
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis PIK3CA SpectrumGreen FISH Probe Kit **(CE)** | 20 µL | 06N10-020 | 00884999034907 |

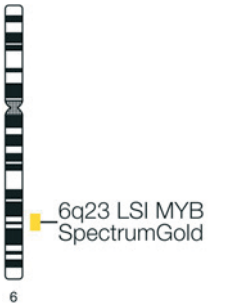
MELANOMA

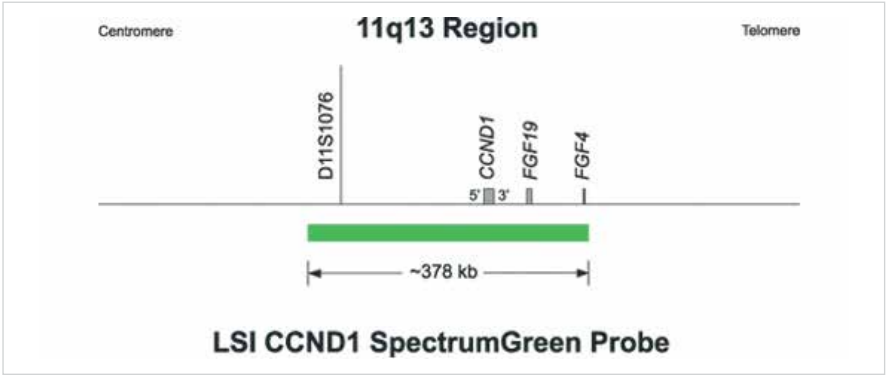
# Vysis Melanoma FISH Probe Kit

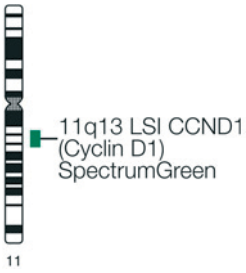






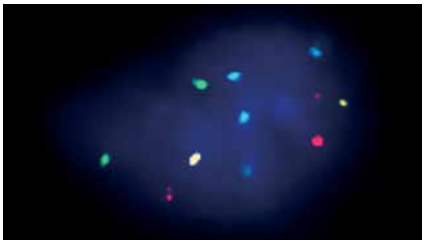
## PRODUCT DESCRIPTION

The Vysis Melanoma FISH Probe Kit is designed to detect copy number of the RREB1 (6p25), MYB (6q23), CCND1 (11q13) genes and of centromere 6 via fluorescence in situ hybridization (FISH) in formalin-fixed, paraffin embedded human skin tissue specimens. The Vysis Melanoma FISH Probe Kit is indicated as an aid in the diagnosis of melanoma in skin biopsy specimens.

The RREB1 (6p25) Probe is labeled with SpectrumRed and covers an approximately 638 kb region that contains the entire RREB1 gene. The MYB (6q23) probe is labeled with SpectrumGold and covers an approximately 740 kb region that contains the entire MYB gene. The CCND1 (11q13) probe is labeled with SpectrumGreen and covers an approximately 378 kb region that contains the entire CCND1 gene. The CEP 6 probe, labeled with SpectrumAqua, hybridizes to the alpha satellite DNA located at the centromere of chromosome 6 (6p11.1-q11.1).

## RESULTS OF HYBRIDIZATION

In a normal cell, two copies of each signal will be observed.

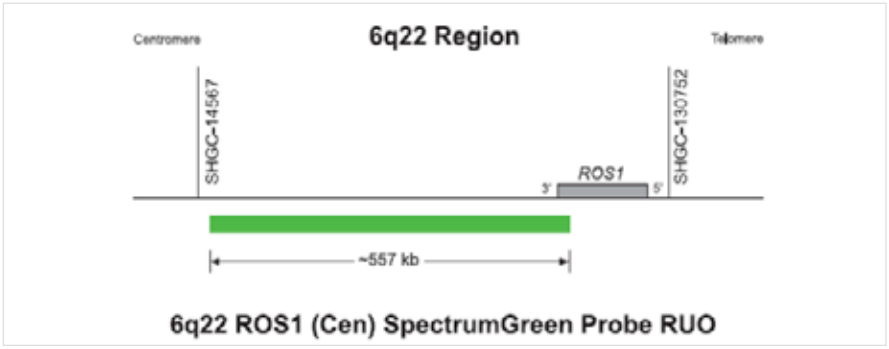


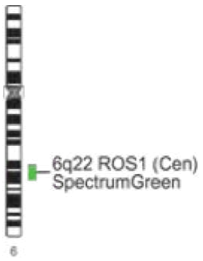
**Normal hybridization:** Results of hybridization of the Vysis Melanoma FISH Probe Kit with an abnormal cell with multiple copies of RREB1 (red) and Chromosome 6 (Aqua).

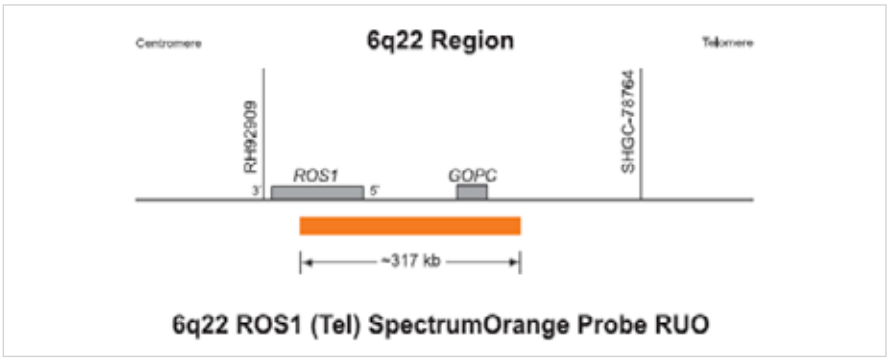
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Melanoma FISH Probe Kit **(CE)** | 200 µL | 01N89-020 | 00884999001312 |

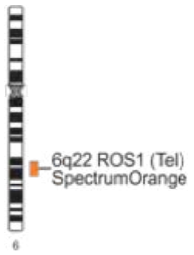
OTHER CANCERS

# Vysis 6q22 ROS1 Break Apart FISH Probe



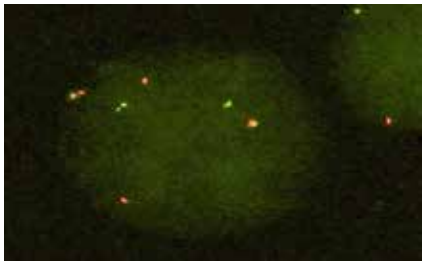




## PRODUCT DESCRIPTION

6q22 ROS1 Break Apart FISH Probe RUO Kit is comprised of two probes necessary to identify ROS1 genetic rearrangements. The SpectrumOrange 6q22 ROS1 (Tel) Fluorescence in situ hybridization (FISH) probe is targeted to the 6q22 region on chromosome 6. The probe is approximately 317 kb in size and positioned telomeric to the ROS1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes. The SpectrumGreen Vysis LSI ROS1 (Cen) Fluorescence in situ hybridization (FISH) probe is targeted to the 6q22 region on chromosome 6. The probe is approximately 557 kb in size and positioned telomeric to the ROS1 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.

The 6q22 ROS1 Break Apart FISH Probe RUO Kit is available for Research Use Only (RUO), and not for use in diagnostic procedures.

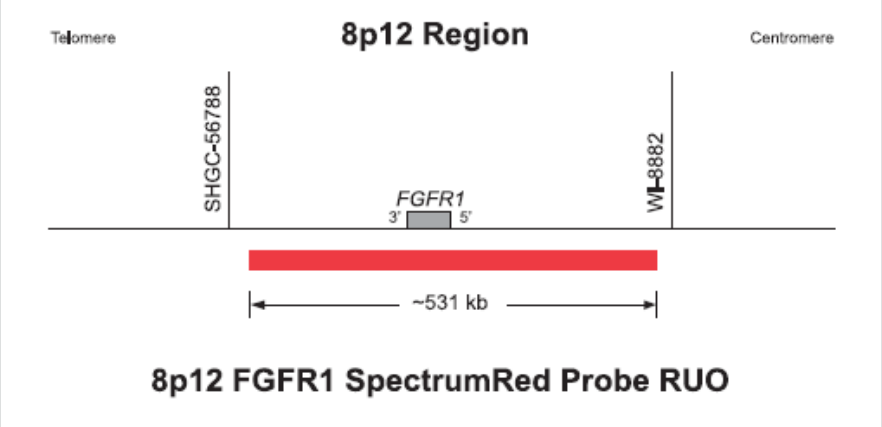


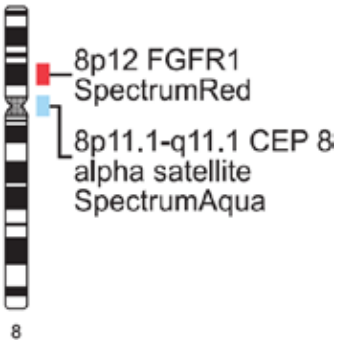
## RESULTS OF HYBRIDIZATION

The signal pattern observed in a cell line containing the ROS1 rearrangement is the expected pattern of at least one green/orange (yellow) fusion signal. In addition, a single green (1G) and a single orange (1O) is also visible.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis 6q22 ROS1 Break Apart FISH Probe **(RUO)** | 20 µL | 08N29-020 | 00884999037892 |

# Vysis 8p12 FGFR1 SpectrumRed/ CEP 8 SpectrumAqua FISH



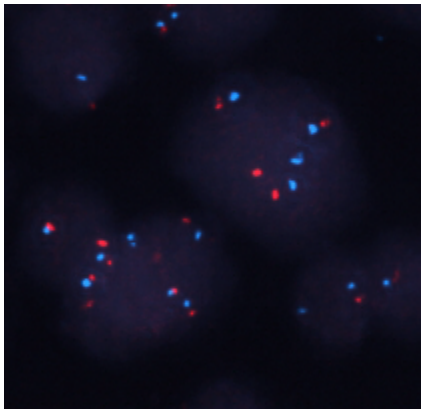




## PRODUCT DESCRIPTION

The SpectrumRed 8q12 FGFR1 Fluorescence in situ hybridization (FISH) probe is targeted to the 8q12 region on chromosome 8. The probe is approximately 531 kb in size and contains the entire FGFR1 gene.

The CEP 8 SpectrumAqua probe hybridizes to the alpha satellite DNA located at the centromere of chromosome 8 (8p11.1-q11.1).

The hybridized probe fluoresces both in interphase nuclei and metaphase chromosomes.

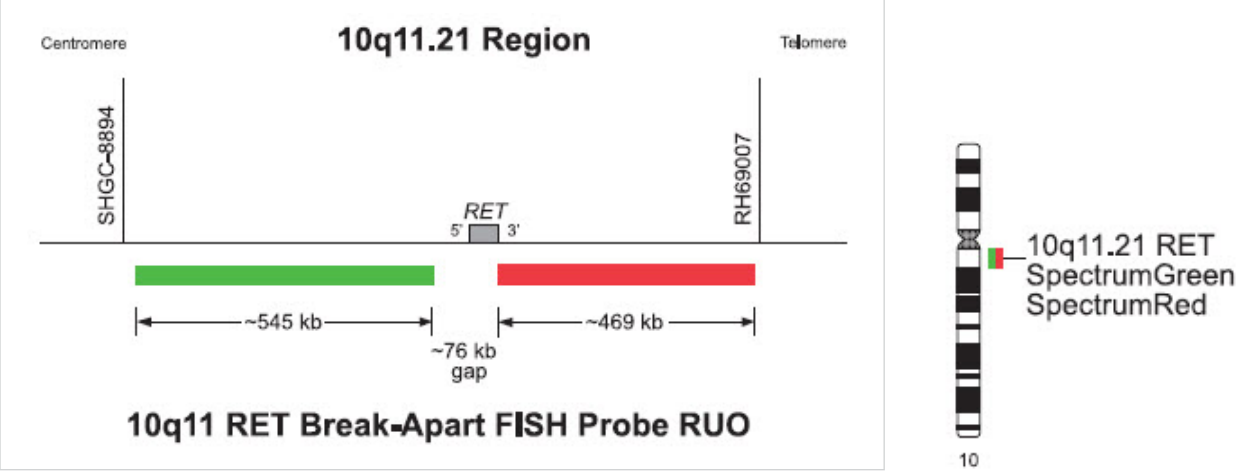


Merged Image viewed under Vysis single-band Red, single-band Aqua and single-band DAPI filters

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis 8p12 FGFR1 SpectrumRed/CEP 8 SpectrumAqua FISH **(RUO)** | 20 µL | 08N21-060 | 00884999038059 |

OTHER CANCERS

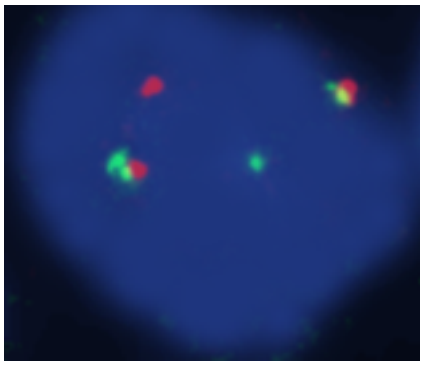
# Vysis 10q11 RET Break-Apart FISH Probe



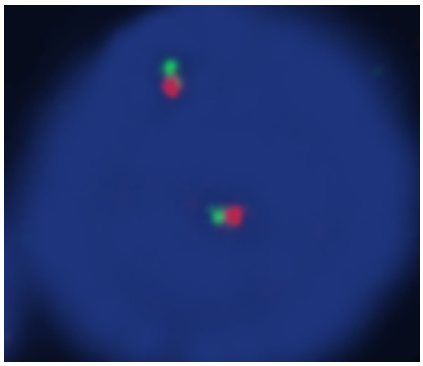

## PRODUCT DESCRIPTION

The 10q11 RET (Tel) SpectrumRed probe is approximately 469 kb in size and is positioned telomeric of the RET gene.

The 10q11 RET (Cen) SpectrumGreen probe is approximately 545 kb in size and is positioned centromeric of the RET gene.



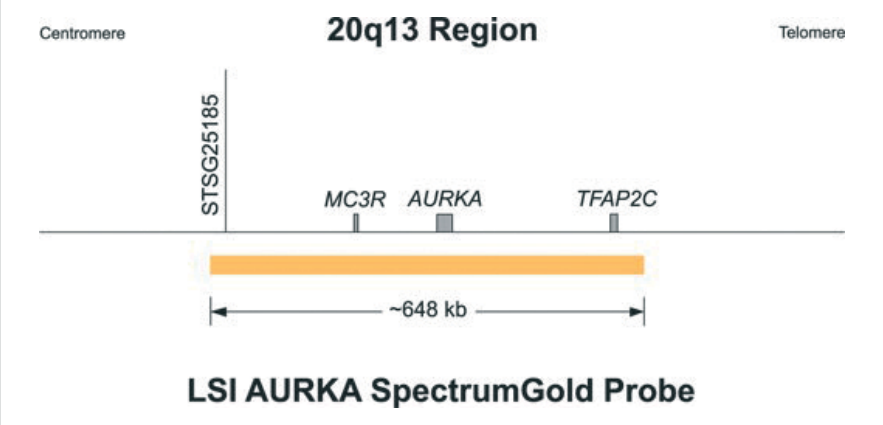
**Positive**



**Negative**

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis 10q11 RET Break-Apart FISH Probe **(RUO)** | 20 µL | 08N31-060 | 00884999038097 |

# Vysis AURKA SpectrumGold FISH Probe Kit

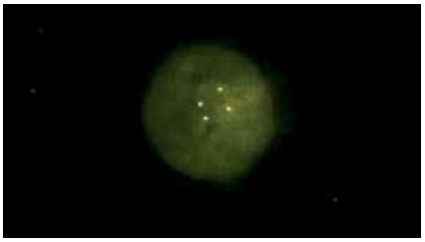




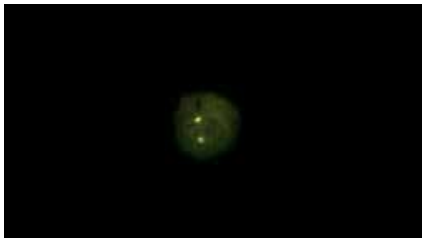
## PRODUCT DESCRIPTION

The Vysis AURKA SpectrumGold FISH Probe Kit is designed to detect the copy number of Aurora Kinase A (AURKA) locus localized in chromosome 20 at the 20q13.2 band via fluorescence in situ hybridization (FISH) in human urine specimens.

The Vysis AURKA SpectrumGold FISH assay is based on the ability of the Aurora Kinase A Locus-Specific Identifier (LSI) probe to identify copy number changes of the 20q13.2 chromosomal locus using a FISH test. Experimental data suggest that inappropriately high or low levels of Aurora Kinase activity are linked to genetic instability and that a high level of expression of Aurora Kinase A is often associated with amplification of the region of chromosome 20 encoding AURKA, indicating that deregulated expression of at least one gene in the amplified region provides a survival/proliferation advantage to a tumor cell and is therefore linked directly to neoplasia. Over-expression of the Aurora Kinase A gene has also been shown to be associated with aneuploidy, chromosome instability and promotion of tumorigenic transformation and progression in mammalian cells and in several human tumors, including urothelial carcinoma. AURKA amplification has been demonstrated in breast, colon, brain, bladder, head/neck and endometrium cancers, and its expression in tumors is often associated with genetic instability and poor prognosis. FISH data on voided urine samples from patients with bladder cancer indicate that amplification of AURKA is frequent in bladder cancer and can be detected in urothelialcells. Further, amplification of chromosome 20q has been associated with clinically aggressive variants of several common malignancies, including bladder cancer.



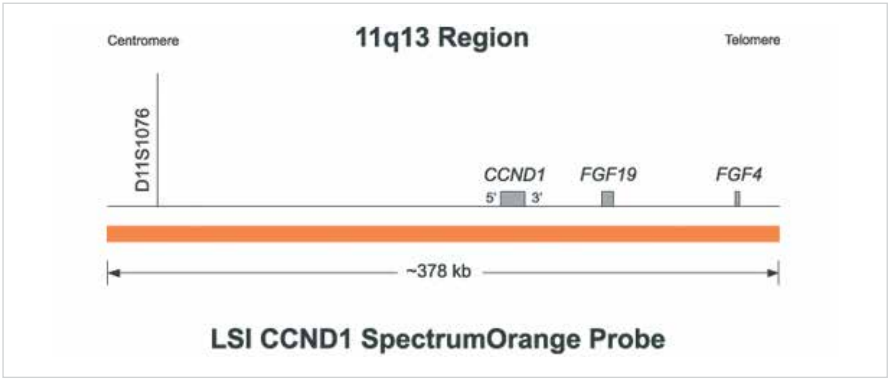
**Abnormal hybridization:** Abnormal copy number of the AURKA gene is indicated by more than two copies of the gold probe signal. Disregard nuclei with less than 2 copies of the gold probe signal.

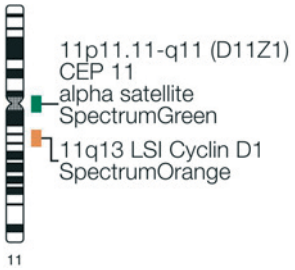


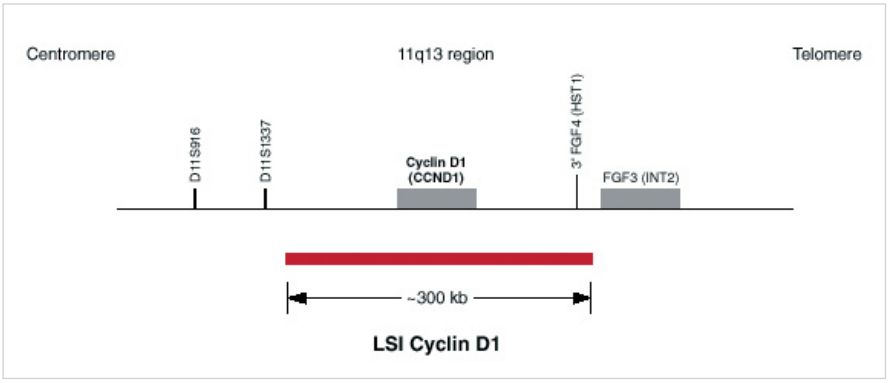
**Normal hybridization:** In a nucleus with a normal copy number of the AURKA gene, two gold signals will be observed.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis AURKA SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 05N93-020 | 00884999015470 |

# Vysis CCND1 / CEP 11 FISH Probe Kit




## PRODUCT DESCRIPTION

Amplification of the chromosome 11q13 region, which harbors the Cyclin D1 (CCND1, PRAD1) oncogene, has been reported to occur in up to 15% of breast cancers. CCND1 amplification has been reported to be a prognostic marker.

Several studies used the Vysis CCND1/CEP 11 FISH Probe Kit to detect CCND1 amplification in breast cancer samples. Al-Karaya et al. analyzed a tissue microarray of 2197 breast cancer samples using the probe kit and found CCND1 amplification in 20.1% of cases. CCND1 amplification was associated with high tumor grade and a tendency toward shortened survival. Jirstrom et al. analyzed a tissue microarray of 500 breast cancer specimens from patients treated and not treated with adjuvant tamoxifen. The study found CCND1 amplification to be agonistic to tamoxifen with amplified patients having a significantly higher risk of recurrence.

The Vysis LSI CCND1 SpectrumOrange/CEP11 SpectrumGreen Probes have been applied to cancers other than breast cancer. For example, Katz et al. found elevated CCND1 copy number to be sensitive indicator of mantle cell lymphoma, and could distinguish mantle cell lymphoma from most other B-cell non Hodgkins lymphoma specimens.

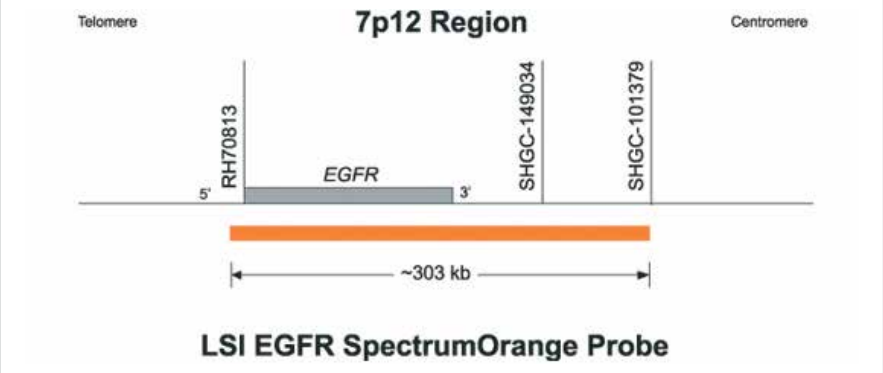
The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/ CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange orange signals. Other patterns may be observed if additional genetic alterations are present.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 |

# Vysis EGFR / CEP 7 FISH Probe Kit





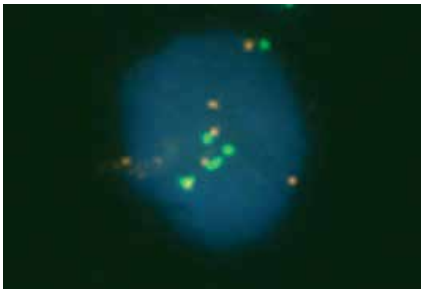
## PRODUCT DESCRIPTION

EGFR abnormalities including increased copy number and amplification have been correlated with the development of many solid tumors, including non-small cell lung cancer (NSCLC) which is the leading cause of cancer death worldwide.

NSCLC has a 5-year survival rate of approximately 15%. There is a pressing need for improvement in identifying patients most likely to respond to specific treatments for NSCLC. Inhibition of EGFR by agents that block its tyrosine kinase domain has been demonstrated to reduce proliferation of lung cancer cells, resulting in suppression of tumor growth.

## RESULTS OF HYBRIDIZATION

In a cell with normal copy number of the EGFR gene and chromosome 7, two orange signals (EGFR), and two green signals (chromosome 7) will be observed. Simultaneously, the copy number of chromosome 7 can be quantified by enumeration of the green signals observed within the same cell. Therefore, enumeration of both the orange EGFR and green CEP 7 signals provide a mechanism for determining EGFR copy number relative to total chromosome 7 copy number.

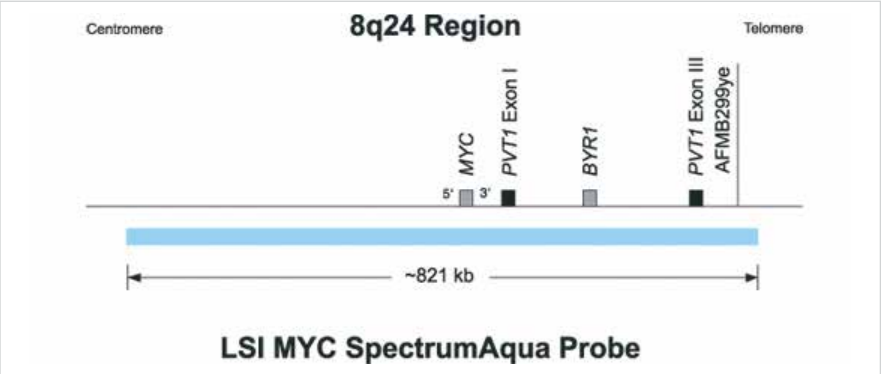


**Abnormal hybridization:** An abnormal cell hybridized with the Vysis LSI EGFR SpectrumOrange /CEP 7 SpectrumGreen Probes. The cell contains multiple EGFR (orange) signals and chromosome 7 (green signals).

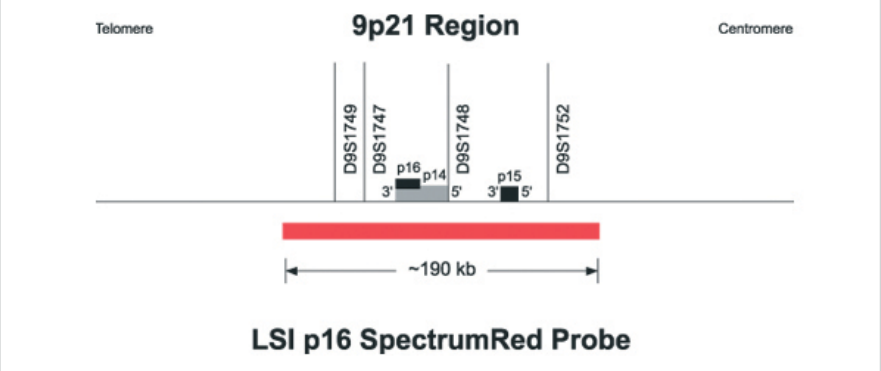
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 200 µL | 01N35-020 | 00884999000773 |

OTHER CANCERS

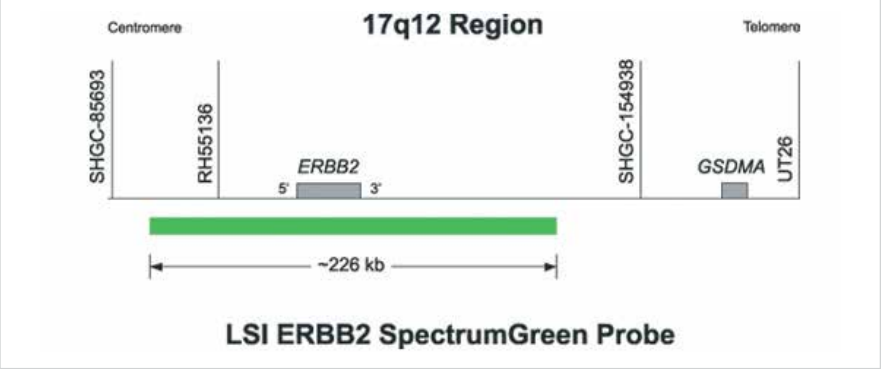
# Vysis Esophageal FISH Probe Kit



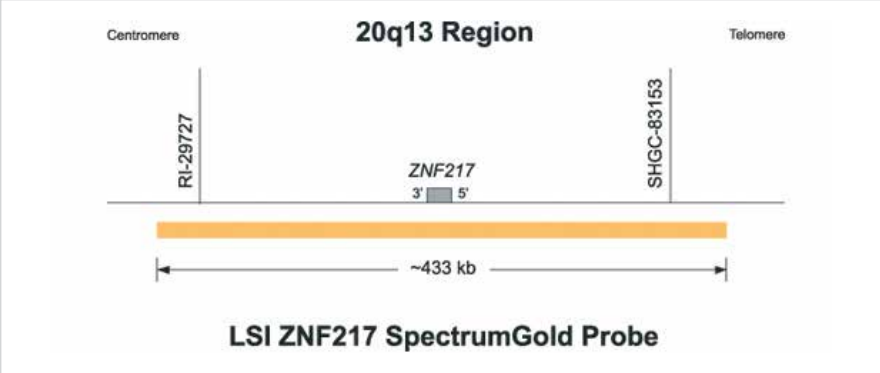

LSI MYC SpectrumAqua Probe




LSI p16 SpectrumRed Probe




LSI ERBB2 SpectrumGreen Probe




## PRODUCT DESCRIPTION

The Vysis Esophageal FISH Probe Kit is designed to detect copy number of ERBB2 (17q12), p16 (9p21), MYC (8q24) and ZNF217 (20q13.2) loci via fluorescence in situ hybridization (FISH) in cytology (esophageal brushing) specimens and in formalin-fixed, paraffin-embedded esophageal tissue specimens.

The Vysis Esophageal FISH Probe Kit utilizes four Locus-Specific Identifier (LSI) probes to identify copy number changes of the ERBB2 (17q12), p16 (9p21), MYC (8q24), and ZNF217 (20q13.2) chromosomal loci, using a multi-color FISH test. These four loci have been shown to be associated with dysplasia and esophageal adenocarcinoma (EAC) in patients with Barrett's esophagus (BE). BE is believed to increase the risk of EAC. The rise in incidence of this pre-malignant condition has been linked to a rapid increase in the incidence of EAC in Western European countries, Canada, and the US . The incidence of EAC has been growing at a rate exceeding that of any other cancer, 4% to 10% annually over the past two decades, while the 5-year survival rate remains less than 10%.

FISH is a technique that allows the visualization of specific nucleic acid sequences within a cellular preparation. Specifically, FISH involves the precise annealing of a single stranded, fluorescently-labeled DNA probe to complementary target sequences. The hybridization of the probe with the cellular DNA site is visible by direct detection using fluorescence microscopy. Interpretation of FISH results should be made utilizing appropriate controls and analytical techniques as well as taking into consideration other clinical and diagnostic test data.

The Vysis Esophageal FISH Probe Kit contains fluorescently labeled nucleic acid probes for use in in situ hybridization assays on esophageal brushing cytology specimens fixed on slides, or on formalin-fixed, paraffin-embedded human esophageal tissue. The Vysis Esophageal FISH Probe Kit is a four-color mixture of four DNA probe sequences.

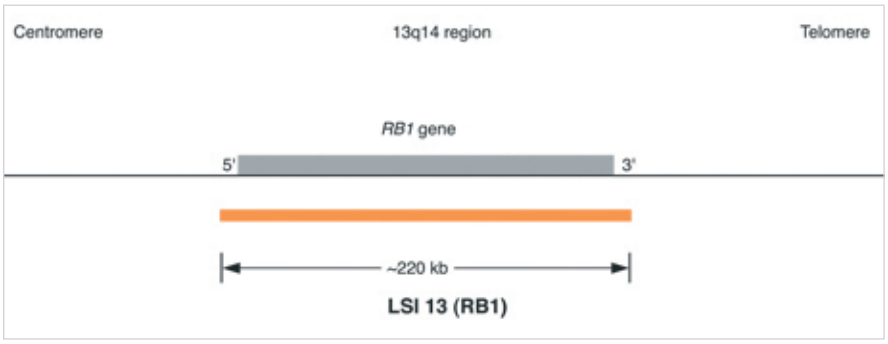
The probes are pre-mixed in hybridization buffer for ease of use. Unlabeled blocking DNA is also included with the probes to suppress sequences contained within the target loci that are common to other chromosomes. When hybridized and visualized, these probes provide information on chromosome copy number.

The ERBB2 probe is labeled with SpectrumGreen and covers an approximately 226 kb region that encompasses the entire ERBB2 gene on chromosome 17. The p16 probe is labeled with SpectrumRed and covers an approximately 190 kb region that encompasses the entire p16 gene on chromosome 9 as well as adjacent regions. The MYC probe is labeled with SpectrumAqua and covers an approximately 821 kb region that encompasses the entire MYC gene on chromosome 8 as well as adjacent regions. The ZNF217 probe is labeled with SpectrumGold and covers an approximately 433 kb region that encompasses the entire ZNF217 gene on chromosome 20 as well as adjacent regions.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Esophageal FISH Probe Kit **(CE)** | 20 µL | 04N19-020 | 00884999008021 |

OTHER CANCERS

# Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe





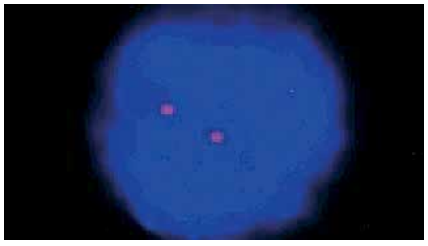
## PRODUCT DESCRIPTION

The LSI 13 (RB1) 13q14 SpectrumOrange Probe contains unique DNA sequences specific to the RB1 gene within the 13q14 region of chromosome 13. The presence or absence of the RB1 gene region may be detected using the LSI 13 (RB1) 13q14 Probe. This probe may be used to detect deletion (not mutation) of the RB1 gene locus.

The LSI 13 (RB1) 13q14 SpectrumOrange Probe is approximately 220 kb and contains sequences that target the entire RB1 gene.

## RESULTS OF HYBRIDIZATION

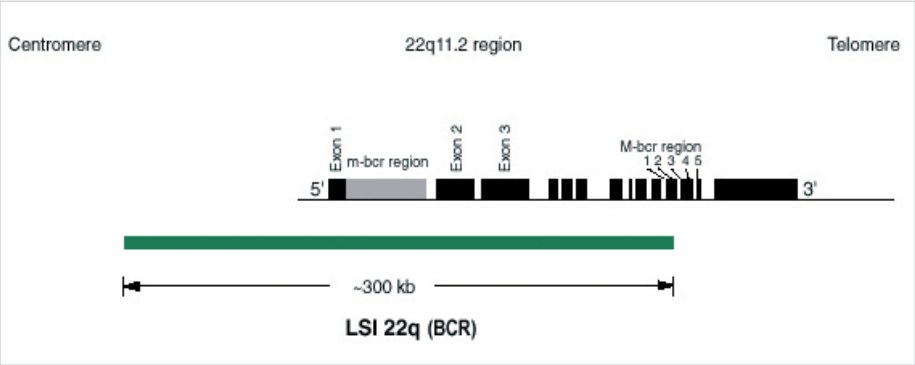
In a normal cell, the expected result for a nucleus hybridized with the LSI 13 (RB1) probe is a two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.



**Normal hybridization:** LSI 13 (RB1) 13q14 Probe hybridized to a normal nucleus showing a two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe **(CE)** | 20 µL | 08L65-020 | 00884999031555 |

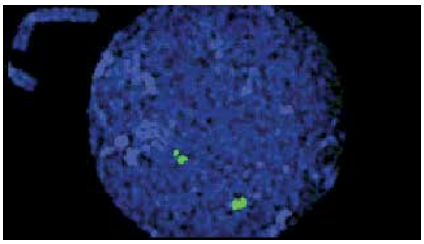
# Vysis LSI 22 (BCR) SpectrumGreen Probe





## PRODUCT DESCRIPTION

The LSI 22 (BCR) Probe is an approximately 300 kb SpectrumGreen probe corresponding to 22q11.2.

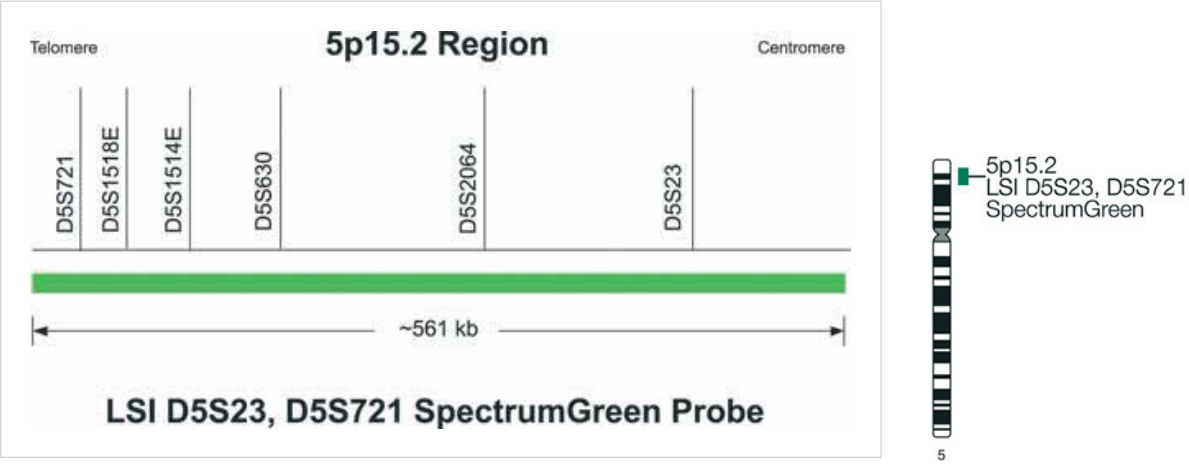


**Normal hybridization:** LSI 22 (BCR) SpectrumGreen hybridized to an interphase cell.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 22 (BCR) SpectrumGreen Probe (**ASR**) | 20 µL | 05J17-024 | 00884999011236 |

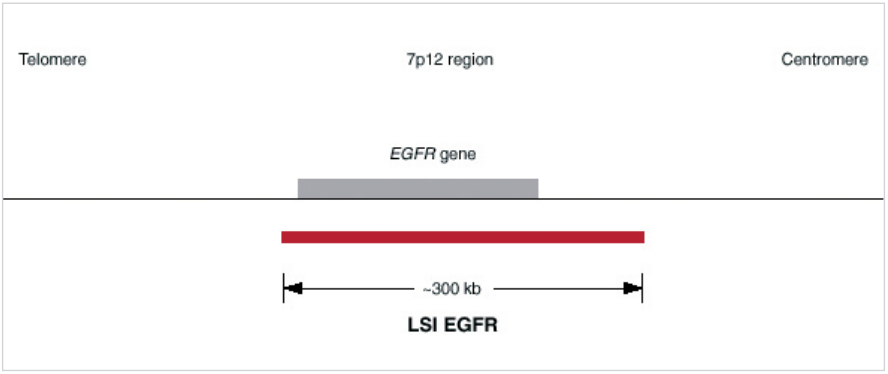
OTHER CANCERS

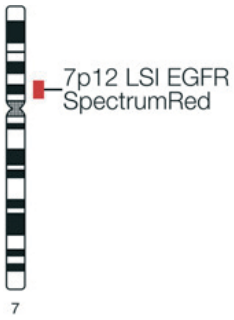
# Vysis LSI D5S23, D5S721 SpectrumGreen Probe




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI D5S23, D5S721 SpectrumGreen Probe **(ASR)** | 20 µL | 04N30-020 | 00884999008274 |

# LSI EGFR SpectrumRed Probe

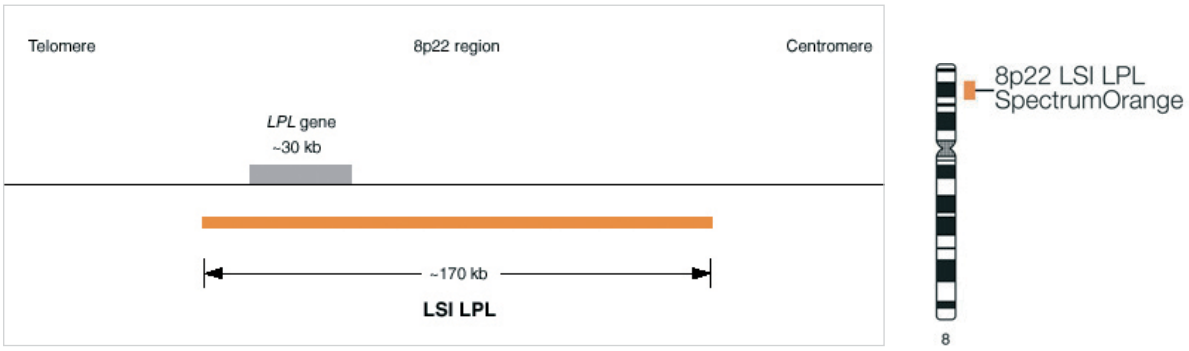



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI EGFR SpectrumRed Probe **(ASR)** | 20 µL | 04N31-020 | 00884999008281 |

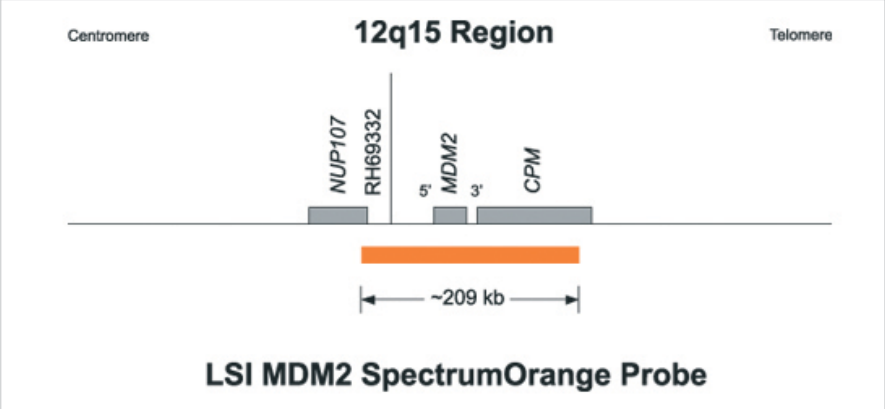
OTHER CANCERS

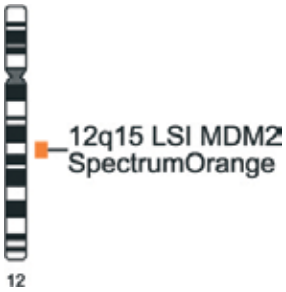
# Vysis LSI LPL SpectrumOrange Probe




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI LPL SpectrumOrange Probe **(ASR)** | 20 µL | 04N34-020 | 00884999008335 |

# Vysis LSI MDM2 SpectrumOrange Probe



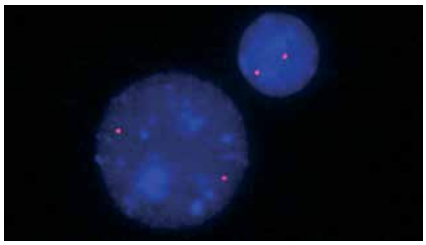

## PRODUCT DESCRIPTION

The chromosomal region 12q13-q15 is often affected by translocations and amplifications in soft tissue sarcoma in humans. This region includes the mouse double minute 2 (MDM2) gene. MDM2 inhibits p53 transcriptional activity by binding to p53 and moving the protein into the cytoplasm. This results in inactivation of the tumor suppressor and the formation of tumors which ultimately leads to cancer. The use of MDM2 as an aid in differential diagnosis of sarcomas has been documented.

The SpectrumOrange Vysis LSI MDM2 fluorescence in situ hybridization (FISH) probe is targeted to the 12q15 region on chromosome 12. The probe is ~209 kb in size and spans the MDM2 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and on metaphase chromosomes.

## RESULTS OF HYBRIDIZATION

In a cell with normal copy number of the MDM2 gene, two orange signals will be observed.

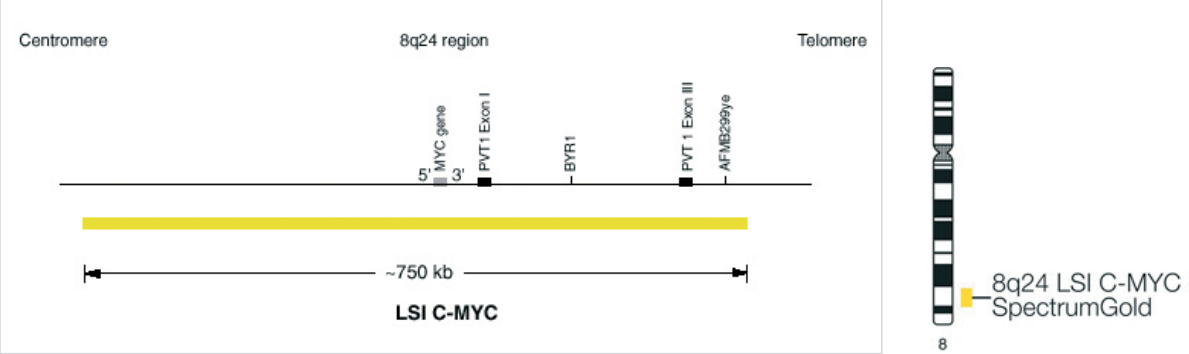


**Normal hybridization:** Cells hybridized with the Vysis LSI MDM2 SpectrumOrange probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MDM2 SpectrumOrange Probe (**ASR**) | 20 µL | 01N15-020 | 00884999000513 |

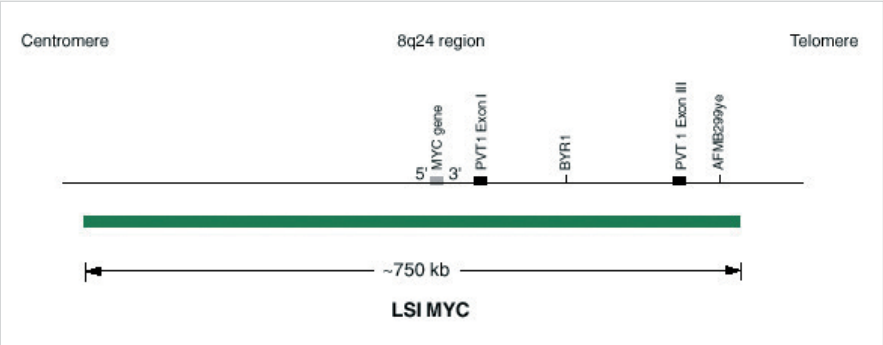
OTHER CANCERS

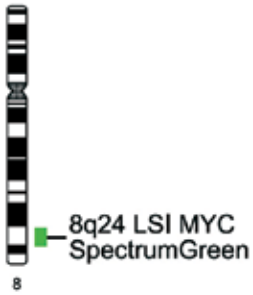
# Vysis LSI MYC SpectrumGold Probe




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYC SpectrumGold Probe **(ASR)** | 20 µL | 04N35-020 | 00884999008342 |

# Vysis LSI MYC SpectrumGreen Probe

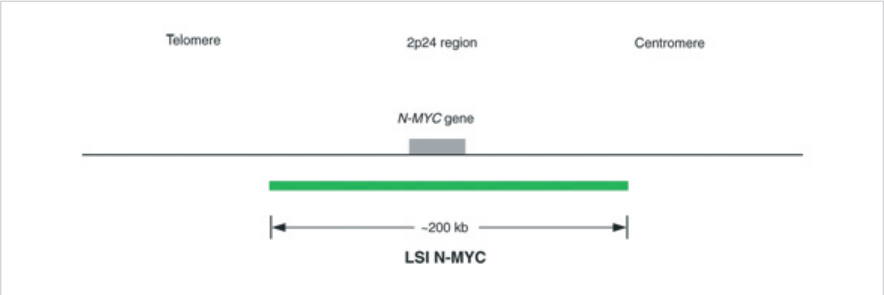


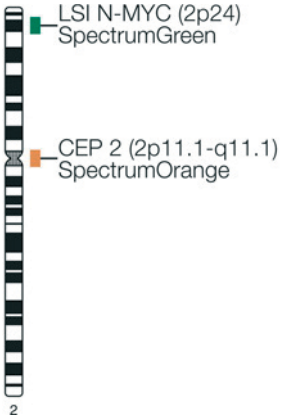




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYC SpectrumGreen Probe **(ASR)** | 20 µL | 04N36-020 | 00884999008359 |

OTHER CANCERS

# Vysis LSI N-MYC (2p24) SpectrumGreen/ Vysis CEP 2 SpectrumOrange Probe



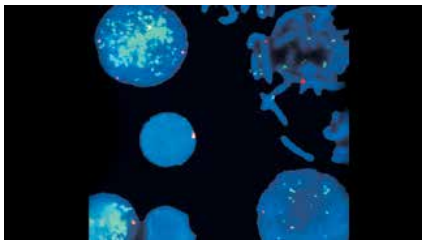

## PRODUCT DESCRIPTION

The LSI N-MYC (2p24) probe contains unique DNA sequences specific to the N-MYC oncogene located within the 2p24 region of chromosome 2. This probe may be used to detect the N-MYC oncogene copy number.

The LSI N-MYC (2p24)/ CEP 2 (2p11.1-q11.1) Dual ColorProbe is a mixture of LSI N-MYC (2p24) labeled with SpectrumGreen and CEP 2 (2p11.1-q11.1) labeled with SpectrumOrange. The LSI N-MYC (2p24) SpectrumGreen probe is an approximately 200 kb probe that hybridizes to the 2p24 region on chromosome 2 and contains sequences that flank both 5' and 3' ends of the N-MYC gene. The CEP 2 (2p11.1-q11.1) SpectrumOrange probe hybridizes to alpha satellite sequences specific to chromosome 2.

## RESULTS OF HYBRIDIZATION

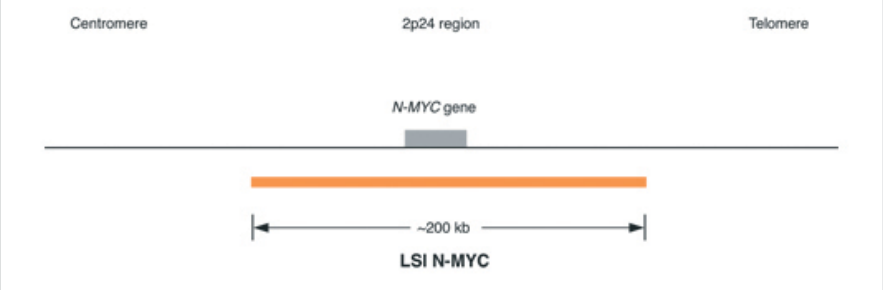
In a normal cell with two intact copies of chromosome 2, two green and two orange signals will be observed. In an abnormal cell containing amplification of the N-MYC oncogene, greater than two green signals will be observed.



**Abnormal hybridization:** An abnormal sample hybridized with the LSI N-MYC (2p24)/ CEP 2 (2p11.1-q11.1) Dual Color Probe showing a high level of amplification of the N-MYC oncogene.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI N-MYC (2p24) SpectrumGreen/Vysis CEP 2 SpectrumOrange Probe **(ASR)** | 20 µL | 07J72-001 | 00884999029156 |

# Vysis LSI N-MYC (2p24.1) SpectrumOrange Probe





## PRODUCT DESCRIPTION

The LSI N-MYC (2p24.1) Probe contains unique DNA sequences specific to the N-MYC oncogene located within the 2p24.1 region of chromosome 2. This probe may be used to detect the N-MYC oncogene copy number.

The N-MYC (2p24.1) Probe is an approximately 200 kb SpectrumOrange labeled probe.

## RESULTS OF HYBRIDIZATION

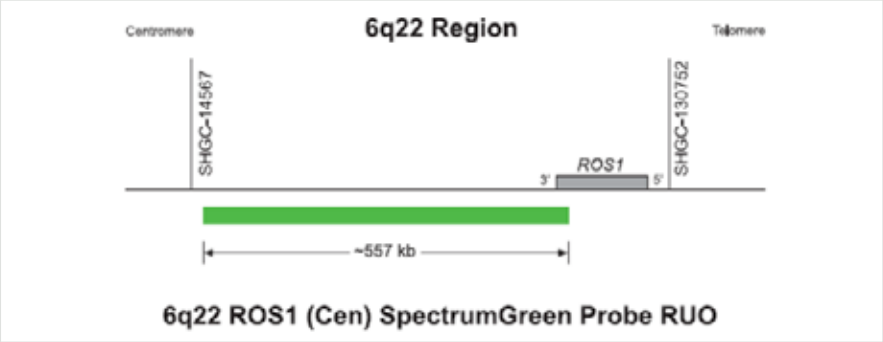
In a normal cell, the expected pattern for a nucleus hybridized with the LSI N-MYC Probe is the two orange (2O) signal pattern. In an abnormal cell containing amplification of the N-MYC oncogene, greater than two orange signals will be observed.

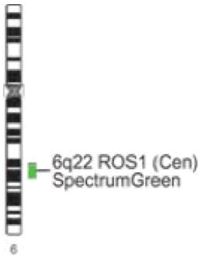
**Abnormal hybridization:** LSI N-MYC Probe hybridized to a cell showing a high level of amplification of the N-MYC oncogene.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI N-MYC (2p24.1) SpectrumOrange Probe **(ASR)** | 20 µL | 05J50-001 | 00884999011984 |

OTHER CANCERS

# Vysis LSI ROS1 (Cen) SpectrumGreen Probe



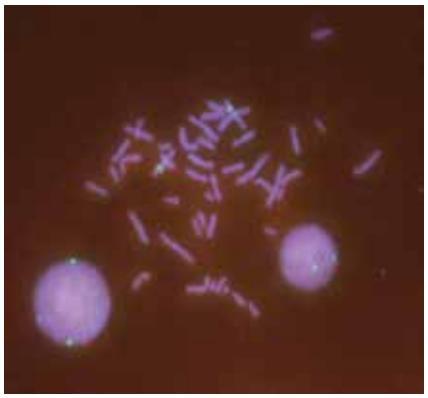




## PRODUCT DESCRIPTION

The SpectrumGreen Vysis LSI ROS1 (Cen) Fluorescence in situ hybridization (FISH) probe is targeted to the 6q22 region on chromosome 6. The probe is approximately 557 kb in size and positioned telomeric to the ROS1 gene.

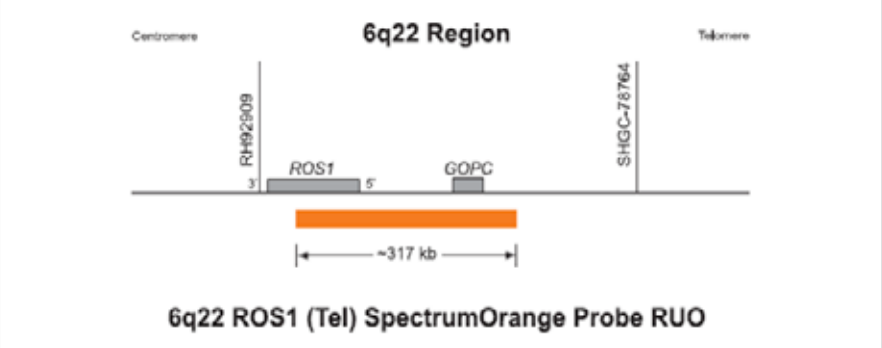
## RESULTS OF HYBRIDIZATION

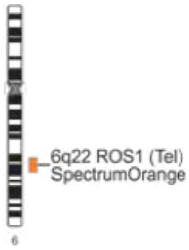
The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI ROS1 (Cen) SpectrumGreen Probe **(ASR)** | 20 µL | 08N07-020 | 00884999037120 |

# Vysis LSI ROS1 (Tel) SpectrumOrange Probe



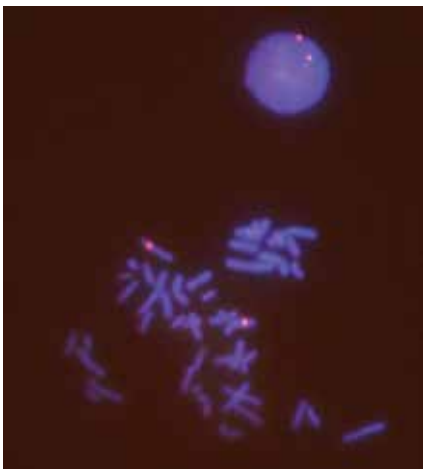




## PRODUCT DESCRIPTION

The SpectrumOrange Vysis LSI ROS1 (Tel) Fluorescence in situ hybridization (FISH) probe is targeted to the 6q22 region on chromosome 6. The probe is approximately 317 kb in size and positioned telomeric to the ROS1 gene.

## RESULTS OF HYBRIDIZATION

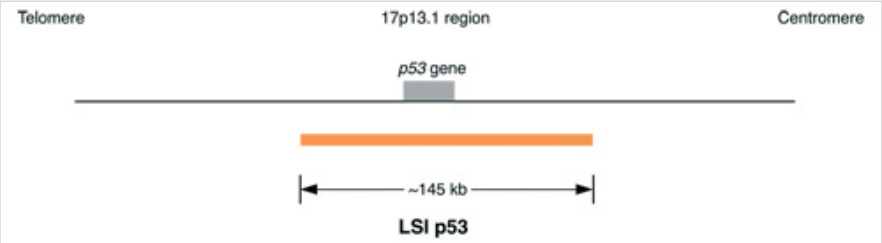
The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and metaphase chromosomes.



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI ROS1 (Tel) SpectrumOrange Probe **(ASR)** | 20 µL | 08N05-020 | 00884999037458 |

OTHER CANCERS

# Vysis LSI TP53 (17p13.1) SpectrumOrange Probe Kit



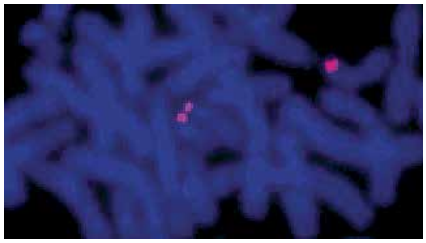


## PRODUCT DESCRIPTION

The LSI TP53 (previously designated as p53) Probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene. The ability to use FISH probes such as the LSI p53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the p53 locus.The LSI p53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.

## RESULTS OF HYBRIDIZATION

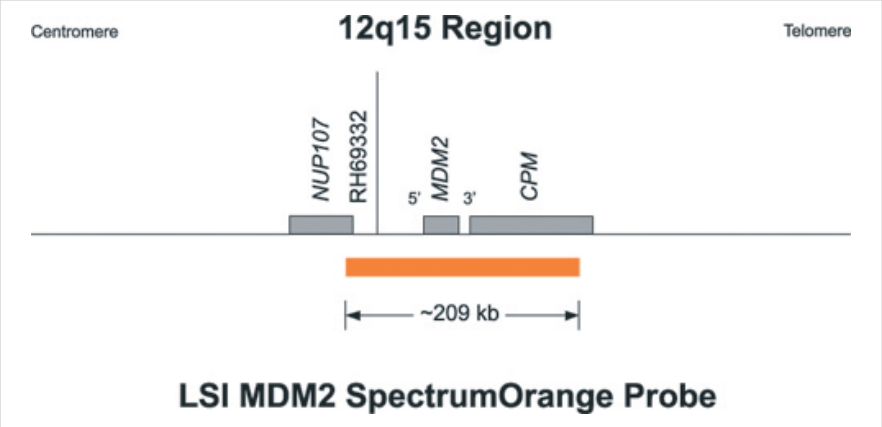
In a cell containing a deletion of the LSI p53 locus, one orange LSI p53 signal will be observed (1O signal pattern). In a cell harboring amplification of the p53 locus multiple copies of the orange signal will be observed. In a normal cell the two orange (2O) signal pattern is observed.

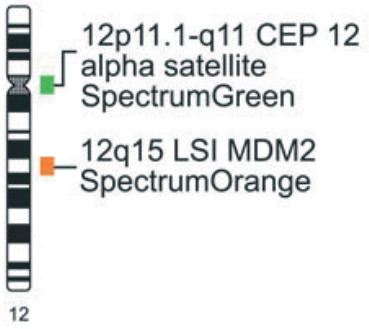


**Normal hybridization:** LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 |

# Vysis MDM2/CEP 12 FISH Probe Kit

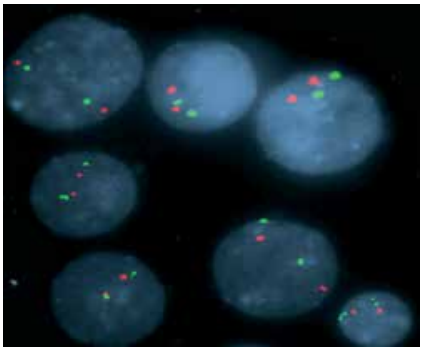



## PRODUCT DESCRIPTION

The Vysis MDM2/CEP 12 FISH Probe Kit uses a dual-color probe designed to detect the copy number of the LSI MDM2 probe target located at chromosome 12q15 using FISH.

The chromosomal region 12q13-q15 is often affected by translocations and amplifications in soft tissue sarcoma and chronic lymphocyticleukemia in humans. This region includes the mouse double minute2 (MDM2) gene. MDM2 inhibits p53 transcriptional activity by binding to p53 and moving the protein into the cytoplasm. This results ininactivation of the tumor suppressor and the formation of tumors, which ultimately leads to cancer.



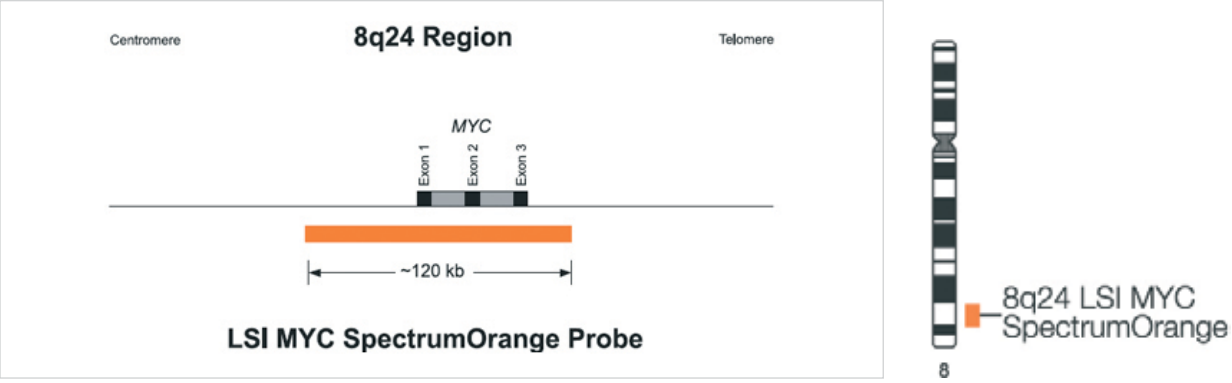
## RESULTS OF HYBRIDIZATION

Nuclei or metaphase chromosome sets lacking the MDM2 amplification are expected to exhibit two orange and two green signals. Amplification of MDM2 would exhibit more than two orange signals and amplification of centromere 12 would exhibit more than two green signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis MDM2/CEP 12 FISH Probe Kit **(CE)** | 10 µL | 01N15-010 | 00884999035362 |

OTHER CANCERS

# Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12 - q24.13)




## PRODUCT DESCRIPTION

The MYC (C-MYC) oncogene has been reported to be amplified in >20% of breast carcinoma and various other malignancies and is a prognostic factor for breast cancer. FISH is a rapid and reproducible method that allows the accurate measurement of the level of oncogene amplification within interphase nuclei in human tumors. This probe may be used to determine the MYC copy number or as a general purpose probe for the 8q24 region.

The Vysis LSI MYC SpectrumOrange Probe was employed in a number of studies. Park et al. used the Vysis LSI MYC Probe to investigate co-amplification of the MYC and HER2 genes in 214 consecutive breast cancers. For detecting lung cancer, Sokolava et al. compared a FISH-based assay, that included Vysis LSI MYC, to conventional cytology in 74 bronchial washing specimens, and achieved significantly higher sensitivity with the FISH assay (82% vers. 54%). In a recent study, Rygiel et al. used the Vysis LSI MYC (8q24.12-q24.13) SpectrumOrange Probe to evaluate amplification of MYC as a diagnostic marker to identify patients with Barrett's esophagus with high-grade dysplasia or esophageal adenocarcinoma.

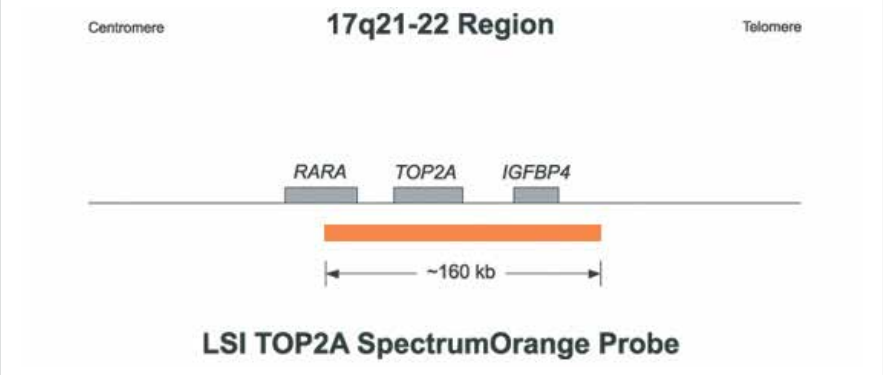
The LSI C-MYC (8q24.12-q24.13) Probe is an approximately 120 kb SpectrumOrange labeled probe.

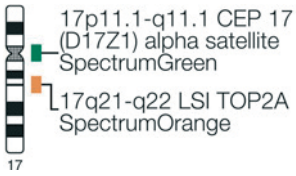
## RESULTS OF HYBRIDIZATION

In a cell with amplification of the C-MYC locus,multiple copies of the orange signal may be seen when hybridized with the C-MYC probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12-q24.13) **(CE)** | 20 µL | 03N87-020 | 00884999006256 |

# Vysis TOP2A / CEP 17 FISH Probe Kit




## PRODUCT DESCRIPTION

The TOP2A gene, located at 17q21-q22, encodes topoisomerase II- a key enzyme in DNA replication, cell cycle progression, and chromosome segregations. As a key enzyme in DNA replication, TOP2A protein is the molecular target for many inhibitors. The TOP2A gene is located telomeric to the HER-2 oncogene, which is located in the 17q11.2-q12 region. HER-2 is one member of a family of transmembrane protein receptors. The close proximity of HER-2, TOP2A, and other genes in the 17q region, suggest a potential relationship between these genes. This probe set is premixed in Hybridization Buffer.

LSI TOP2A is a single ~160kb unique sequence probe that hybridizes to the 17q21-22 region containing the TOP2A gene and is directly labeled with SpectrumOrange. The CEP 17 probe, which hybridizes to alpha satellite DNA at 17p11.1-q11.1, is directly labeled with SpectrumGreen.

In a cell with the normal quantity (two copies) of the TOP2A gene, two orange signals will be observed. If amplification or deletion of the TOP2A gene has occured, more or less than two signals will be present. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi-color probe.

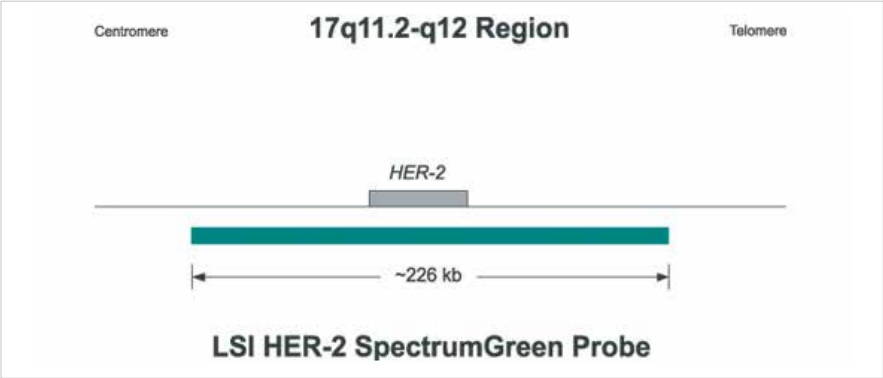
## RESULTS OF HYBRIDIZATION

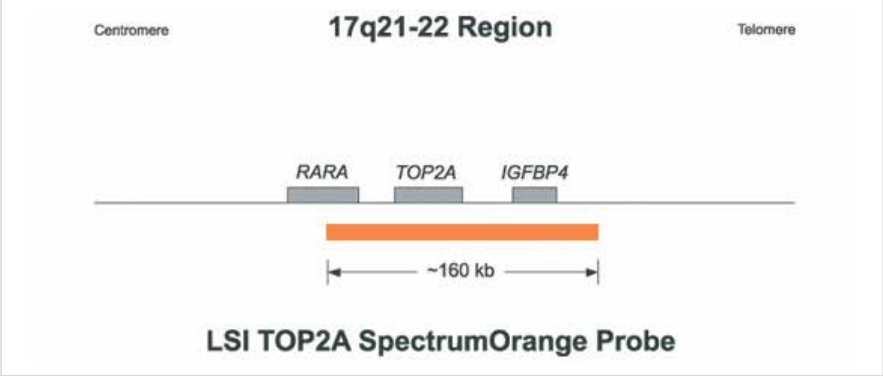
LSI TOP2A/CEP17 Dual-color Probe: In a cell with the normal quantity (two copies) of the TOP2A gene, two orange signals will be observed. If amplification or deletion of the TOP2A gene has occured, more or less than two signals will be present.

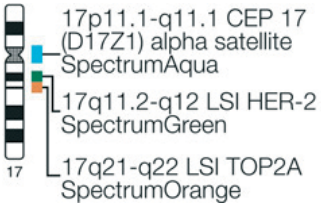
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TOP2A / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N89-020 | 00884999006270 |

OTHER CANCERS

# Vysis TOP2A / HER-2 / CEP 17 FISH Probe Kit




## PRODUCT DESCRIPTION

The TOP2A gene, located at 17q21-q22 encodes topoisomerase II-α, a key enzyme in DNA replication, cell cycle progression, and chromosome segregation. As a key enzyme in DNA replication, TOP2A protein is the molecular target for many inhibitors. The TOP2A gene is located telomeric to the HER-2 oncogene, which is located in the 17q11.2-q12 region. HER-2 is one member of a family of transmembrane protein receptors. The close proximity of HER-2, TOP2A, and other genes in the 17q region, suggest a potential relationship between these genes. The TOP2A gene has also been shown to be co-amplified with HER-2 in cell lines and in human breast cancers.

The Vysis Locus Specific Identifier (LSI) TOP2A SpectrumOrange/HER-2 SpectrumGreen/CEP17 SpectrumAqua Probe Set utilizes locus specific probes for TOP2A and HER-2 as well as chromosome 17 centromeric probe. Each probe

is labeled with a different fluorophore to allow accurate enumeration of each locus within individual nuclei. Simultaneous enumeration of all three probes reveals the copy number gains or losses of HER-2 and TOP2A relative to the copy number of chromosome 17. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi color probe.

TOP2A and HER-2 gene status is of interest since topoisomerase II-α is a molecular target of anthracycline drugs and HER-2 is targeted by several small molecule tyrosine kinase inhibitors as well as antibodies against the HER-2 receptor protein. Beser et al. used the Vysis TOP2A/HER-2/CEP17 FISH Probe Kit to examine the frequency of TOP2A amplification and deletion relative to the HER-2 gene status and chromosome 17 aneusomy in a series of 50 breast tumors. Hicks et al. used the same probe set to similarly document the relationship between TOP2A and HER-2 genomic alterations and chromosome 17 aneusomy in 138 breast cancers.

LSI TOP2A is a single ~160 kb unique sequence probe that hybridizes to the 17q21-22 region containing the TOP2A gene. In both products, the probe is directly labeled with SpectrumOrange. The HER-2 probe that spans the entire HER-2 gene at 17q11.2-q12 is an an ~190 kb unique sequence probe. In the LSI TOP2A/HER-2/CEP 17 product, this probe is directly labeled with SpectrumGreen. The The CEP 17 probe, which hybridizes to alpha satellite DNA at 17p11.1-q11.1, is directly labeled with SpectrumGreen or SpectrumAqua SpectrumAqua in the LSI TOP2A/CEP 17 and LSI TOP2A/HER-2/ CEP 17 products, respectively.

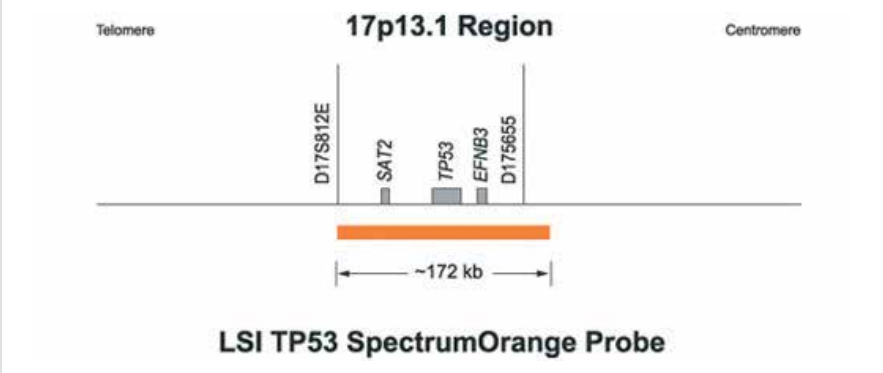
## RESULTS OF HYBRIDIZATION

LSI TOP2A/HER-2/CEP 17 Multi-color Probe: As with TOP2A and chromosome 17, a nucleus with a normal quantity (two copies) of HER-2 will appear with two green signals. Simultaneous enumeration of all three probes will reveal the copy number of each as well well as the amplification or deletion status of TOP2A and HER-2 relative to chromosome 17 copy number. The ability to distinguish true gene amplification or deletion from aneusomy of chromosome 17 or nuclei truncation is an added benefit of this multi-color probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TOP2A / HER-2 / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N90-020 | 00884999006287 |

OTHER CANCERS

# Vysis TP53/CEP 17 FISH Probe Kit

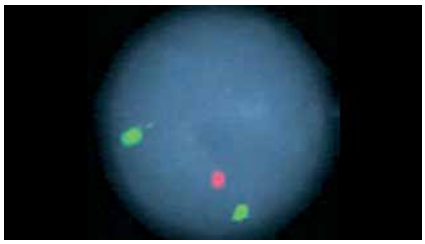




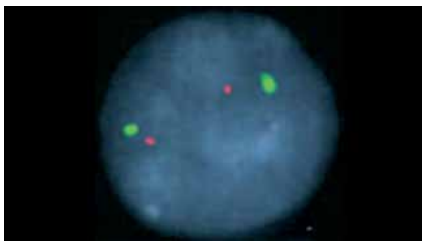
## PRODUCT DESCRIPTION

The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma. The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.



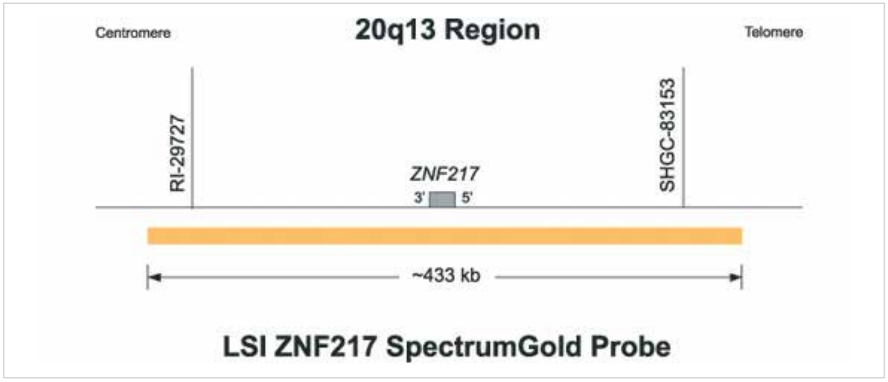
**Abnormal hybridization:** Nucleus showing the two green and one orange signal.



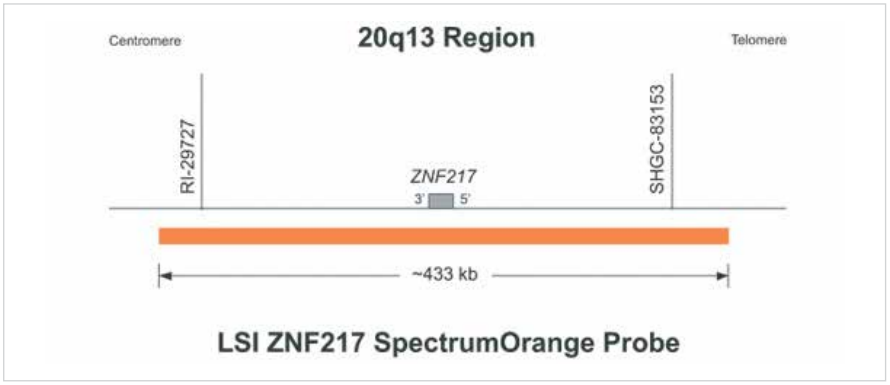
**Normal hybridization:** Nucleus showing the two green and two orange signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 |

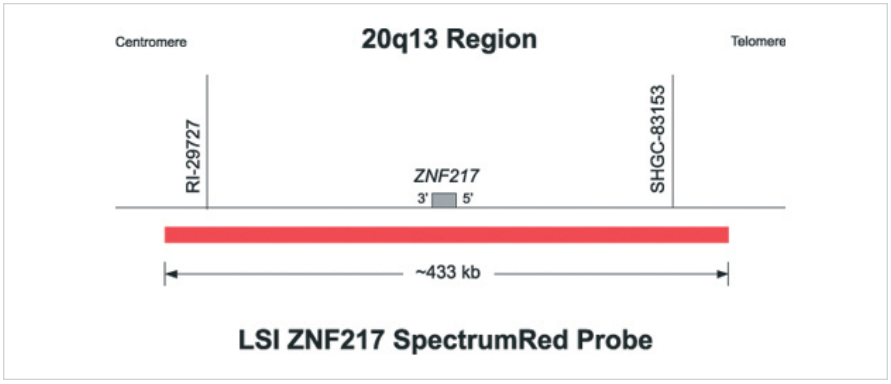
# Vysis LSI ZNF217 SpectrumGold, SpectrumOrange, SpectrumRed












## PRODUCT DESCRIPTION

The ZNF217 gene is a candidate oncogene suggested to play a key role during neoplastic transformation. ZNF217 is located at 20q13, which is a region that is frequently amplified in a variety of tumor types. Amplification of ZNF217 in breast cancer is associated with aggressive tumor behaviour and poor clinical prognosis.

The Vysis LSI ZNF217 SpectrumOrange** Probe was used in a study that indicated distinct differences in the role of genes known to be amplified in female breast cancer and their relevance for the pathogenesis of male breast cancer. In another study, fluorescence in situ hybridization was performed on 128 male breast tumors using the Vysis LSI ZNF217 SpectrumOrange Probe**in addition to other Vysis probes including LSI HER-2, LSI CCND1, LSI MYC, and the corresponding centromeric probes to evaluate the frequency of amplification of the genes in MBC. A third study used the Vysis LSI ZNF217 SpectrumOrange** Probe to identify gain of ZNF217 as an important abnormality and prognostic factor in larynx tumorigenesis. For this study a tissue microarray consisting of 863 larynx carcinomas was analysed.

The LSI ZNF217 (20q13.2) Probe hybridizes within an approximately 1 Mb amplified segment within the 20q13.2 region. The LSI ZNF217 Probe contains the ZNF217 gene centrally located within this region of amplification. The ZNF217 gene is a candidate oncogene. Using the LSI ZNF217 probe, copy number or amplification of this region can be detected.

The LSI ZNF217 is an approximately 433 kb SpectrumOrange labeled probe.

The Vysis ZNF217 SpectrumGold Probe Kit consists of a single probe direct labeled with SpectrumGold. The probe covers approximately a 433kb region that encompasses the entire 17.5-kb ZNF217 gene on chromosome 20 as well as adjacent regions.

The Vysis LSI ZNF217 SpectrumRed Probe is a single approximately 433 kb unique sequence probe direct labeled in SpectrumRed, that hybridizes to the 20q13.2 region of chromosome 20 and includes the 17.5 kb ZNF217 gene.

**The Vysis LSI ZNF217 SpectrumOrange Probe was used in studies, which are referenced above. Vysis LSI ZNF217 SpectrumGold Probe hybridizes to the same sequence as the Vysis LSI ZNF217 SpectrumOrange Probe, but is labeled with SpectrumGold Fluorophore.

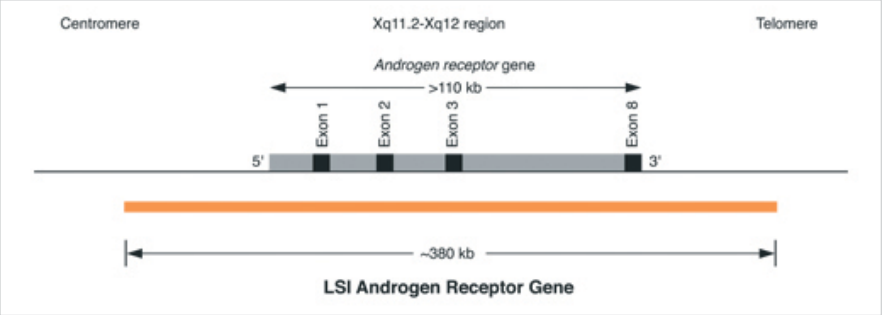
## RESULTS OF HYBRIDIZATION

When hybridized with the LSI ZNF217 Probe, a normal cell containing two copies of the 20q13.2 region will exhibit two gold signals. signals. In a cell harboring amplification of the ZNF217 gene or 20q13.2 region, multiple copies of the gold signal will be observed.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI ZNF217 SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 05N15-020 | 00884999014602 |
| Vysis LSI ZNF217 SpectrumOrange FISH Probe Kit **(CE)** | 20 µL | 03N91-020 | 00884999006294 |
| Vysis LSI ZNF217 SpectrumRed FISH Probe Kit **(CE)** | 10 µL | 05N16-010 | 00884999014619 |

PROSTATE CANCER

# Vysis LSI Androgen Receptor Gene (Xq12) SpectrumOrange Probe





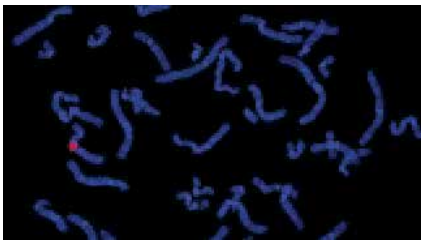
## PRODUCT DESCRIPTION

The LSI Androgen Receptor Gene (Xq12) Probe may be used to detect copy number of the androgen receptor (AR) gene.

LSI Androgen Receptor (Xq12) Probe is an approximately 380 kb SpectrumOrange labeled probe.

## RESULTS OF HYBRIDIZATION

In a normal male cell hybridized with LSI Androgen Receptor Gene (Xq12) Probe, the expected signal pattern is one orange (1O) signal. In a cell harboring amplification of the LSI Androgen Receptor Gene multiple copies of the orange signal will be observed.

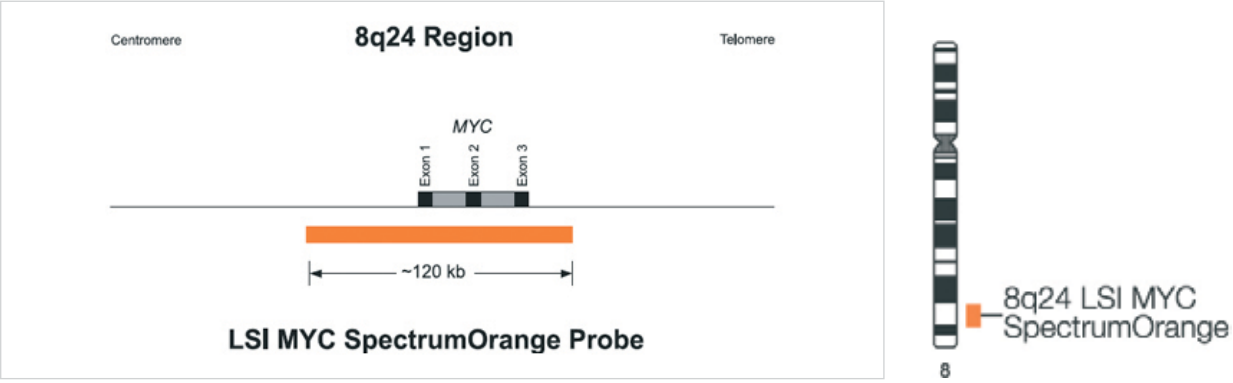


**Normal hybridization:** LSI Androgen Receptor Gene (Xq12) Probe hybridized to a normal male cell showing the one orange (1O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI Androgen Receptor Gene (Xq12) SpectrumOrange Probe **(ASR)** | 20 µL | 05J44-001 | 00884999011793 |

PROSTATE CANCER

# Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12 - q24.13)







## PRODUCT DESCRIPTION

The MYC (C-MYC) oncogene has been reported to be amplified in >20% of breast carcinoma and various other malignancies and is a prognostic factor for breast cancer. FISH is a rapid and reproducible method that allows the accurate measurement of the level of oncogene amplification within interphase nuclei in human tumors. This probe may be used to determine the MYC copy number or as a general purpose probe for the 8q24 region.

The Vysis LSI MYC SpectrumOrange Probe was employed in a number of studies. Park et al. used the Vysis LSI MYC Probe to investigate co-amplification of the MYC and HER2 genes in 214 consecutive breast cancers. For detecting lung cancer, Sokolava et al. compared a FISH-based assay, that included Vysis LSI MYC, to conventional cytology in 74 bronchial washing specimens, and achieved significantly higher sensitivity with the FISH assay (82% vers. 54%). In a recent study, Rygiel et al. used the Vysis LSI MYC (8q24.12-q24.13) SpectrumOrange Probe to evaluate amplification of MYC as a diagnostic marker to identify patients with Barrett's esophagus with high-grade dysplasia or esophageal adenocarcinoma.

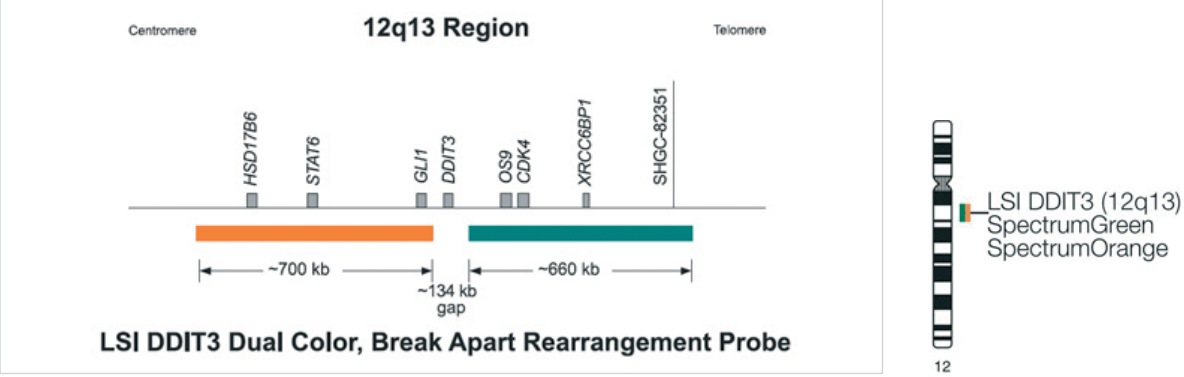
The LSI C-MYC (8q24.12-q24.13) Probe is an approximately 120 kb SpectrumOrange labeled probe.

## RESULTS OF HYBRIDIZATION

In a cell with amplification of the C-MYC locus,multiple copies of the orange signal may be seen when hybridized with the C-MYC probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12-q24.13) **(CE)** | 20 µL | 03N87-020 | 00884999006256 |

# Vysis DDIT3 Break Apart FISH Probe Kit




## PRODUCT DESCRIPTION

Chromosomal rearrangements involving the DDIT3 gene located on chromosome 12q13, are common in myxoid liposarcomas (MLS) and have also been identified in round cell (RC) and mixed liposarcomas (combined myxoid and round cell). A unique translocation

t(12;16)(q13;p11) is present in >95% of MLS cases and is thus regarded as a diagnostic marker for MLS/RC. t(12;16) results in the fusion (and transcriptional deregulation ) of the genes TLS (FUS) and DDIT3, a C/EBP-family transcription factor implicated in adipocyte differentiation. Hybridization with the LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe will identify chromosomal rearrangement in the DDIT3 gene but not a specific gene-fusion partner.

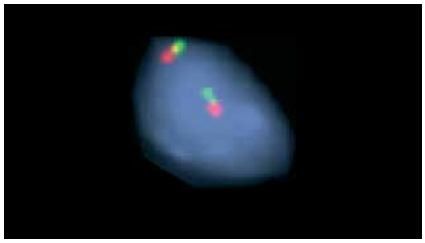
The DDIT3 Dual Color, Break Apart Rearrangement Probe has been used in different studies to detect DDIT3 (12q13) gene rearrangements. Vysis LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe successfully detected rearrangment of the DDIT3 (CHOP) gene in 18/18 formalin-fixed, paraffin-emmbedded tissues from myxoid liposarcoma. Matsui et al. used the LSI DDIT3 (CHOP) Dual Color, Break Apart Rearrangement Probe (Abbott Molecular, Inc.) to confirm rearrangement of the DDIT3 gene in a rare case of MLS bearing a variant chromosomal translocation t(12;22)(q13;q12) resulting in EWS-DDIT3 fusion gene.

The Vysis LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe consists of a mixture of two FISH DNA probes. The first probe, a 700 kb probe labeled in SpectrumOrange lies proximal to the DDIT3 gene. The second probe labeled in SpectrumGreen extends distally from the DDIT3 gene and is approximately 660 kb in length. The centromeric SpectrumOrange probe contains most of the GLI1 oncogene, and this probe may be useful in detecting GLI amplification. The telomeric SpectrumGreen probe contains the CDK4 gene. CDK4 can be amplified in sarcoma and glioblastoma. Not all the genes within the probes are shown on the map.

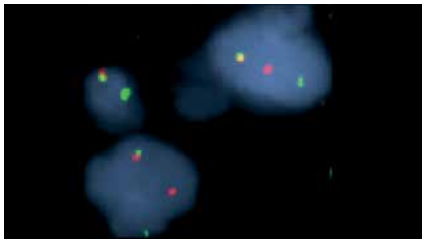
## RESULTS OF HYBRIDIZATION

In a normal cell that lacks a t(12q13) in the DDIT3 gene region, a two fusion signal pattern will be observed which reflects the two intact copies of DDIT3.

In an abnormal cell with a simple t(12q13), a one fusion, one green, and one orange signal pattern will be expected.



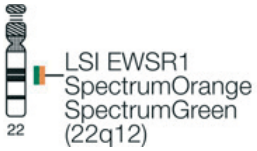
**Normal hybridization:** Result of the hybridization of the Vysis LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe, showing the two fusion signal pattern as observed in normal interphase cells.



**Abnormal hybridization:** Abnormal cells hybridized with the Vysis LSI DDIT3 (12q13) Dual Color, Break Apart Rearrangement Probe. Two of the cells in this image show the one fusion, one orange, and one green signal pattern indicative of a rearrangement of one copy of the DDIT3 gene region.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis DDIT3 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N57-020 | 00884999005778 |

# Vysis EWSR1 Break Apart FISH Probe Kit


## PRODUCT DESCRIPTION

Chromosome rearrangements involving the EWSR1 (Ewing sarcoma breakpoint region 1) have been observed in several types of tumors. Approximately 90% of the translocations involving the EWSR1 gene result in the t(11;22) (q24;q12), which juxtaposes the EWSR1 with the FLI1 (Friend leukemia virus integration 1) gene on chromosome 11q24. The resulting fusion produces chimeric transcripts and proteins that consist of the N-terminus of EWSR1 and the C-terminal portion of FLI1. Hybridization with the LSI EWSR1 (22q12) Break Apart Rearrangement Probe will identify chromosomal rearrangement in the EWSR1 gene region, but not a specific gene-fusion partner. The probe will also identify aneuploidy of chromosome 22.

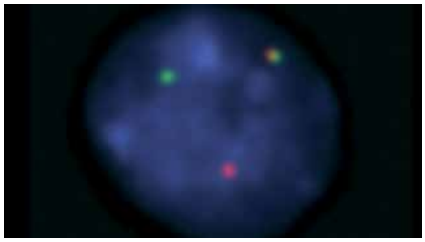
The Vysis LSI EWSR1 (22q12) Dual Color, Break Apart Rearrangement Probe has been used in several studies to detect EWSR1 gene rearrangements. In a study set consisting of 67 archival round cell tumors, including 27 EWS/PNETs (Ewing sarcoma/primitive neurodectodermal tumor) the Vysis LSI EWSR1 (22q12) Dual Color, Break Apart Rerrangement Probe successfully detected 90% of EWS/PNET cases and showed no false positives. Sensitivity and specificity were significantly higher compared to reverse transcriptase-polymerase chain reaction in formalin-fixed paraffin-embedded tissue. Patel et al. successfully used the Vysis LSI EWSR1 (22q12) Dual Color, Break Apart Rearrangement Probe to distinguish clear cell sarcoma of soft tissue from malignant melanoma. Clear cell sarcomas bear a unique t(12;22)(q13;q12) translocation resulting in an EWS-ATF1 fusion protein.

The Vysis LSI EWSR1 (22q12) Dual Color, Break Apart Rearrangement Probe consists of a mixture of two FISH DNA probes. The first probe, a ~500 kb probe labeled in SpectrumOrange, flanks the 5' side of the EWSR1 gene and extends inward into intron 4. The second probe, a ~1100 kb probe labeled in SpectrumGreen, flanks the 3' side of the EWSR1 gene. There is a 7 kb gap between the two probes. The known break points within the EWSR1 gene are restricted to introns 7 through 10.

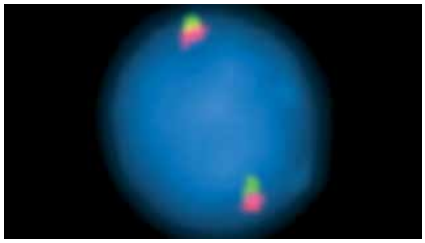
## RESULTS OF HYBRIDIZATION

In an abnormal cell with a simple t(22q12), a one fusion, one green, one orange signal pattern will be expected.

In a normal cell that lacks a t(22q12) in the EWSR1 gene region, a two fusion signal pattern will be observed reflecting the two intact copies of EWSR1.



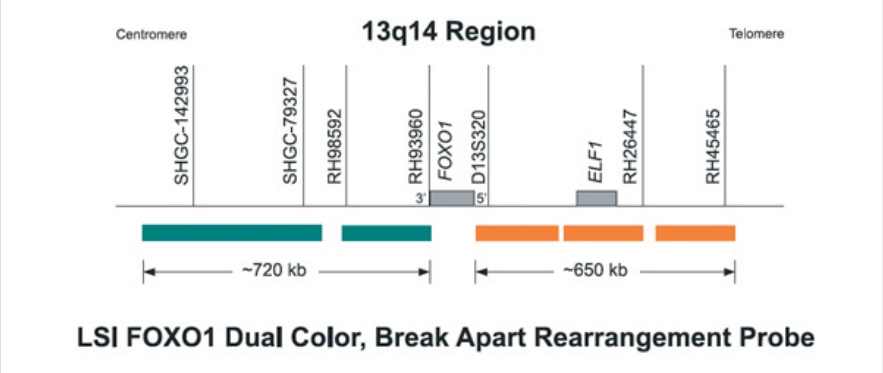
**Abnormal hybridization:** An abnormal cell hybridized with the Vysis LSI EWSR1 (22q12) Dual Color, Break Apart Rearrangement Probe. The cell in this image shows the one fusion, one orange, and one green signal pattern indicative of a rearrangement of one copy of the EWSR1 region.

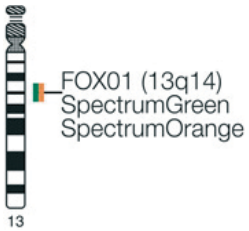


**Normal hybridization:** Result of the hybridization of the Vysis LSI EWSR1 (22q12) Dual Color, Break Apart Rearrangement Probe as observed in a normal interphase cell.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis EWSR1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N59-020 | 00884999005792 |

# Vysis FOXO1 Break Apart FISH Probe Kit




## PRODUCT DESCRIPTION

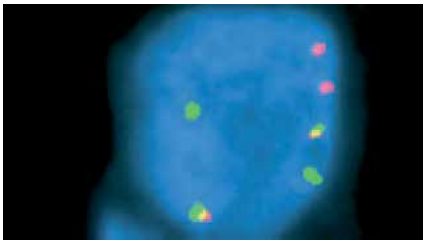
Chromosomal rearrangements involving the FOXO1 gene on chromosome 13q14 are associated with alveolar rhabdomyosarcoma (ARMS). Identification of RMS is a diagnostic dilemma for pathologists, requiring a significant amount of rule out testing for this and other soft-tissue cancers. ARMS is characterized by two consistent chromosomal translocations, the common t(2;13)(q35.2;q14) and the variant t(1;13)(p36;q14) resulting in the formation of PAX3-FOXO1 and PAX7-FOXO1fusion genes respectively (~80% of cases of ARMS). Hybridization with the Vysis LSI FOXO1 (13q14) Dual Color, Break Apart Rearrangement Probe will identify a chromosomal rearrangement at the FOXO1 gene but not a specific gene-fusion partner.

The Vysis LSI FOXO1 (13q14) Dual Color, Break Apart Rearrangement Probe consists of a mixture of two FISH DNA probes. The first probe, a 720 kb probe labeled in SpectrumGreen lies proximal to the FOXO1 gene. The second probe labeled in SpectrumOrange extends distally from the FOXO1 gene and is approximately 650 kb in length.

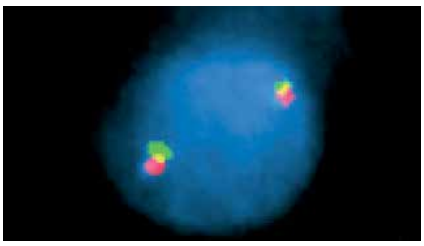
## RESULTS OF HYBRIDIZATION

In a normal cell that lacks a t(13q14) in the FOXO1 gene region, a two fusion signal pattern will be observed.

In a normal cell that lacks a t(13q14) in the FOXO1 gene region, a two fusion signal pattern will be observed.



**Abnormal hybridization:** Abnormal cells hybridized with the Vysis LSI FOXO1 (13q14) Dual Color Break Apart Rearrangement Probe. The cell in this image shows fusion, orange and green signals suggesting rearrangement of the FOXO1 gene region. The extra signals in the cell suggest aneuploidy.

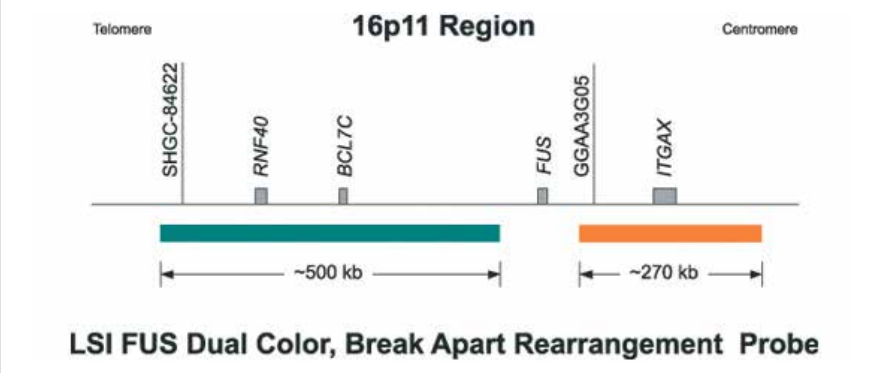


**Normal hybridization:** Result of the hybridization of the Vysis LSI FOXO1 (13q14) Dual Color Break Apart Rearrangement Probe, showing the two fusion signal pattern as observed in normal interphase cells.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis FOXO1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N60-020 | 00884999005808 |

SARCOMAS

# Vysis FUS Break Apart FISH Probe Kit

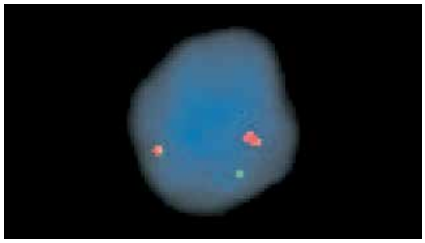




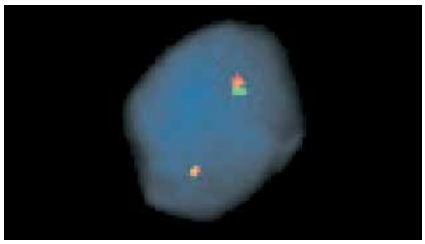
## PRODUCT DESCRIPTION

Chromosomal rearrangements involving the FUS gene located on chromosome 16p11 have been observed in many tumor types including several soft tissue sarcomas (STS). Different types of STS are characterized by specific chromosomal translocations including t(12;16)(q13;p11) FUS-DDIT3 (Myxoid liposarcoma), t(16;21)(p11;q22) FUS-ERG (Acute myeloid leukemia), t(12;16)(q13;p11) FUS-ATF1 (Angiomatoid-fibrous histiocytoma) and t(7;16)(q32-34;p11) FUS-CREB3L2 (Low grade fibromyxoid sarcoma). The resulting chimeric fusion proteins are mainly transactivators exerting deregulation of differentiation control on the tumor-target cell. Hybridization with the LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe will identify a chromosomal rearrangement in the FUS gene region but not a specific gene-fusion partner.

FUS FISH-probes were successfully used to confirm diagnosis of different sarcomas as demonstrated by several studies. The Vysis LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe detected rearrangement of the FUS gene in 7/10 formalin-fixed, paraffin-embedded tissues from low-grade fibromyxoid sarcomas. In another study the Vysis LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe was used to detect rearrangement of the FUS gene in a rare case of Ewing bone sarcoma bearing a variant chromosomal translocation t(2;16)(q35;p11) resulting in a FUS-FEV fusion gene.



**Abnormal hybridization:** Abnormal cell hybridization using the Vysis LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe.



**Normal hybridization:** Normal cell hybridization using the Vysis LSI FUS (16p11) Dual Color, Break Apart Rearrangement Probe.

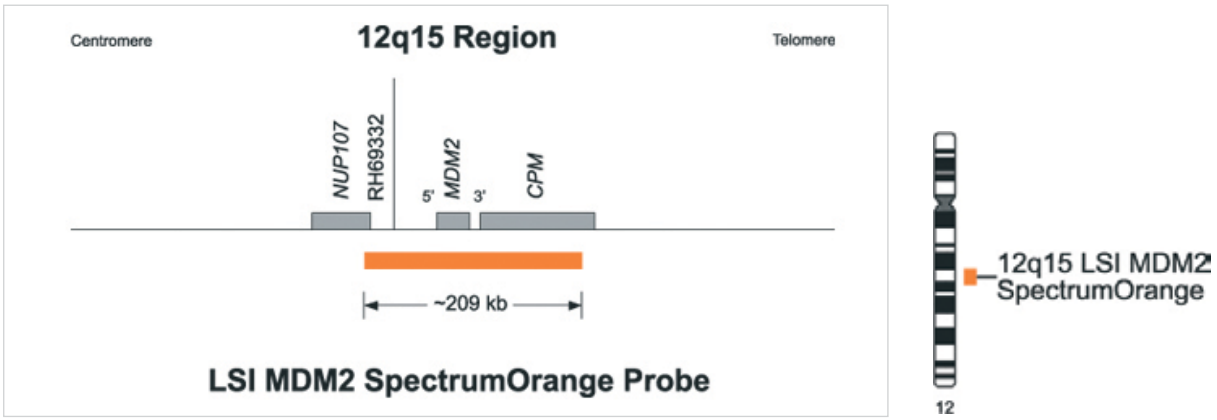
## RESULTS OF HYBRIDIZATION

The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 16 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis FUS Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N58-020 | 00884999005785 |

# Vysis LSI MDM2 SpectrumOrange Probe



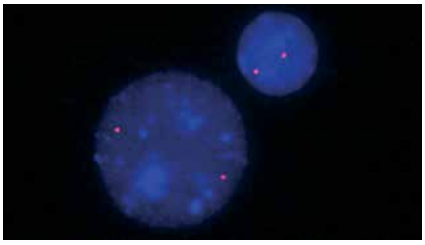

## PRODUCT DESCRIPTION

The chromosomal region 12q13-q15 is often affected by translocations and amplifications in soft tissue sarcoma in humans. This region includes the mouse double minute 2 (MDM2) gene. MDM2 inhibits p53 transcriptional activity by binding to p53 and moving the protein into the cytoplasm. This results in inactivation of the tumor suppressor and the formation of tumors which ultimately leads to cancer. The use of MDM2 as an aid in differential diagnosis of sarcomas has been documented.

The SpectrumOrange Vysis LSI MDM2 fluorescence in situ hybridization (FISH) probe is targeted to the 12q15 region on chromosome 12. The probe is ~209 kb in size and spans the MDM2 gene. The hybridized probe fluoresces with moderate to bright intensity both in interphase nuclei and on metaphase chromosomes.

## RESULTS OF HYBRIDIZATION

In a cell with normal copy number of the MDM2 gene, two orange signals will be observed.

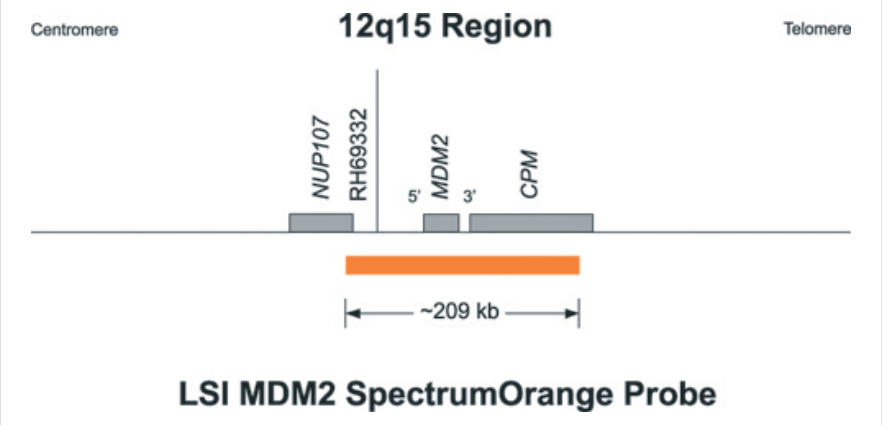


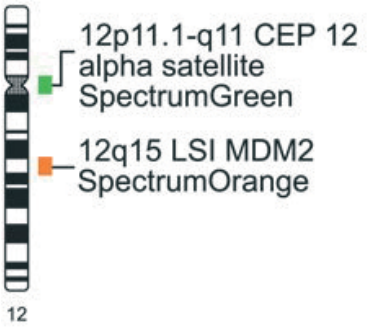
**Normal hybridization:** Cells hybridized with the Vysis LSI MDM2 SpectrumOrange probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MDM2 SpectrumOrange Probe **(ASR)** | 20 µL | 01N15-020 | 00884999000513 |

SARCOMAS

# Vysis MDM2/CEP 12 FISH Probe Kit

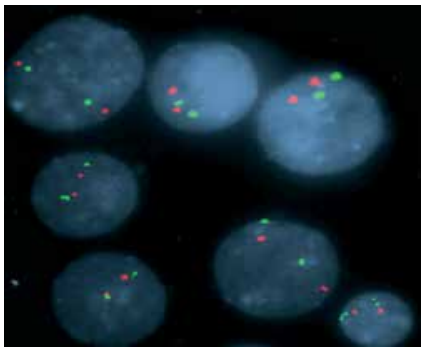



## PRODUCT DESCRIPTION

The Vysis MDM2/CEP 12 FISH Probe Kit uses a dual-color probe designed to detect the copy number of the LSI MDM2 probe target located at chromosome 12q15 using FISH.

The chromosomal region 12q13-q15 is often affected by translocations and amplifications in soft tissue sarcoma and chronic lymphocyticleukemia in humans. This region includes the mouse double minute2 (MDM2) gene. MDM2 inhibits p53 transcriptional activity by binding to p53 and moving the protein into the cytoplasm. This results ininactivation of the tumor suppressor and the formation of tumors, which ultimately leads to cancer.



## RESULTS OF HYBRIDIZATION

Nuclei or metaphase chromosome sets lacking the MDM2 amplification are expected to exhibit two orange and two green signals. Amplification of MDM2 would exhibit more than two orange signals and amplification of centromere 12 would exhibit more than two green signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis MDM2/CEP 12 FISH Probe Kit **(CE)** | 10 µL | 01N15-010 | 00884999035362 |

SARCOMAS

# Vysis SS18 Break Apart FISH Probe Kit



## PRODUCT DESCRIPTION

Chromosomal rearrangements involving the SS18 gene located in the breakpoint region of chromsome 18q11.2 are common among synovial sarcoma soft tissue tumors. Several studies have indicated that the t(X;18)(p11.2;q11.2) translocation arises exclusively in synovial sarcoma (SS). Hybridization with the Vysis LSI SS18 (18q11.2) Dual Color, Break Apart Rearrangement Probe will identify a chromosomal rearrangement at the SS18 gene but not a specific gene-fusion partner.

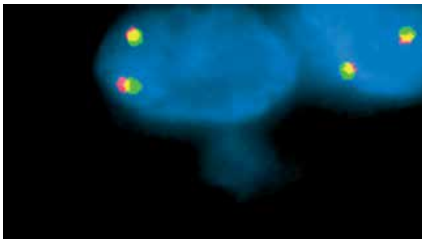
SS18 gene break-apart probes are a reliable diagnostic tool to identify SYT disruption in synovial sarcomas. In a study using 134 paraffin-embedded tumors, in which SS was the favored diagnosis, the Vysis LSI SS18 (18q11.2) Dual Color, Break Apart Rearrangement Probe identified 86% of positive cases. The conclusion from this study is that the combination of the FISH and RT-PCR approach is a powerful aid to diagnosing SS, giving at least 96% sensitivity and 100% specificity. However, using the Vysis LSI SS18 (18q11.2) Dual Color, Break Apart Rearrangement Probe in a tissue microarray assay, FISH has been favored as the method of choice because of its versatile application to tissues with varying fixation conditions. FISH allows easier detection of a true positive result and permits a direct correlation of the translocation event with the morphology on paraffin-embedded specimen.

The Vysis LSI SS18 Dual Color Break Apart Rearrangement Probe consists of a mixture of two FISH DNA probes. The first probe, an ~650 KB probe labeled in SpectrumOrange, extends distally from the SS18 gene. The second probe labeled in SpectrumGreen lies 3' or proximal to the SS18 gene and is approximately ~1040 kb in length.

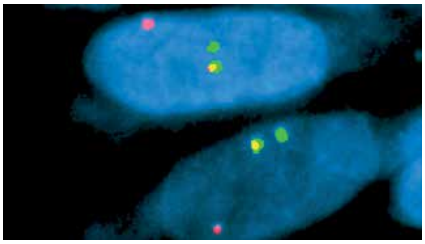
## RESULTS OF HYBRIDIZATION

In a normal cell that lacks a t(18q11.2) in the SS18 gene region, a two fusion signal pattern will be observed, reflecting the two intact copies of SS18

In an abnormal cell with a simple t(18q11.2), a one fusion, one green and one orange signal pattern will be expected.

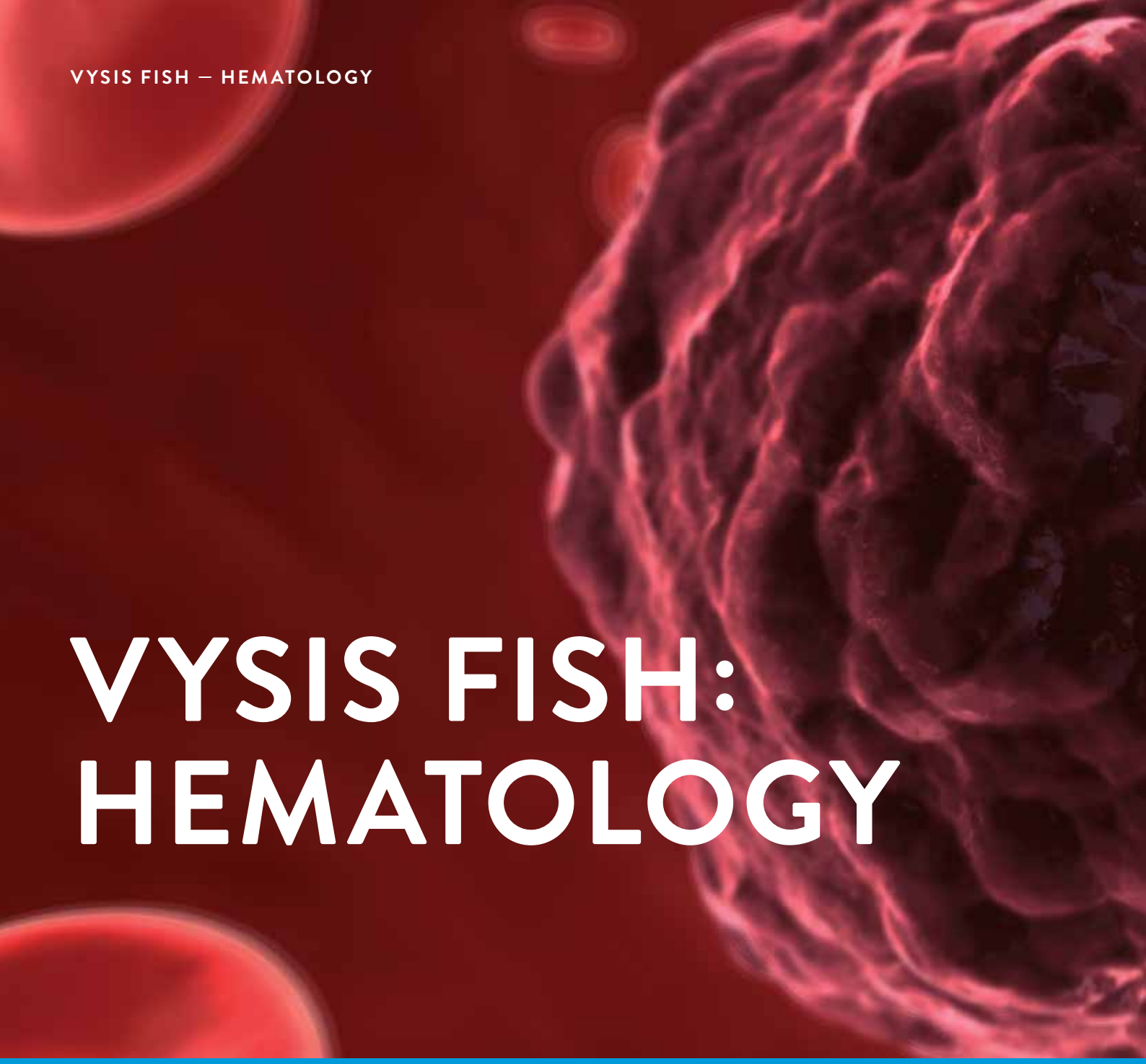


**Normal hybridization:** Result of the hybridization of the Vysis LSI SS18 (18q11.2) Dual Color Break Apart Rearrangement Probe, showing the two fusion signal pattern as observed in normal interphase cells. (Photo courtesy of Arie Perrry, M.D., Washington University School of Medicine.)



**Abnormal hybridization:** Abnormal cells hybridized with the Vysis LSI SS18 (18q11.2) Dual Color, Break Apart Rearrangement Probe. The cells in this image show the one fusion, one orange and one green signal pattern indicative of a rearrangement of one copy of the SS18 gene region. (Photo courtesy of Arie Perry, M.D., Washington University School of Medicine.)

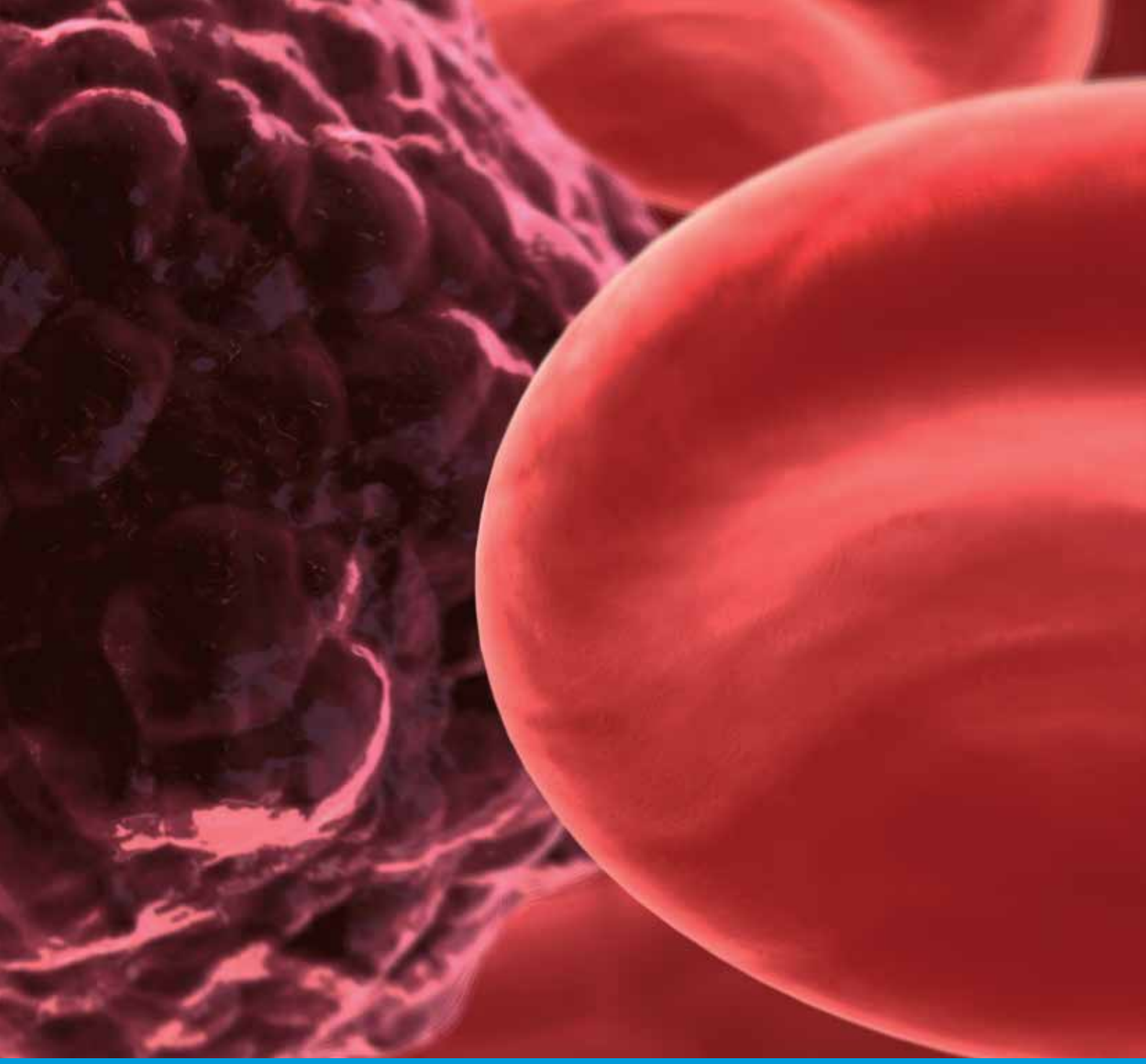
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis SS18 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N61-020 | 00884999005815 |



# VYSIS FISH: HEMATOLOGY

Abbott Molecular offers a wide range of DNA Fluorescence in *situ* Hybridization (FISH) products for the effective and rapid identification of genetic aberrations associated with hematopoietic disorders. Used as single probes, or in multi-color probe sets, these products are designed to identify various chromosome translocations, deletions, chromosomal gains, as well as other rearrangements associated with specific hematopoietic disorders. These probes can be applied to a variety of sample types prepared for metaphase or interphase analysis.

 Please note some products may not be for sale in all markets. Contact your local representative for availability.



## VYSIS FISH TECHNOLOGY FOR HEMATOLOGICAL DISORDERS PROVIDES THE FOLLOWING ADVANTAGES:

- Dual color, single fusion
  - Useful in detecting high percentages of cells possessing a specific chromosomal translocation.
  - The DNA probe hybridization targets are located on one side of each of the two genetic breakpoints.
- ES (Extra Signal)
  - Reduces the frequency of normal cells exhibiting an abnormal FISH pattern due to the random co-localization of probe signals in a normal nucleus.
  - One large probe spans one breakpoint, while the other probe flanks the breakpoint on the other gene.
- Dual color, break apart
  - Useful in cases where there may be multiple translocation partners associate with a known genetic breakpoint.
  - This labeling scheme features two differently colored probes that hybridize to targets on opposite sides of a breakpoint in one gene
- Dual color, dual fusion
  - Reduces the number of normal nuclei exhibiting abnormal signal patterns.
  - The probe offers advantages in detecting low levels of nuclei possessing a simple balanced translocation. Large probes span two breakpoints on different chromosomes.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **ACUTE LYMPHOCYTIC LEUKEMIA** | | | | |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 20 µL | 05N54-020 | 00884999015029 | 114 |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 50 µL | 05N54-050 | 00884999015036 | 114 |
| Vysis CDKN2A / CEP 9 FISH Probe Kit **(CE)** | 20 µL | 04N61-020 | 00884999009295 | 116 |
| Vysis ETV6 Break Apart FISH Probe Kit **(CE)** | 20 µL | 04N09-020 | 00884999007932 | 117 |
| Vysis ETV6/RUNX1 DF FISH Probe Kit **(CE)** | 10 µL | 05N96-010 | 00884999015487 | 119 |
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe **(ASR)** | 20 µL | 05J77-001 | 00884999012462 | 121 |
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L56-050 | 00884999031463 | 121 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe **(ASR)** | 20 µL | 05J78-001 | 00884999012479 | 122 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L55-020 | 00884999031456 | 122 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 05J82-001 | 00884999012592 | 123 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe **(ASR)** | 50 µL | 05J82-010 | 00884999012615 | 123 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L10-001 | 00884999031166 | 123 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 50 µL | 08L10-002 | 00884999031173 | 123 |
| Vysis LSI BCR/ABL1/ASS1 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL | 08L79-020 | 00884999031647 | 114 |
| Vysis LSI BCR/ABL1/ASS1 Tri-Color Dual Fusion Probes **(ASR)** | 50 µL | 08L79-050 | 00884999031654 | 114 |
| Vysis LSI CBFB Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J65-001 | 00884999012240 | 125 |
| Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe **(ASR)** | 20 µL | 05J62-001 | 00884999012202 | 126 |
| Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L66-020 | 00884999031562 | 126 |
| Vysis LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probe Kit **(CE)** | 20 µL | 04N10-020 | 00884999007949 | 127 |
| Vysis LSI IGH/MYC/Vysis CEP 8 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL | 05J75-001 | 00884999012431 | 127 |
| Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J90-001 | 00884999012837 | 129 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L57-020 | 00884999031470 | 129 |
| Vysis LSI MYB (6q23) SpectrumAqua Probe **(ASR)** | 20 µL | 07J86-001 | 00884999029378 | 131 |
| Vysis LSI MYB SpectrumAqua Probe Kit **(CE)** | 20 µL | 05N40-020 | 00884999014916 | 131 |
| Vysis LSI MYC Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 01N63-020 | 00884999000827 | 132 |
| Vysis LSI MYC Dual Color Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J91-001 | 00884999012844 | 132 |
| Vysis LSI TCF3/PBX1 Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 01N24-020 | 00884999000605 | 133 |
| Vysis TRA/D Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N41-020 | 00884999014923 | 135 |
| **ACUTE MYELOGENOUS LEUKEMIA** | | | | |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 20 µL | 05N54-020 | 00884999015029 | 136 |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 50 µL | 05N54-050 | 00884999015036 | 136 |
| Vysis CBFB Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N44-020 | 00884999014930 | 138 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 | 139 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 | 139 |
| Vysis Cri-du-Chat Region Probe - LSI EGR1 SpectrumOrange/LSI D5S23, D5S721 SpectrumGreen **(ASR)** | 20 µL | 05J76-001 | 00884999012455 | 141 |
| Vysis CSF1R/D5S23, D5S721 FISH Probe Kit **(CE)** | 20 µL | 05N03-020 | 00884999014336 | 154 |
| Vysis D20S108 FISH Probe Kit **(CE)** | 20 µL | 05N02-020 | 00884999014329 | 142 |
| Vysis D7S486/ Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N07-020 | 00884999014367 | 143 |
| Vysis D7S486/ Vysis CEP 7 FISH Probes **(ASR)** | 20 µL | 05J61-001 | 00884999012196 | 143 |
| Vysis D7S522/Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N08-020 | 00884999014374 | 144 |
| Vysis EGR1 FISH Probe Kit - SC (Specimen Characterization) **(CE)** | 20 µL | 04N37-001 | 00884999038165 | 145 |
| Vysis ETV6 Break Apart FISH Probe Kit **(CE)** | 20 µL | 04N09-020 | 00884999007932 | 147 |
| Vysis ETV6/RUNX1 DF FISH Probe Kit **(CE)** | 10 µL | 05N96-010 | 00884999015487 | 149 |
| Vysis LSI BCR/ABLI/ASSI Tri-Color Dual Fusion Probes **(ASR)** | 20 µL | 08L79-020 | 00884999031647 | 136 |
| Vysis LSI BCR/ABLI/ASSI Tri-Color Dual Fusion Probes **(ASR)** | 50 µL | 08L79-050 | 00884999031654 | 136 |

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L56-050 | 00884999031463 | 151 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L55-020 | 00884999031456 | 152 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L10-001 | 00884999031166 | 153 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 50 µL | 08L10-002 | 00884999031173 | 153 |
| Vysis LSI CSF1R / D5S23, D5S721 Probes **(ASR)** | 20 µL | 05J60-001 | 00884999012189 | 154 |
| Vysis LSI D7S522 SpectrumOrange / Vysis CEP 7 SpectrumGreen Probes **(ASR)** | 20 µL | 05J85-001 | 00884999012752 | 144 |
| Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit **(CE)** | 20 µL | 08L68-020 | 00884999031586 | 155 |
| Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L57-020 | 00884999031470 | 156 |
| Vysis PML/RARA Single Fusion FISH Probe Kit **(ASR)** | 20 µL | 05J66-001 | 00884999012257 | 157 |
| Vysis PML/RARA Single Fusion FISH Probe Kit **(CE)** | 20 µL | 05N45-020 | 00884999014947 | 157 |
| Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 05J70-001 | 00884999012325 | 159 |
| Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 01N36-020 | 00884999000780 | 159 |
| Vysis LSI RARA Dual Color Break Apart Rearrangement Probe **(CE)** | 20 µL | 05N46-020 | 00884999014954 | 161 |
| Vysis LSI TP53 SpectrumOrange/ Vysis CEP 17 SpectrumGreen Probe **(ASR)** | 20 µL | 01N17-020 | 00884999000520 | 162 |
| Vysis RPN1/MECOM DF FISH Probe Kit **(CE)** | 10 µL | 06N60-010 | 00884999034914 | 163 |
| Vysis RUNX1/RUNX1T1 DF FISH Probe Kit **(CE)** | 20 µL | 08L70-020 | 00884999031609 | 165 |
| **CHRONIC LYMPHOCYTIC LEUKEMIA** | | | | |
| LSI Cyclin D1 (11q13) SpectrumOrange/ Vysis CEP 11 SpectrumGreen **(ASR)** | 20 µL | 05J41-001 | 00884999011755 | 167 |
| ProbeChek Control Slides for FISH using CEP 8 and CEP 12 Assay, Negative Control 0%, trisomy 8/12 **(CE)** | 5 Slides | 07J21-001 | 00884999027039 | - |
| ProbeChek Control Slides for FISH using CEP 8 and CEP 12 Assay, Positive Control 10%, trisomy 8/12 **(CE)** | 5 Slides | 07J21-002 | 00884999027046 | - |
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 | 168 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-012 | 00884999027084 | 171 |
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-012 | 00884999027015 | 171 |
| Vysis D13S319 (13q14.3) Probe **(ASR)** | 20 µL | 05J86-001 | 00884999012769 | 172 |
| Vysis D13s319/13q34 FISH Probe Kit **(CE)** | 20 µL | 05N37-020 | 00884999014893 | 173 |
| Vysis IGH/CCND1 DF FISH Probe Kit **(CE)** | 20 µL | 08L58-020 | 00884999031487 | 175 |
| Vysis IGH/CCND1 XT DF FISH Probe Kit **(CE)** | 20 µL | 05N33-020 | 00884999014862 | 177 |
| Vysis LSI 4q12 Tricolor, Rearrangement Probe **(ASR)** | 20 µL | 01N79-020 | 00884999001039 | 179 |
| Vysis LSI ATM (11q22.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N33-020 | 00884999000759 | 180 |
| Vysis LSI ATM SpectrumOrange/Vysis CEP 11 SpectrumGreen Probes **(ASR)** | 20 µL | 01N18-020 | 00884999000537 | 181 |
| Vysis LSI ATM/CEP 11 FISH Probe Kit **(CE)** | 20 µL | 05N55-020 | 00884999015043 | 181 |
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J96-001 | 00884999013445 | 182 |
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 05N38-020 | 00884999014909 | 182 |
| Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N37-020 | 00884999000797 | 183 |
| Vysis LSI D13S319 (13q14.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N34-020 | 00884999000766 | 184 |
| Vysis LSI D13S319 SpectrumOrange/ 13q34 SpectrumGreen Probes **(ASR)** | 20 µL | 01N20-020 | 00884999000544 | 185 |
| Vysis LSI IGH/CCND1 Dual Color Dual Fusion Probes **(ASR)** | 20 µL | 05J69-001 | 00884999012301 | 175 |
| Vysis LSI IGH/CCND1 XT Dual Color, Dual Fusion Translocation Probes **(ASR)** | 20 µL | 05J72-001 | 00884999012370 | 177 |
| Vysis LSI MYB SpectrumAqua Probe Kit **(CE)** | 20 µL | 05N40-020 | 00884999014916 | 187 |
| Vysis LSI p53 (17p13.1) SpectrumOrange Probe **(ASR)** | 20 µL | 05J52-001 | 00884999012028 | 188 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe **(ASR)** | 20 µL | 05J83-001 | 00884999012622 | 189 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe Set **(CE)** | 20 µL | 08L53-020 | 00884999031432 | 189 |
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 | 192 |
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 | 193 |

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **CHRONIC MYELOGENOUS LEUKEMIA** | | | | |
| Vysis 4q12 Tri-Color Rearrangement FISH Probe Kit **(CE)** | 20 µL | 05N52-020 | 00884999015005 | 194 |
| Vysis 9q34 SpectrumAqua FISH Probe Kit **(CE)** | 20 µL | 05N53-020 | 00884999015012 | 196 |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 20 µL | 05N54-020 | 00884999015029 | 198 |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 50 µL | 05N54-050 | 00884999015036 | 198 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 | 200 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 | 200 |
| Vysis LSI 9q34 SpectrumAqua Probe **(ASR)** | 20 µL | 05J79-011 | 00884999012530 | 196 |
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L56-050 | 00884999031463 | 203 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L55-020 | 00884999031456 | 204 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L10-001 | 00884999031166 | 205 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 50 µL | 08L10-002 | 00884999031173 | 205 |
| Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J73-001 | 00884999012394 | 207 |
| Vysis PDGFRB Break Apart FISH Probe Kit **(CE)** | 10 µL | 06N24-010 | 00884999025585 | 208 |
| **MULTIPLE MYELOMA** | | | | |
| Vysis 13q34 SpectrumGreen FISH Probe Kit **(CE)** | 20 µL | 05N34-020 | 00884999014879 | 210 |
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 | 211 |
| Vysis IGH/CCND1 DF FISH Probe Kit **(CE)** | 20 µL | 08L58-020 | 00884999031487 | 213 |
| Vysis IGH/CCND1 XT DF FISH Probe Kit **(CE)** | 20 µL | 05N33-020 | 00884999014862 | 215 |
| Vysis IGH/FGFR3 DF FISH Probe Kit **(CE)** | 20 µL | 01N69-020 | 00884999000834 | 217 |
| Vysis IGH/MAF DF FISH Probes **(ASR)** | 20 µL | 05J84-004 | 00884999012691 | 219 |
| Vysis LSI 13 (13q14) SpectrumGreen Probe **(CE)** | 20 µL | 08L67-020 | 00884999031579 | 220 |
| Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe **(CE)** | 20 µL | 08L65-020 | 00884999031555 | 221 |
| Vysis LSI 13q34 SpectrumGreen Probe **(ASR)** | 20 µL | 05J80-001 | 00884999012547 | 222 |

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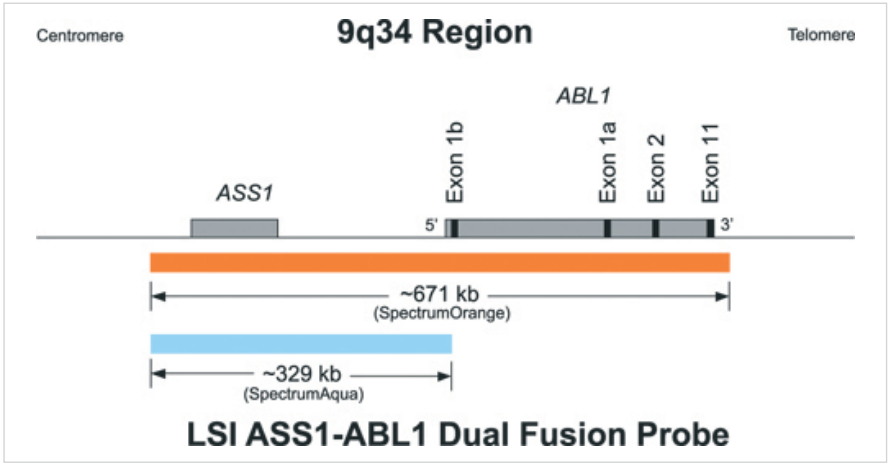
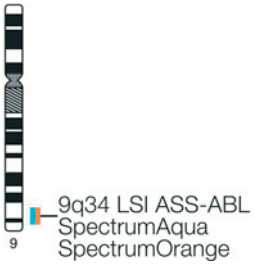
| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 05N38-020 | 00884999014909 | 223 |
| Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N37-020 | 00884999000797 | 224 |
| Vysis LSI D5S23, D5S721/CEP 9/CEP 15 FISH Probe Kit **(CE)** | 20 µL | 05N35-020 | 00884999014886 | 225 |
| Vysis LSI D5S23/D5S721, Vysis CEP 9, Vysis CEP 15 Multi-Color Probe **(ASR)** | 20 µL | 05J84-007 | 00884999012721 | 225 |
| Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L63-020 | 00884999031531 | 227 |
| Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe Kit **(ASR)** | 20 µL | 05J71-001 | 00884999012356 | 229 |
| Vysis LSI IGH/FGFR3 Dual Color Dual Fusion Probes **(ASR)** | 20 µL | 05J74-001 | 00884999012417 | 217 |
| Vysis LSI IGH/MAF DF Probe Kit **(CE)** | 20 µL | 05N32-020 | 00884999014855 | 230 |
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 | 232 |
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 | 233 |
| **MYELODYSPLASTIC SYNDROME** | | | | |
| ProbeChek Control Slides for FISH using CEP 8 and CEP 12 Assay, Negative Control 0%, trisomy 8/12 **(CE)** | 5 Slides | 07J21-001 | 00884999027039 | - |
| ProbeChek Control Slides for FISH using CEP 8 and CEP 12 Assay, Positive Control 10%, trisomy 8/12 **(CE)** | 5 Slides | 07J21-002 | 00884999027046 | - |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 | 234 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 | 234 |
| Vysis CSF1R/D5S23, D5S721 FISH Probe Kit **(CE)** | 20 µL | 05N03-020 | 00884999014336 | 236 |
| Vysis D20S108 FISH Probe Kit **(CE)** | 20 µL | 05N02-020 | 00884999014329 | 238 |
| Vysis D7S486/ Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N07-020 | 00884999014367 | 239 |
| Vysis D7S522/Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N08-020 | 00884999014374 | 240 |
| Vysis ETV6 Break Apart FISH Probe Kit **(CE)** | 20 µL | 04N09-020 | 00884999007932 | 241 |
| Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit **(CE)** | 20 µL | 08L68-020 | 00884999031586 | 243 |
| Vysis RPN1/MECOM DF FISH Probe Kit **(CE)** | 10 µL | 06N60-010 | 00884999034914 | 244 |

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **NON-HODGKINS LYMPHOMA** | | | | |
| Vysis BIRC3/MALT1 DF FISH Probe Kit **(CE)** | 20 µL | 05N50-020 | 00884999014985 | 246 |
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 | 248 |
| Vysis IGH/CCND1 DF FISH Probe Kit **(CE)** | 20 µL | 08L58-020 | 00884999031487 | 250 |
| Vysis IGH/CCND1 XT DF FISH Probe Kit **(CE)** | 20 µL | 05N33-020 | 00884999014862 | 252 |
| Vysis LSI 21 SpectrumOrange **(ASR)** | 20 µL | 05J13-002 | 00884999011168 | 254 |
| Vysis LSI BCL2 Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N51-020 | 00884999014992 | 255 |
| Vysis LSI BCL6 (ABR) Dual Color Break Apart Rearrangement Probe **(ASR)** | 20 µL | 01N23-020 | 00884999000582 | 256 |
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 05N38-020 | 00884999014909 | 257 |
| Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L63-020 | 00884999031531 | 258 |
| Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe **(CE)** | 20µl | 08L60-020 | 00884999031500 | 260 |
| Vysis LSI IGH/MALT1 DF FISH Probe Kit **(CE)** | 20 µL | 05N47-020 | 00884999014961 | 262 |
| Vysis LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probe Kit **(CE)** | 20 µL | 04N10-020 | 00884999007949 | 264 |
| Vysis LSI MALT1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N48-020 | 00884999014978 | 266 |
| Vysis LSI MYC Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 01N63-020 | 00884999000827 | 268 |
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 | 269 |
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 | 270 |
| **SEX MISMATCHED BONE-MARROW TRANSPLANTATION** | | | | |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-050 | 00884999027091 | 271 |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-050 | 00884999027022 | 271 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit



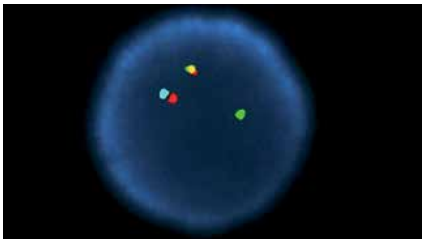



## PRODUCT DESCRIPTION

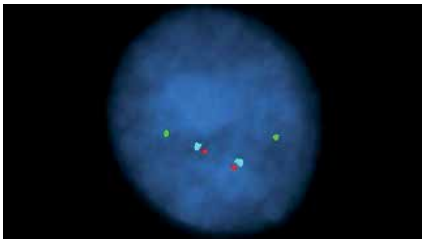
The Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit is intended to detect the t(9;22)(q34;q11.2) reciprocal translocation involving the BCR and ABL1 gene regions using the fluorescence in situ hybridization (FISH) technique.

The t(9;22) translocation which fuses the BCR gene on chromosome 22q11.2 and the ABL1 gene on chromosome 9q34 is observed by cytogenetics in greater than 80% of patients with chronic myelogenous leukemia (CML). In CML cases lacking a cytogenetically detectable translocation, the BCR/ABL1 fusion can still almost always be detected by FISH or other molecular techniques. BCR/ABL1 fusions also occur in a portion of acute lymphocytic leukemia cases and

more rarely in acute myeloid leukemia. In about 15 to 20 percent of CML cases, the t(9;22) results in the loss of genetic material flanking the BCR and/or ABL1 breakpoints on the derivative 9 chromosome. This loss can prevent the production of the highly specific two-fusion signal patterns expected of dual fusion probes and balanced translocations. If both BCR and ABL1 targets are deleted on the der(9) chromosome, low-level random overlap of orange and green signals within normal cells (producing a 1 orange, 1 green, 1 fusion pattern) cannot be discriminated from low-level true BCR/ABL1 fusions producing the same pattern. The Tri-Color design of this test uses a probe in a third color (aqua) on the centromeric side of the ABL1 breakpoint, which co-localizes with the orange signal in a random orange/green signal fusion, but is absent from a true BCR/ABL1 molecular fusion on the der(22) chromosome. The probes in this kit have been used in published papers to detect low levels of positive cells in CML patients who were undergoing therapy and had deletions of FISH signals on the derivative chromosome 9.



**Abnormal hybridization:** Nucleus showing the one aqua/orange, one green, and one orange/green fusion (yellow) signal pattern.

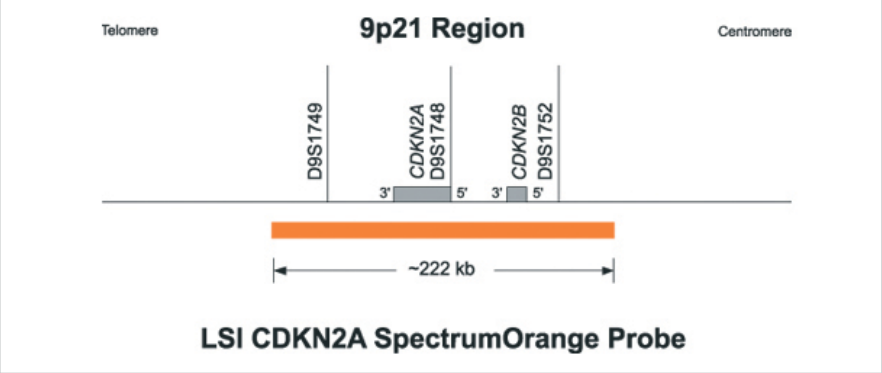


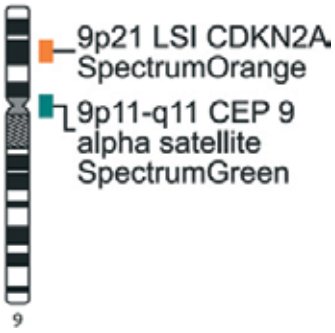
**Normal hybridization:** Nucleus showing the two aqua/orange and two green signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 20 µL<br>50 µL | 05N54-020<br>05N54-050 | 00884999015029<br>00884999015036 |
| Vysis LSI BCR/ABL1/ASS1 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL<br>50 µL | 08L79-020<br>08L79-050 | 00884999031647<br>00884999031654 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis CDKN2A/CEP 9 FISH Probe Kit




## PRODUCT DESCRIPTION

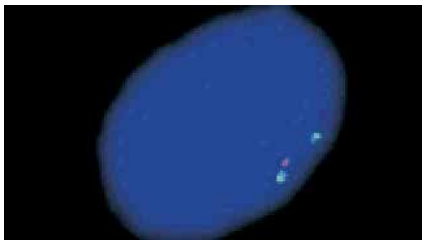
Alterations of the 9p21 locus including the tumor suppressor gene CDKN2A (p16) are implicated in different Meningiomas and Gliomas. Studies support the association of CDKN2A homozygous deletion with malignant progression and suggest that it is a marker of worse prognosis in anaplastic oligodendrogliomas.

The Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes have been used in several cytogenetic studies to detect losses of the CDKN2A gene. Using this probe set as well as other relevant markers (e.g. p53, RB1, 1p36, 19q13, all Vysis FISH probes), Kramar et al. investigated 82 samples from 81 patients with histolgically confirmed glial tumors. In a study using the Vysis LSI CDKN2A SpectrumOrange/CEP 9 SpectrumGreen Probes on 189 confirmed glioblastoma patients less than 50 years old, Korshunov et al. found 9p21 deletion to be correlated with an unfavorable prognosis.

Vysis LSI CDKN2A/CEP 9 Probes are provided in one vial as a mixture of the LSI CDKN2A (p16) probe labeled with SpectrumOrange and the CEP 9 probe labeled with SpectrumGreen. The LSI CDKN2A probe spans approximately222 kb and contains a number of genetic loci including D9S1749, DS1747, p16 (INK4B), p14 (ARF), D9S1748, p15(INK4B), and D9S1752. The CEP 9 SpectrumGreen probe hybridizes to alpha satellite sequences specific to chromosome 9.

## RESULTS OF HYBRIDIZATION

In a normal sample, the expected pattern for a nucleus hybridized with the Vysis LSI CDKN2A / CEP 9 Probes is the two orange, two green (2O2G) signal pattern. If a deletion at the 190 kb region covered by the LSI p16 probe occurs on one chromosome 9 homolog and both centromeres from chromosome 9 are retained, the one orange, two green (1O2G) signal pattern is expected.Very small deletions may occur that do not delete the entire LSI p16 probe target and therefore will not be detected.

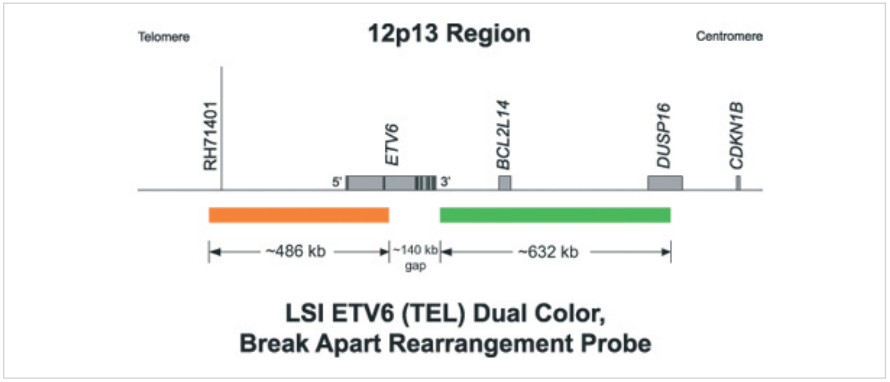


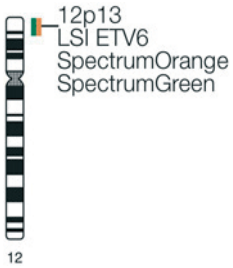
**Abnormal hybridization:** Vysis LSI CDKN2A / CEP 9 Probe hybridized to a nucleus exhibiting the one orange and two green signal (1O2G) pattern. One p16 gene locus is deleted and both chromosome 9 homologs are present as indicated by one orange and two green signals, respectively.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CDKN2A / CEP 9 FISH Probe Kit **(CE)** | 20 µL | 04N61-020 | 00884999009295 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis ETV6 Break Apart FISH Probe Kit




## PRODUCT DESCRIPTION

The LSI ETV6 fluorescence in situ hybridization (FISH) probe set is intended to detect rearrangements of the ETV6 gene locus in the chromosome 12p13 region.

Rearrangements of the short arm of chromosome 12 are frequently recurring abnormalities found in a variety of hematologic malignancies of both myelocytic and lymphoid origin. They include balanced and unbalanced translocations which prevalently involve band 12p13. The ETV6 (TEL) gene is the most common target found to be rearranged with more than 40 chromosome bands. ETV6-RUNX1 (AML1) gene fusion resulting from a t(12;21) has been characterized as the most common genetic lesion in pediatric acute lymphoblastic leukemia (ALL) and is associated with a favorable outcome.

The Vysis LSI ETV6 Dual Color Break Apart Rearrangement Probe has successfully been used in disease and therapy monitoring of different poor prognosis AML cases.

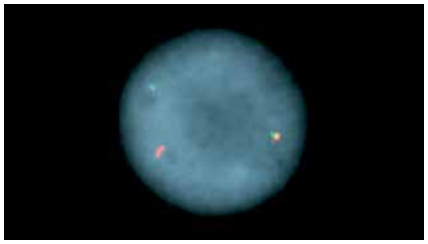
The Vysis LSI ETV6 (TEL) (12p13) Dual Color Break Apart Rearrangement Probe is a mixture of two probes. The 632 kb SpectrumGreen probe begins about 6 kb proximal to the ETV6 (TEL) gene and extends to toward the centromere. The SpectrumOrange probe begins within ETV6 intron 2 and extends toward the 12p telomere for approximately 490 kb. There is a gap between the two probes of about 140 kb.

## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals.

The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 12 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

**Normal hybridization:** Normal cell hybridization using the LSI ETV6 (TEL) (12p13) Dual Color, Break Apart Rearrangement Probe.

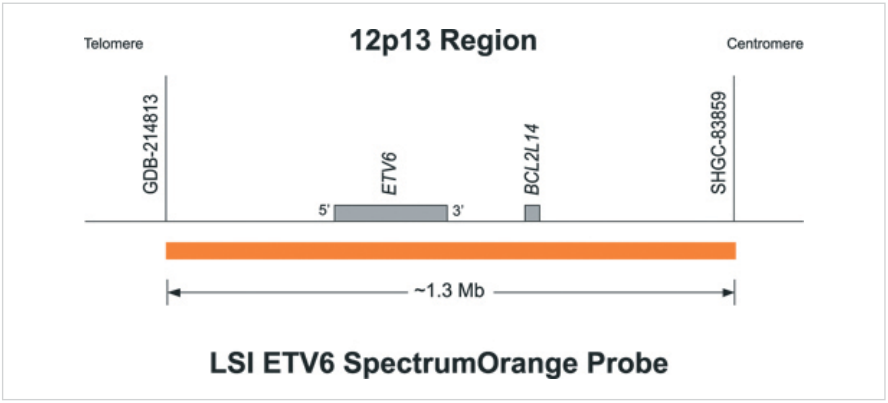


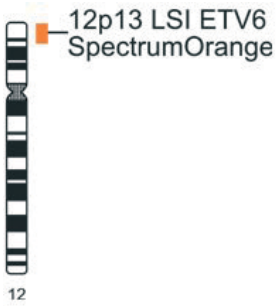
**Abnormal hybridization:** Abnormal cell hybridization using the LSI ETV6 (TEL) (12p13) Dual Color, Break Apart Rearrangement Probe.

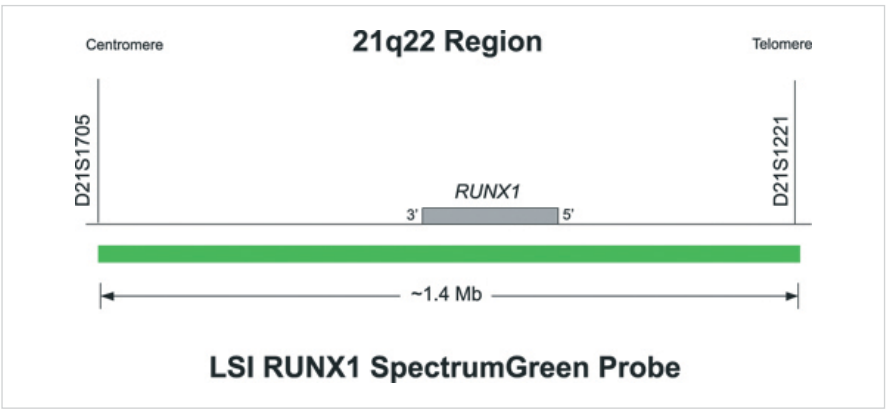
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ETV6 Break Apart FISH Probe Kit **(CE)** | 20 µL | 04N09-020 | 00884999007932 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis ETV6/RUNX1 DF FISH Probe Kit





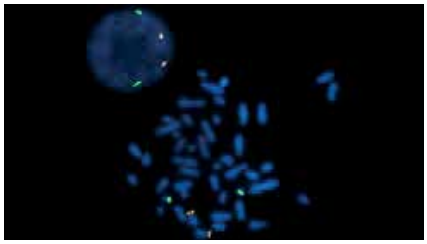
## PRODUCT DESCRIPTION

The Vysis ETV6/RUNX1 DF FISH Probe Kit is intended to detect the t(12;21)(p13;q22) translocation between the ETV6 gene and the RUNX1 gene using the fluorescence in situ hybridization (FISH) technique.

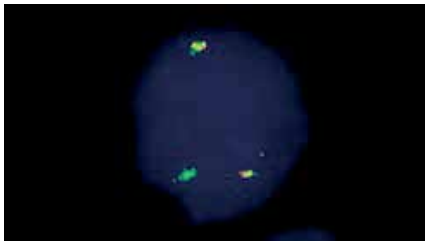
The t(12;21)(p13;q22) chromosomal translocation is the most common chromosomal rearrangement in childhood acute lymphocytic leukemia (ALL). Although not detectable by classical cytogenetics, the t(12;21) resulting in the fusion of the 5' section of the ETV6 (TEL) gene on chromosome 12p13 to almost the entire RUNX1 (AML1) gene located on chromosome 21q22 occurs in about 25% of childhood ALL. The Vysis ETV6/RUNX1 DF FISH Probe Kit uses a dual-color, dual-fusion probe design to detect the t(12;21) by fluorescence in situ hybridization.

## HYBRIDIZATION RESULTS

Two lymphocyte cells, one in interphase (upper left) next to chromosomes from a metaphase cell (lower right), that have been hybridized with the LSI ETV6/RUNX1 Dual Color Dual Fusion Probe. Both cells show the two orange (RUNX1), two green (ETV6) signal pattern.



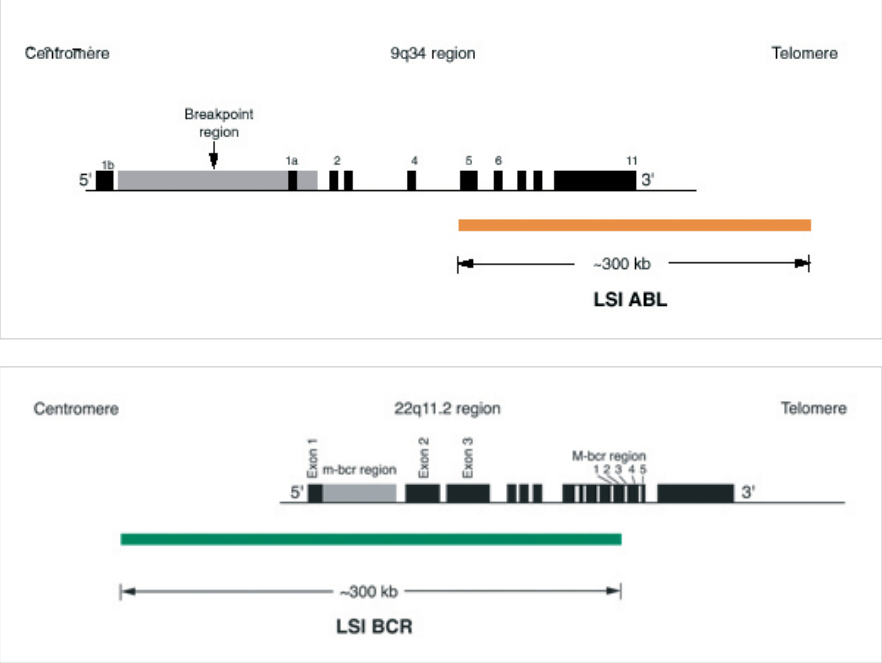
A bone marrow cell in interphase hybridized with the LSI ETV6/RUNX1 Dual Color Dual Fusion Probe. The cell in this image shows the one orange (RUNX1), one green (ETV6), two fusion (der (12) and der (21)) signal pattern.



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ETV6/RUNX1 DF FISH Probe Kit **(CE)** | 10 µL | 05N96-010 | 00884999015487 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit



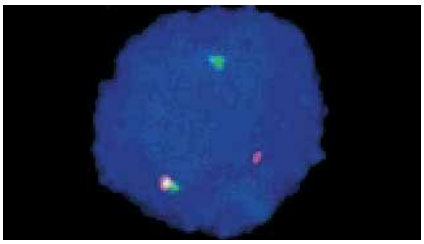


## PRODUCT DESCRIPTION

The LSI BCR/ABL Dual Color, Single Fusion Translocation Probe is a mixture of the LSI ABL probe labeled with SpectrumOrange and the LSI BCR probe labeled with SpectrumGreen. The ABL probe begins between exons 4 and 5 and continues for about 300 kb toward the telomere of chromosome 9. The LSI BCR probe begins between BCR exons 13 and 14 (M-bcr exons 2 and 3) and extends toward the centromere on chromosome 22 for approximately 300 kb, extending well beyond the m-bcr region.

## RESULTS OF HYBRIDIZATION

A nucleus lacking the t(9;22) will exhibit the two orange, two green (2O2G) signal pattern. In a cell harboring the t(9;22), one orange, one green, and one orange/green (yellow) fusion signal pattern (1O1G1F) will be observed. This simple probe design detects the 5' BCR/3' ABL gene fusion and is useful for detecting samples with a high percentage of cells possessing this translocation.

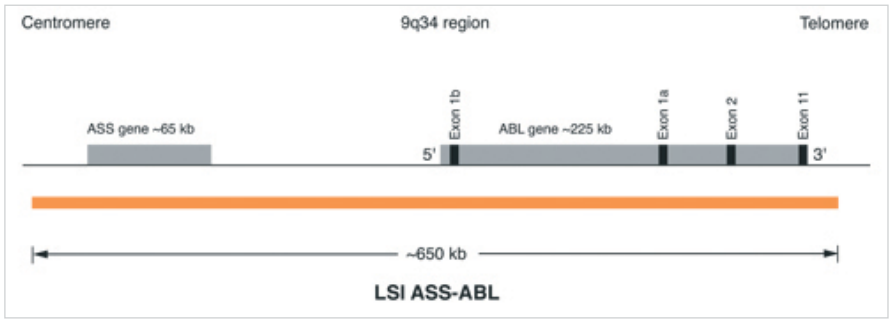


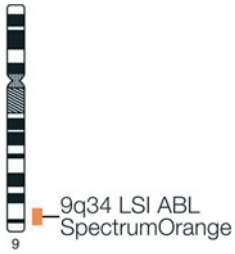
LSI BCR/ABL Dual Color, Single Fusion Translocation Probe hybridized to a nucleus containing the t(9;22). One orange, one green and one fusion (IOIGIF) signal pattern is observed.

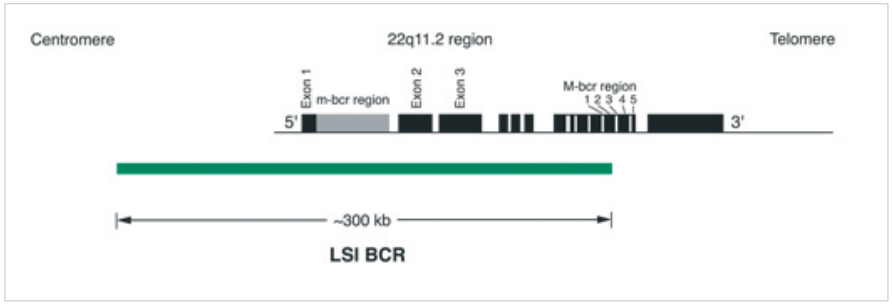
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L56-050 | 00884999031463 |
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe **(ASR)** | 20 µL | 05J77-001 | 00884999012462 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit



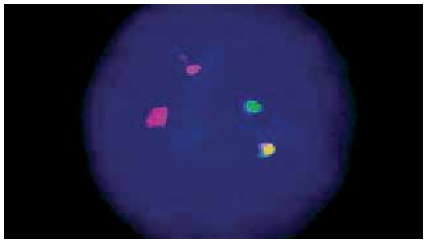


## PRODUCT DESCRIPTION

The BCR/ABL ES Dual Color Translocation Probe Kit is a mixture of the LSI ABL probe labeled with SpectrumOrange and the LSI BCR probe labeled with SpectrumGreen. The spanning ABL probe is approximately 650 kb extending from an area centromeric of the ASS gene to well telomeric of the last ABL exon. The SpectrumGreen BCR probe is approximately 300 kb beginning between BCR exons 13 and 14 (M-bcr exons 2 and 3) and extending well beyond the m-bcr region.

## RESULTS OF HYBRIDIZATION

A nucleus lacking the t(9;22) will exhibit a two orange, two green(2O2G) signal pattern. In a nucleus possessing the t(9;22) involvingthe M-bcr, one green (native BCR), one large orange (native ABL), onesmaller orange (ES), and one fused orange/green signal (5' BCR/3' ABL),(2O1G1F) will be observed. Minor breakpoint (m-bcr) signal patterns mayappear as one orange, one green, and two fusion signals. In some cellsa deletion may occur 5' of the ABL breakpoint that may reduce the ESpattern to a single fusion pattern.

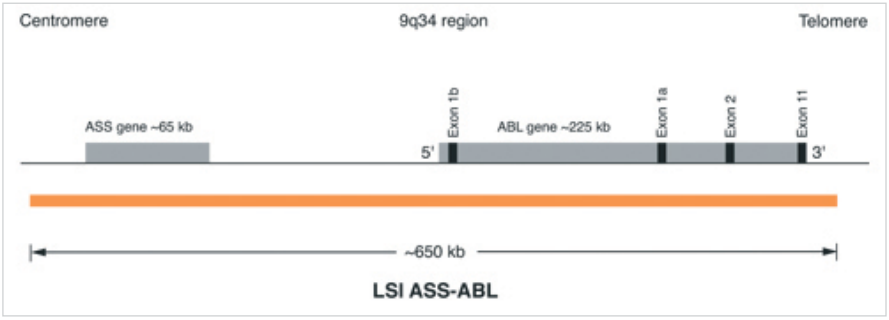


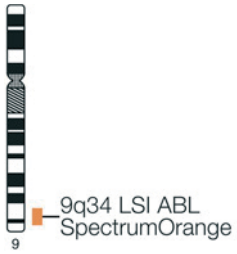
**Abnormal hybridization:** LSI BCR/ ABL ES Dual Color Translocation Probe hybridized to a nucleuscontaining the t(9;22) showing one green (native BCR), one large orange(native ABL), one smaller orange (ES) and one fused orange/ green(20IGIF) signal pattern.

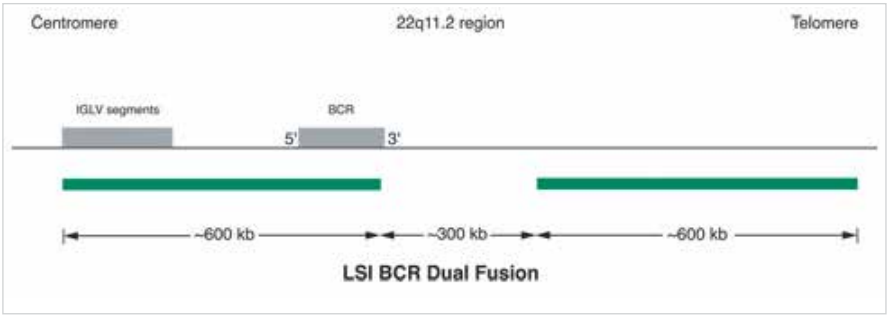
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe **(ASR)** | 20 µL | 05J78-001 | 00884999012479 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L55-020 | 00884999031456 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit



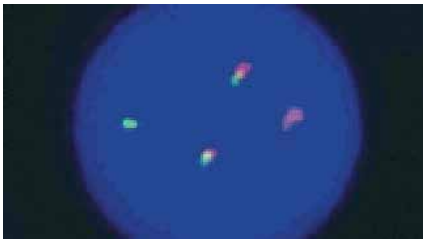


## PRODUCT DESCRIPTION

The LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe is a mixture of the LSI BCR probe labeled with SpectrumGreen and the LSI ABL probe labeled with SpectrumOrange. The spanning ABL probe has a genomic target of approximately 650 kb extending from an area centromeric of the argininosuccinate synthetase gene (ASS) to well telomeric of the last ABL exon. The BCR probe target spans a genomic distance of about 1.5 Mb. The BCR probe begins within the variable segments of the immunoglobulin lambda light chain locus (IGLV), extends along chromosome 22 through the BCR gene, and ends at a point approximately 900 kb telomeric of BCR. A region of about 300 kb containing low-copy number repeats has been eliminated from the probe which introduces a gap in the coverage of the probe target. Both probes span their respective breakpoints.

## RESULTS OF HYBRIDIZATION

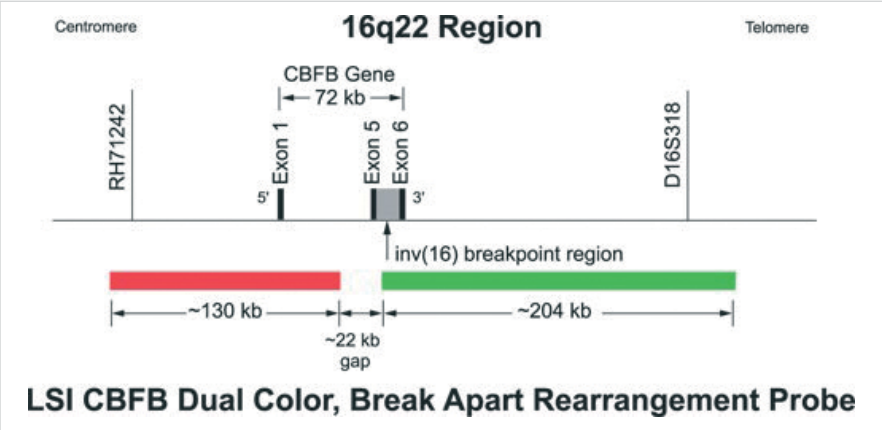
A nucleus lacking the t(9;22) translocation will exhibit the two orange, two green (2O2G) signal pattern. In a nucleus containing a simple balanced t(9;22), one orange and one green signal from the normal 9 and 22 chromosomes and two orange/green (yellow) fusion signals, one each from the derivative 9 and 22 chromosomes, will be observed (1O1G2F). In some instances, deletions may occur 3' of the BCR breakpoint and/or 5' of the ABL breakpoint resulting in either an ES (extra orange or green) signal pattern or a single fusion pattern.



**Abnormal hybridization:** LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe hybridized to a nucleus containing a simple balanced t(9;22). One orange, one green and two orange/green fusion signals are observed (1O1G2F).

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL<br>50 µL | 08L10-001<br>08L10-020 | 00884999031166<br>00884999031173 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL<br>50 µL | 05J82-001<br>05J82-010 | 00884999012592<br>00884999012615 |

# Vysis LSI CBFB Break Apart Rearrangement Probe





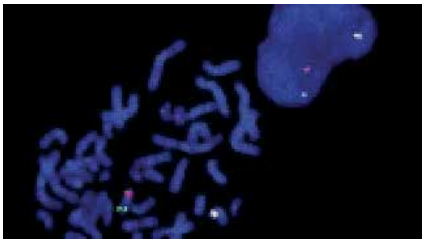
## PRODUCT DESCRIPTION

The Vysis CBFB Break Apart FISH Probe is intended to detect chromosomal rearrangements at the CBFB locus on chromosome 16q22.

Aberrations of chromosome 16q22 have been found to be associated with acute myeloid leukemia (AML). A favorable outcome in AML has been associated with inv(16) and t(16;16). The Vysis CBFB Break Apart FISH Probe has been used to detect inv(16)/t(16;16) in a study of 237 diagnostic specimens from AML patients enrolled in a clinical trial.

## RESULTS OF HYBRIDIZATION

The expected pattern in a nucleus lacking inv(16) will be two fused red/green (yellow) signals (2F). The pattern in a nucleus containing an inv(16) results in separate red and green signals appearing on opposite arms of the inverted 16 chromosome. The pattern of t(16;16)(p13;q22) results in an adjacent or fused red/green signal on the q arm of one of the 16 chromosomes and a green signal on the other arm of 16, while the 16 chromosome homolog will only contain the red signal on one arm.

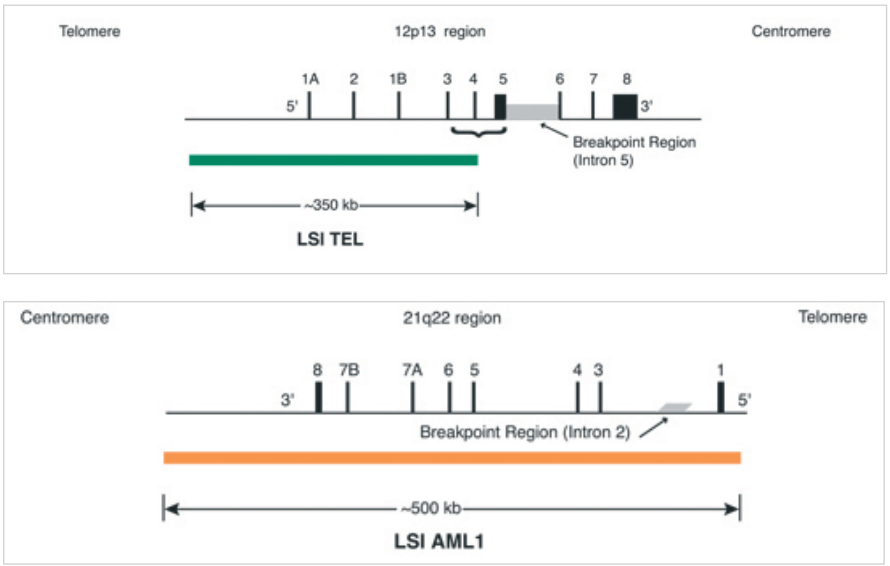


**Normal hybridization:** LSI CBFB Dual Color, Break Apart Rearrangement Probe hybridized to a cell exhibiting one red and one green signal. On the metaphase cell, contains the red signal on one arm and the green signal on the other arm.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI CBFB Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J65-001 | 00884999012240 |
| Vysis LSI CBFB Break Apart Probe Kit **(CE)** | 20 µL | 05N44-020 | 00884999014930 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe Kit





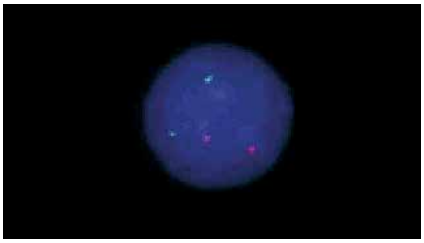
## PRODUCT DESCRIPTION

The LSI TEL/AML1 ES Dual Color Translocation Probe is designed to detect the TEL (ETV6)/AML1 (RUNX1)gene fusion that occurs as a result of a translocation between chromosomes 12p13 and 21q22. Cytogenetically, the t(12;21) is a subtle abnormality and thus not easily detectable with standard cytogenetic banding techniques.

The LSI TEL/AML1 ES Dual Color Translocation Probe is a mixture of the LSI TEL probe labeled with SpectrumGreen and the LSI AML1 probe labeled with SpectrumOrange. The LSI TEL probe begins between exons 3-5 and extends approximately 350 kb toward the telomere on chromosome 12. The approximately 500 kb AML1 probe spans the entire gene.

## RESULTS OF HYBRIDIZATION

In a normal nucleus, the expected pattern for a cell hybridized with the LSI TEL/AML1 ES Dual Color Translocation probe is the two orange (AML1), two green (TEL) (2O2G) signal pattern. In an abnormal cell containing the TEL/AML1 fusion, the expected signal pattern is one green (native TEL), one large orange (native AML1), one smaller orange signal (residual AML1) and one fused orange/green (yellow) signal. The green native signal may be absent in some instances due to the deletion of the non-translocated TEL allele.

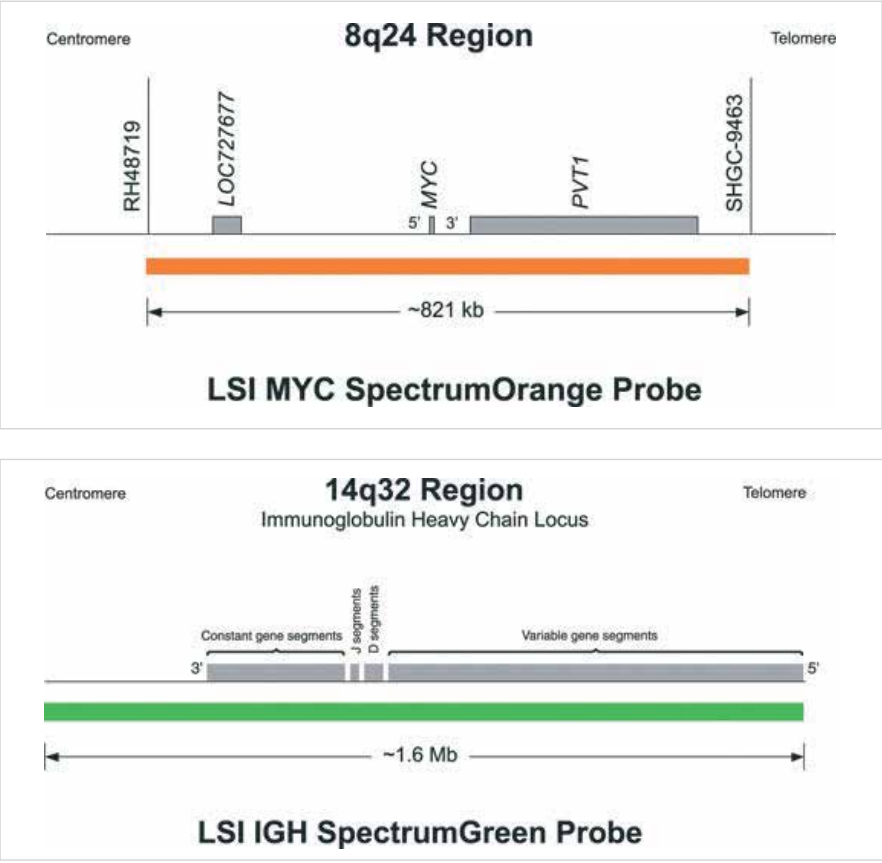


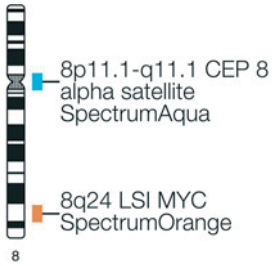
**Normal hybridization:** LSI TEL/AML1 ES Dual Color Translocation Probe hybridized to a nucleus lacking the TEL/AML1 fusion gene showing the two orange and two green (2O2G) signal pattern.

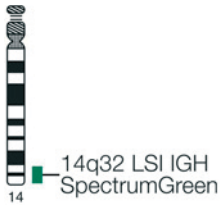
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L66-020 | 00884999031562 |
| Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe **(ASR)** | 20 µL | 05J62-001 | 00884999012202 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probe Kit



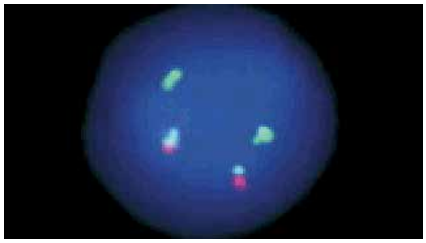

## PRODUCT DESCRIPTION

The Vysis IGH/MYC/CEP 8 Tri-Color Dual Fusion FISH probes are intended to detect the t(8;14)(q24;q32)reciprocal translocation involving the IGH and MYC gene regions.

The t(8;14)(q24;q32) translocation is a hallmark of Burkitt's Lymphoma (BL) and occurs in about 80% of BL cases. As such, testing for t(8;14)(q24;q32) or variants is indicated as an essential test for BL. TheVysis LSI IGH/MYC/CEP 8 Tri-color Dual Fusion probe has been used to identify the t(8;14)(q24;q32) translocation in published reports. The aqua CEP 8 probe serves as a control for the copy number of chromosome 8.

## RESULTS OF HYBRIDIZATION

In a normal cell the expected pattern for a nucleus hybridized with the LSI IGH/MYC/CEP 8 probes is the two aqua, two orange, and two green signal pattern. A cell harboring the reciprocal t(8;14) with the 8q24 breakpoint well within the MYC probe target is expected to produce a pattern of one orange, one green, two orange/green fusions, and two aqua signals (1O1G2F2A). If the cell contains a breakpoint very far 5' of MYC, a fusion on the der(8) may not be visible or may be very weak, as little or no orange probe target would remain on the der(8).

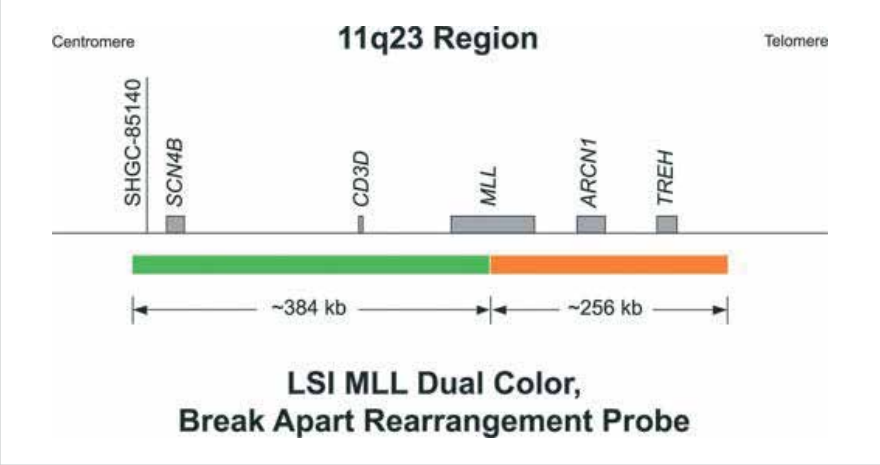


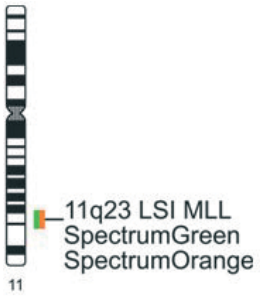
LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probes hybridized to a normal nucleus showing the expected 202G2A signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probe Kit **(CE)** | 20 µL | 04N10-020 | 00884999007949 |
| Vysis LSI IGH/MYC/Vysis CEP 8 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL | 05J75-001 | 00884999012431 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe



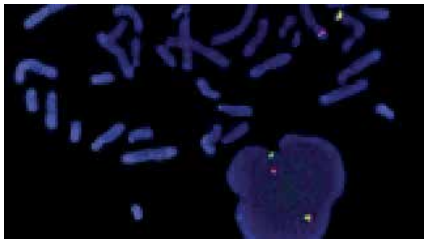

## PRODUCT DESCRIPTION

The LSI MLL Dual Color, Break Apart Rearrangement Probe is designed to detect the 11q23 rearrangement associated with various translocations involving the MLL gene. Translocations disrupting the MLL (ALL-1,HRX) gene are among the most common cytogenetic abnormalities observed in hematopoietic malignancies. Although over 30 variant translocations have been seen involving MLL translocations, the most common abnormalities are t(4;11)(q21;q23), t(9;11)(p22;q23), and t(11;19)(q23;p13).

The LSI MLL Dual Color, Break Apart Rearrangement Probe consists of a 350 kb portion centromeric of the MLL gene breakpoint cluster region (bcr) labeled in SpectrumGreen and approximately 190 kb portion largely telomeric of the bcr labeled in SpectrumOrange. In approximately 25% of 11q23 translocations, a region beginning at the MLL breakpoint and extending distally is deleted. This probe can provide a better indication of the presence of the 11q23 translocation than a single color probe design.

## RESULTS OF HYBRIDIZATION

The signal pattern observed in a cell lacking the MLL rearrangement is expected to show a two orange/green (yellow) fusion signal pattern (2F). In a cell possessing a MLL translocation, the expected pattern is one green/orange (yellow) fusion signal, one orange signal, and one green (1O1G1F) signal. With the MLL Dual Color, Break Apart Rearrangement Probe, a large deletion occurring distally from the MLL breakpoint might weaken or totally eliminate one of the two orange signals, potentially producing a FISH pattern characteristic of concomitant translocation and deletion, i.e., one orange/green fusion and one isolated green signal.

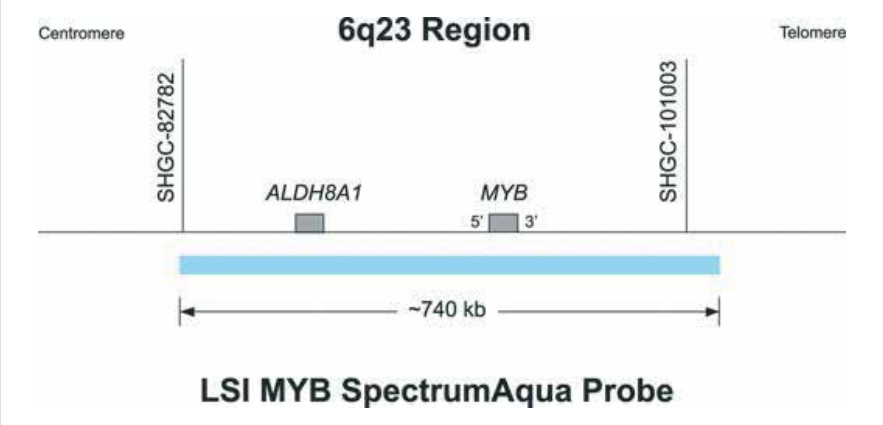


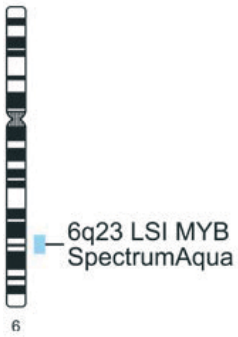
**Abnormal hybridization:** LSI MLL Dual Color, Break Apart Rearrangement Probe hybridized to cells possessing a t(9:11)(p22;q23) and exhibiting the expected one orange, one green and one orange/green fusion signal pattern (1O1G1F).

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L57-020 | 00884999031470 |
| Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J90-001 | 00884999012837 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI MYB SpectrumAqua Probe Kit




## PRODUCT DESCRIPTION

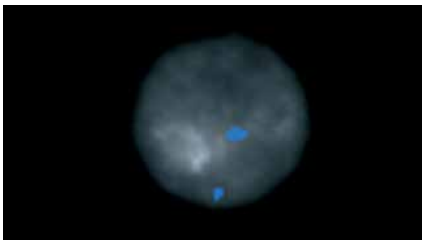
This Vysis MYB SpectrumAqua FISH Probe is intended to detect the copy number of the LSI MYB probe target located at chromosome 6q23.

The Vysis LSI MYB SpectrumAqua Probe was used to detect deletion of its target at 6q23 in a study of 143 chronic lymphocytic leukemia patients. In this study, approximately 5% of patients were found to have this deletion.

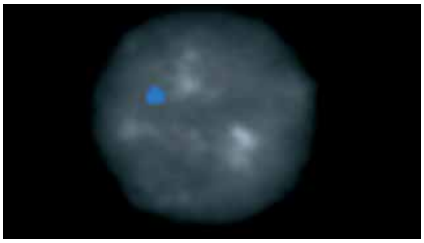
## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase and metaphase nuclei of normal cells is expected to be seen as two aqua signals. The anticipated signal pattern in individuals with a deletion of the 6q23 region would be seen as a single aqua signal. Other patterns may be observed if additional genetic alterations are present.

Hybridization of this probe to interphase and metaphase nuclei of normal cells is expected to be seen as two aqua signals. The anticipated signal pattern in individuals with a deletion of the 6q23 region would be seen as a single aqua signal. Other patterns may be observed if additional genetic alterations are present.



**Normal hybridization:** Normal cell hybridization using the Vysis LSI MYB (6q23) Probe.

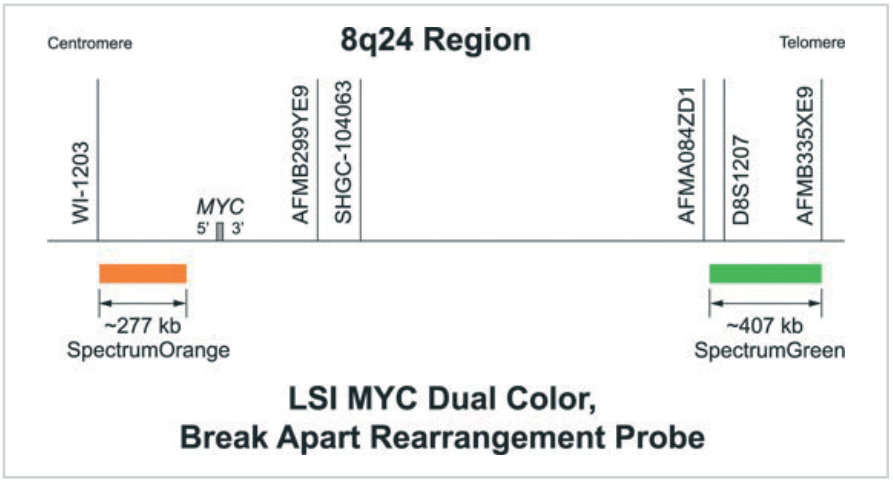


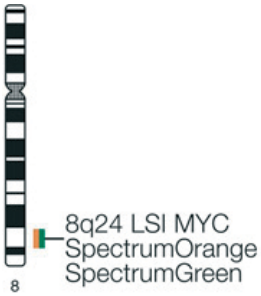
**Abnormal hybridization:** Abnormal cell hybridization using the Vysis LSI MYB (6q23) Probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYB SpectrumAqua Probe Kit **(CE)** | 20 µL | 05N40-020 | 00884999014916 |
| Vysis LSI MYB (6q23) SpectrumAqua Probe **(ASR)** | 20 µL | 07J86-001 | 00884999029378 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI MYC Dual Color Break Apart Rearrangement Probe Kit



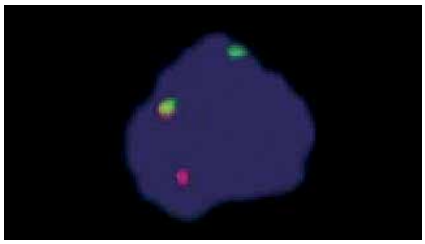

## PRODUCT DESCRIPTION

The Vysis LSI MYC Dual Color Break Apart Rearrangement probe is intended to detect chromosomal rearrangements involving the MYC gene region on chromosome 8q24. It is particularly useful for detection of aberrations with breakpoints located far telomeric to MYC such as those that can occur in the variant t(8;22)(q24.1;q11.2)IGL-MYC and t(2;8)(p11.2;q24.1)IGK-MYC rearrangements.

Translocations involving the MYC region have diagnostic and prognostic importance in B-cell malignancies. In Burkitt's lymphoma approximately 75% to 80% of cases carry t(8;14)IGH-MYC and the remainder are associated with t(8;22)IGL-MYC or t(2;8)IGK-MYC. In approximately 5 to 10% of diffuse large B-cell lymphoma (DLBCL) patients also have MYC region rearrangements, and detection of these rearrangements with the MYC Dual Color Break Apart Rearrangement Probe has been associated with a poor prognosis. It has been suggested that FISHanalysis for MYC rearrangements should be performed on all DLBCL patients.

## RESULTS OF HYBRIDIZATION

An abnormal nucleus hybridized with the LSI MYC Dual Color Break Apart Rearrangement Probe produces a two orange/green (yellow) fusion (2F) pattern. A one orange, one green, and one fusion pattern (1O1G1F) is expected from a sample with a t(2;8), t(8;22) or t(8;14) having a breakpoint within the gap between the hybridization targets of the LSI MYC probes.

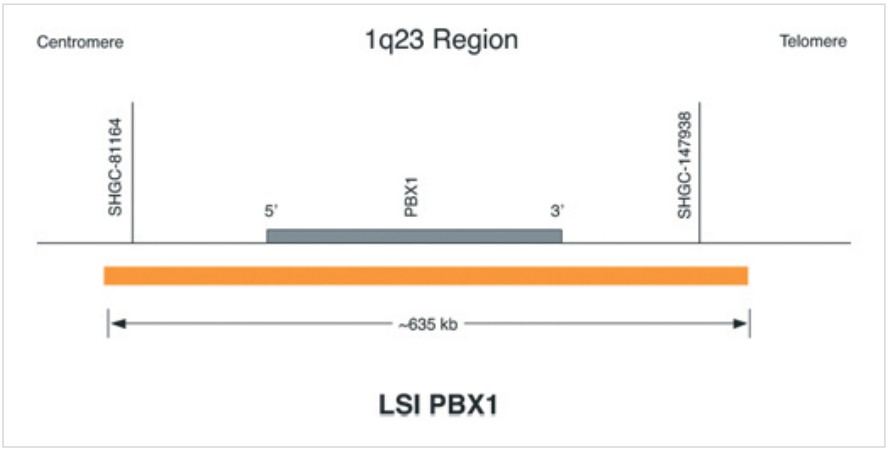


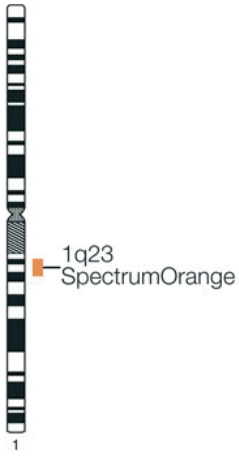
**Abnormal hybridization:** LSI MYC Dual Color Break Apart Rearrangement Probe hybridized to an abnormal nucleus showing a one orange, one green and one orange/green fusion (1O1G1F) signal pattern.

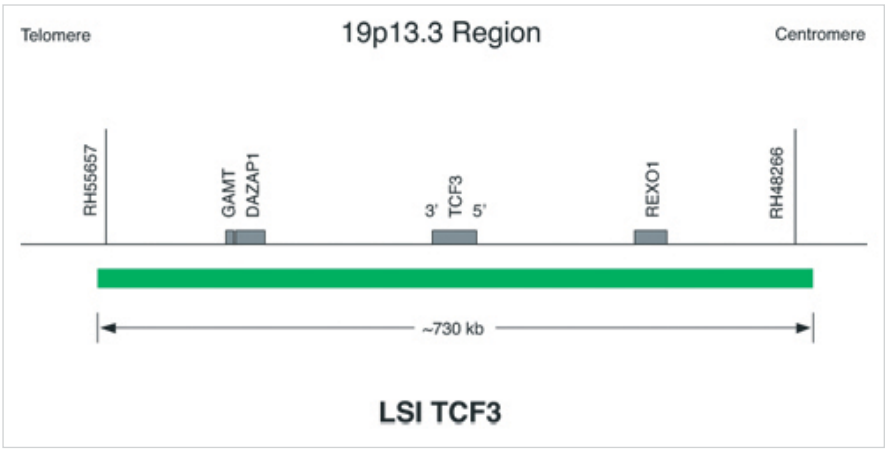
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYC Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 01N63-020 | 00884999000827 |
| Vysis LSI MYC Dual Color Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J91-001 | 00884999012844 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis LSI TCF3/PBX1 Dual Color, Dual Fusion Translocation Probe



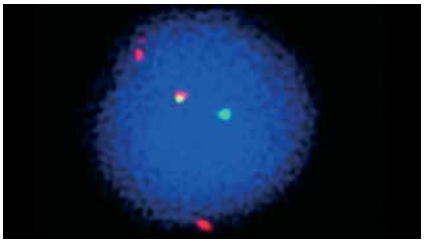





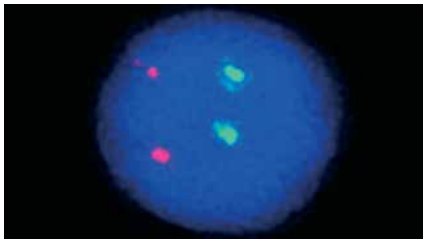
## PRODUCT DESCRIPTION

Translocations occur between the TCF3 locus at chromosome 19p13.3 and the PBX1 locus at chromosome 1q23. The translocation event t(1;19)(q23;p13) produces a fusion of two genes on the derivative 19 chromosome that results in a novel chimeric gene, TCF3/PBX1.

The TCF3 SpectrumGreen probe is 730 kb in size and extends beyond the TCF3 gene to cover a larger region on chromosome 19p13.3. The PBX1 SpectrumOrange probe is 635 kb in size and covers the entire PBX1 gene on chromosome 1q23.



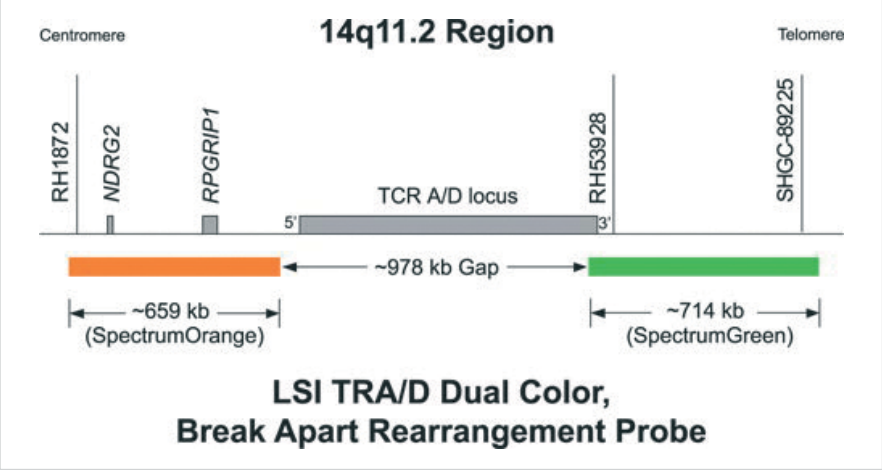
**Abnormal hybridization:** Example abnormal hybridization showing two orange, one green and one fusion signals.



**Normal hybridization:** Normal hybridization showing two orange and two green signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TCF3/PBX1 Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 01N24-020 | 00884999000605 |

# Vysis TRA/D Break Apart FISH Probe Kit

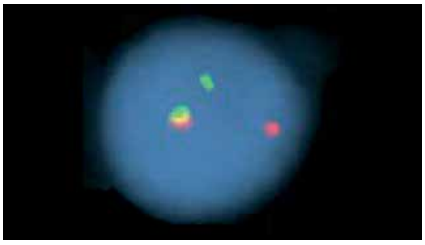




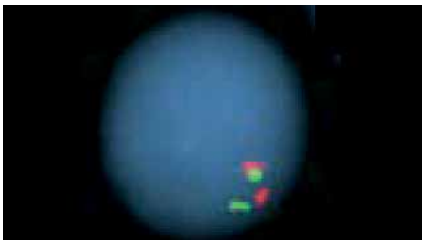
## PRODUCT DESCRIPTION

The Vysis TRA/D Break Apart FISH Probe Kit is intended to detect chromosomal rearrangements involving the T-cell receptor alpha/delta locus at chromosome 14q11.2 using the fluorescence in situ hybridization (FISH) technique.

Acute Lymphoblastic Leukemia (ALL) accounts for 25% of all pediatric cancer and 15% of pediatric ALL is of T-Cell lineage (T-ALL). T-ALL andT-Cell Lymphoblastic Lymphoma (T-LBL) are described by the World Health Organization classification as similar entities that are discerned by the relative percentage of bone marrow infiltration. The Vysis TRA/DDual Color Break Apart Rearrangement Probe was used in a study to detect TCR alpha/delta rearrangements in 22 randomly selected patients for the Children's Oncology Group.



**Abnormal hybridization:** Nucleus showing the one green/orange fusion, one green and one orange signal pattern.

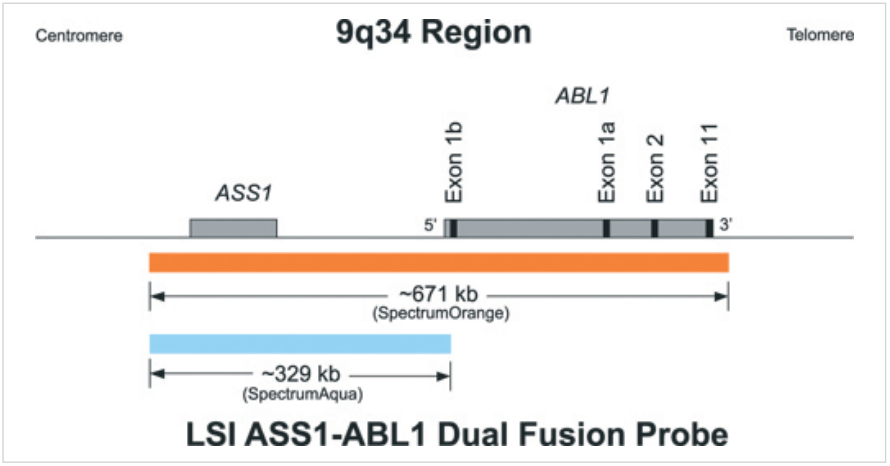


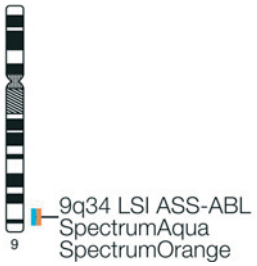
**Normal hybridization:** Nucleus showing the two green/orange fusion signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TRA/D Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N41-020 | 00884999014923 |

ACUTE MYELOGENOUS LEUKEMIA

# Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit



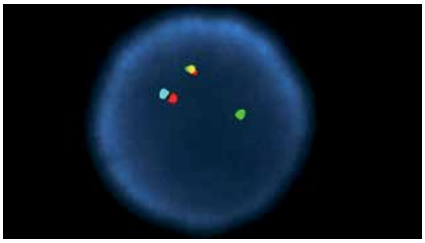



## PRODUCT DESCRIPTION

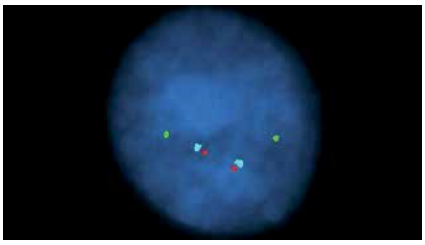
The Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit is intended to detect the t(9;22)(q34;q11.2) reciprocal translocation involving the BCR and ABL1 gene regions using the fluorescence in situ hybridization (FISH) technique.

The t(9;22) translocation which fuses the BCR gene on chromosome 22q11.2 and the ABL1 gene on chromosome 9q34 is observed by cytogenetics in greater than 80% of patients with chronic myelogenous leukemia (CML). In CML cases lacking a cytogenetically detectable translocation, the BCR/ABL1 fusion can still almost always be detected by FISH or other molecular techniques. BCR/ABL1 fusions also occur in a portion of acute lymphocytic leukemia cases and

more rarely in acute myeloid leukemia. In about 15 to 20 percent of CML cases, the t(9;22) results in the loss of genetic material flanking the BCR and/or ABL1 breakpoints on the derivative 9 chromosome. This loss can prevent the production of the highly specific two-fusion signal patterns expected of dual fusion probes and balanced translocations. If both BCR and ABL1 targets are deleted on the der(9) chromosome, low-level random overlap of orange and green signals within normal cells (producing a 1 orange, 1 green, 1 fusion pattern) cannot be discriminated from low-level true BCR/ABL1 fusions producing the same pattern. The Tri-Color design of this test uses a probe in a third color (aqua) on the centromeric side of the ABL1 breakpoint, which co-localizes with the orange signal in a random orange/green signal fusion, but is absent from a true BCR/ABL1 molecular fusion on the der(22) chromosome. The probes in this kit have been used in published papers to detect low levels of positive cells in CML patients who were undergoing therapy and had deletions of FISH signals on the derivative chromosome 9.



**Abnormal hybridization:** Nucleus showing the one aqua/orange, one green, and one orange/green fusion (yellow) signal pattern.

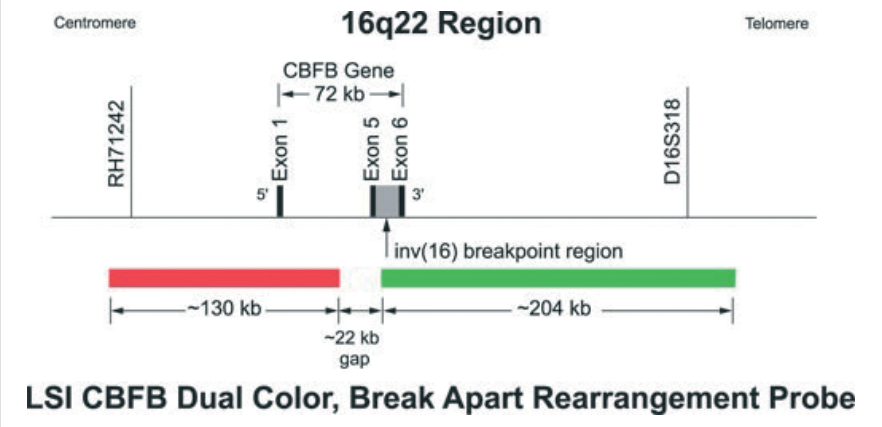


**Normal hybridization:** Nucleus showing the two aqua/orange and two green signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 20 µL<br>50 µL | 05N54-020<br>05N54-050 | 00884999015029<br>00884999015036 |
| Vysis LSI BCR/ABL1/ASS1 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL<br>50 µL | 08L79-020<br>08L79-050 | 00884999031647<br>00884999031654 |

ACUTE MYELOGENOUS LEUKEMIA

# Vysis CBFB Break Apart FISH Probe Kit





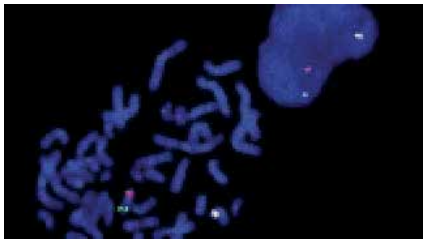
## PRODUCT DESCRIPTION

The Vysis CBFB Break Apart FISH Probe is intended to detect chromosomal rearrangements at the CBFB locus on chromosome 16q22.

Aberrations of chromosome 16q22 have been found to be associated with acute myeloid leukemia (AML). A favorable outcome in AML has been associated with inv(16) and t(16;16). The Vysis CBFB Break Apart FISH Probe has been used to detect inv(16)/t(16;16) in a study of 237 diagnostic specimens from AML patients enrolled in a clinical trial.

## RESULTS OF HYBRIDIZATION

The expected pattern in a nucleus lacking inv(16) will be two fused red/green (yellow) signals (2F). The pattern in a nucleus containing an inv(16) results in separate red and green signals appearing on opposite arms of the inverted 16 chromosome. The pattern of t(16;16)(p13;q22) results in an adjacent or fused red/green signal on the q arm of one of the 16 chromosomes and a green signal on the other arm of 16, while the 16 chromosome homolog will only contain the red signal on one arm.



**Abnormal hybridization:** LSI CBFB Dual Color Break Apart Rearrangement Probe hybridized to a cell exhibiting one red and one green signal. On the metaphase cell, contains the red signal on one arm and the green signal on the other arm.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CBFB Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N44-020 | 00884999014930 |

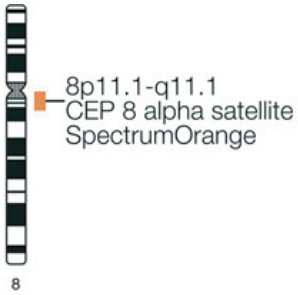
# Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit

## PRODUCT DESCRIPTION

CEP 8 is a SpectrumOrange labeled probe specific for the alpha satellite (centromeric) region, 8p11.1-q11.1.

The CEP 8 DNA Probe Kit which is available for in vitro diagnostic use and may be used as an adjunct to standard karotyping to identify and enumerate chromosome 8 in cells obtained from bone marrow. In multi-site clinical trials, the CEP 8 DNA Probe Kit for interphase analysis was 96% sensitive and 98% specific as compared to traditional cytogenetic analysis. A close association has been made between trisomy 8 and both myeloid blast crisis and basophilia. Trisomy 8 is a prevalent genetic aberration in several specific diseases:

- Chronic Myelogenous Leukemia (CML)
- Acute Myeloid Leukemia (AML)
- Myeloproliferative disorders (MPD)
- Myelodysplastic Syndrome (MDS)
- Other hematologic disorders not specified (HDNOS)



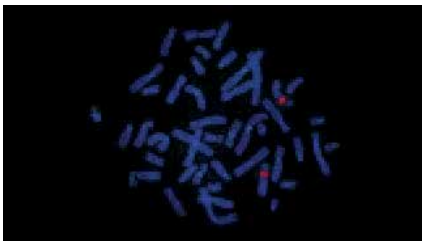

## CEP 8 SPECTRUMORANGE DNA PROBE KIT CONTENT

Components of the CEP 8 SpectrumOrange DNA Probe Kit include:

- CEP 8 SpectrumOrange alpha satellite DNA for centromere region 8p11.1-q11.1 predenatured in hybridization buffer (220 µL)
- NP-40 (detergent for wash solution: 1000 µL)
- DAPI II counterstain (300 µL)
- 20X SSC (66 g)
- Control slides for the CEP 8 kit are also sold separately. See Order No. 30-805000 and Order No. 30-805002.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the CEP 8 probe is a two orange (2O) signal pattern. In an abnormal cell containing trisomy 8, the expected pattern will be a three orange (3O) signal pattern.



**Normal hybridization:** CEP 8 SpectrumOrange hybridized to a normal cell showing two orange signals indicating two copies of chromosome 8.

## INTENDED USE

The CEP 8 SpectrumOrange DNA Probe Kit is intended to detect AT rich alpha satellite sequences in the centromere region of chromosome 8 in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosome 8 via fluorescence in situ hybridization (FISH) in interphase nuclei and in metaphase spreads of cells obtained from bone marrow in patients with myeloid disorders [Chronic myelogenous leukemia (CML), Acute myeloid leukemia (AML), Myeloproliferative disorder (MPD), Myelodysplastic syndrome (MDS), and Hematological disorders not otherwise specified (HDNOS)]. It is not intended to be used as a stand alone assay for test reporting. It is not intended for use in long term cell cultured materials such as amniocytes, fibroblasts and tumor cells.

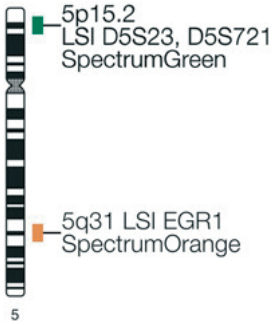
## LIMITATIONS

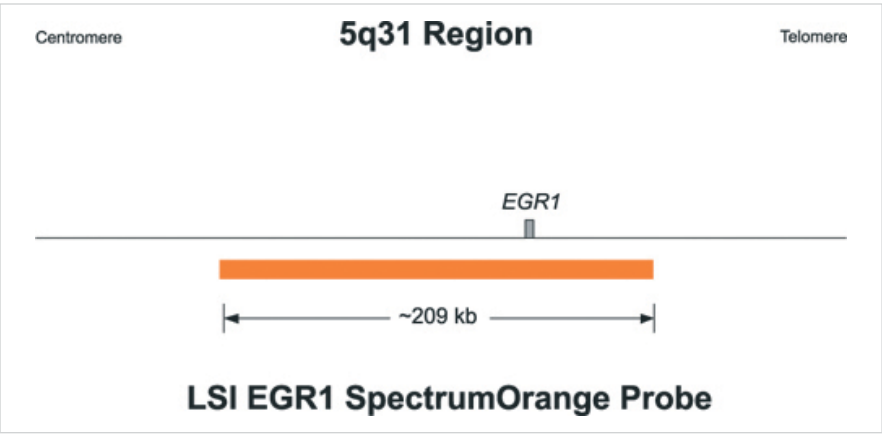
- The CEP 8 SpectrumOrange DNA Probe Kit has been characterized only for identifying chromosomes in nuclear preparations or metaphase spreads from bone marrow specimens.
- The clinical interpretation of any test results should be done in conjunction with standard cytogenetic analysis and should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
- Clinical specimens with >2.2% tri-signaled nuclei are considered to have an abnormal trisomy 8 clone. Those with ≤ 2.2% tri-signaled nuclei should be considered normal, although the presence of trisomy 8 is not completely excluded.
- The CEP 8 SpectrumOrange DNA Probe Kit is not intended for long term cell cultured materials such as amniocytes, fibroblasts and tumor cells.
- FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
- If significant peripheral blood contamination is present in the bone marrow specimen, the blood may dilute the specimen; it is important to recognize the potential effects this dilution effect may have on the FISH assay results.
- It is possible that patients may have chromosome polymorphism which may hybridize with CEP 8 probe. FISH metaphase analysis should be done in addition to FISH interphase analysis. Polymorphism was not investigated in the clinical trials.
- This assay will not detect the presence of other chromosome abnormalities frequently associated with hematological disorders.
- The efficacy of this assay for monitoring of trisomy 8 or disease progression has not been demonstrated.

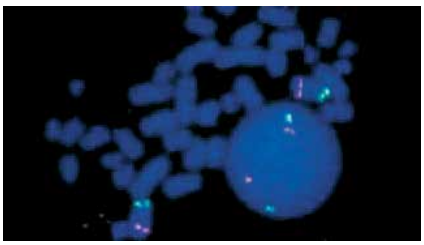
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis Cri-du-Chat Region Probe - LSI EGR1 SpectrumOrange/ LSI D5S23, D5S721 SpectrumGreen

**Normal hybridization:** LSI EGR1/D5S23, D5S721 (5p15.2) hybridized to metaphase and interphase cells.

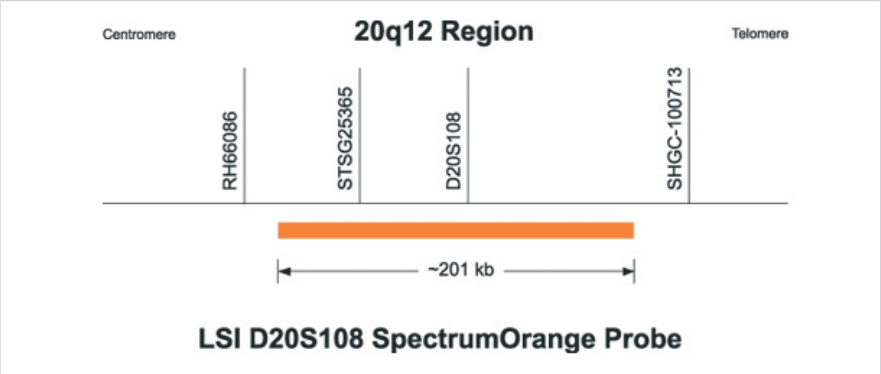
## PRODUCT DESCRIPTION

LSI D5S23, D5S721 probe detects deletions of 5p15.2. The LSI D5S23, D5S721 probe is available alone, or in combination with LSI EGR1 (5q31) as a control.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Cri-du-Chat Region Probe - LSI EGR1 SpectrumOrange, LSI D5S23, D5S721 SpectrumGreen **(ASR)** | 20 µL | 05J76-001 | 00884999012455 |

ACUTE MYELOGENOUS LEUKEMIA

# Vysis D20S108 FISH Probe Kit





## PRODUCT DESCRIPTION

The Vysis LSI D20S108 fluorescence in situ hybridization (FISH) probe is intended to detect deletions of Vysis LSI D20S108 probe target locus on 20q12.

Acquired deletions of the long arm of chromosome 20 are found in ~4% of patients with a myelodysplastic syndrome (MDS) and in 1 to 2% of patients with acute myeloid leukemia (AML) and myeloproliferative disorders (MPD). Cytogenetic analysis of del(20q) revealed that the deletion is variable in size, with a commonly deleted region (CDR) spanning 20q11.2 to q12. Within the commonly deleted segment lies the SRC oncogene and possibly other tumor suppressor genes. The CDR is defined as a 2.7 Mb segment in MPD and a 2.6 Mb segment in AML/MDS, with an overlapping region of 1.7 Mb. In a study of 36 MPD, MDS, and AML patients with del(20q), statistical analyses showed that patients with del(20q) as a sole cytogenetic aberration (favorable subgroup) live longer than patients with del(20q) and other chromosomal changes (poor prognosis subgroup). Among patients from MDS, MPD and MDS/MPD groups, Douet-Guilbert et al identified one commonly deleted region in all 38 investigated samples using FISH, including the Vysis LSI D20S108 FISH Probe.

The Vysis LSI D20S108 Probe is an approximately 201 kb SpectrumOrange labeled probe and contains the D20S108 locus located on chromosome 20q12.

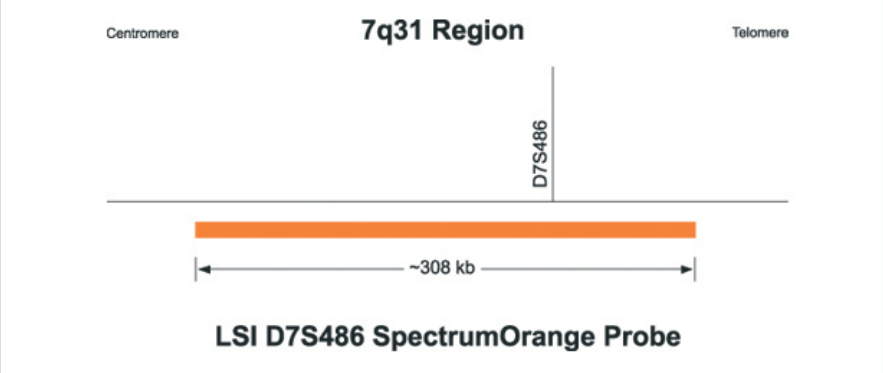
## RESULTS OF HYBRIDIZATION

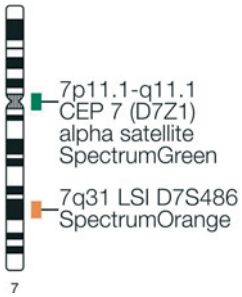
In a normal cell hybridized with the LSI D20S108 probe, the expected pattern is the two orange (2O) signal pattern. In an abnormal cell containing the deletion, the one orange (1O) signal pattern will be observed.

**Normal hybridization:** LSI D20S108 Single Color Probe hybridized to normal cells showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D20S108 FISH Probe Kit **(CE)** | 20 µL | 05N02-020 | 00884999014329 |

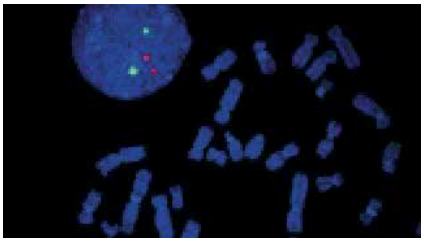
# Vysis D7S486/ Vysis CEP 7 FISH Probe Kit




## PRODUCT DESCRIPTION

The Vysis D7S486/ CEP 7 FISH Probe Kit is a device intended for specimen characterization and detects the LSI D7S486 probe target on chromosome 7q31 and the CEP 7 probe target on chromosome 7p11.1-q11.1 in bone marrow and peripheral blood specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted by a qualified pathologist or cytogeneticist. This device is not intended for high-risk uses such as selecting therapy, predicting therapeutic response or disease screening. The use of this device for diagnosis, prognosis, monitoring, or risk assessment has not been established.

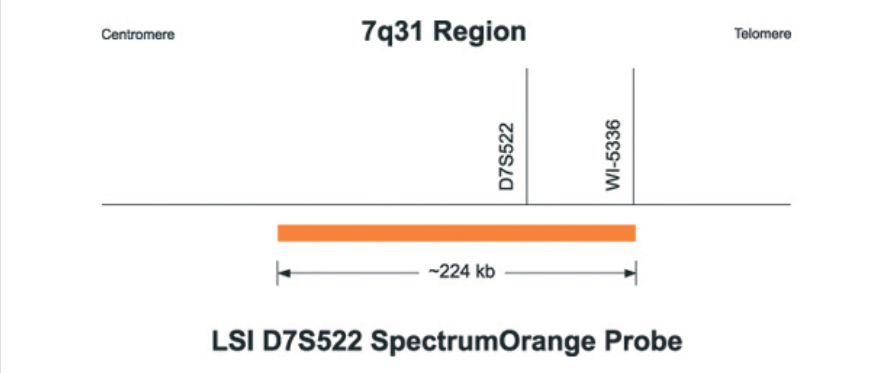


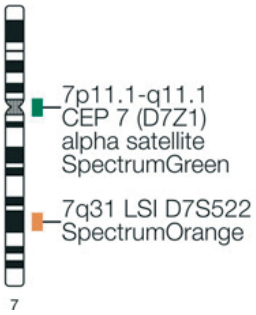
**Normal hybridization:** LSI D7S486/CEP 7 Dual Color Probe hybridized to a nucleus showing the two orange, two green (2O2G) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D7S486/ Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N07-020 | 00884999014367 |
| Vysis D7S486/ Vysis CEP 7 FISH Probes **(ASR)** | 20 µL | 05J61-001 | 00884999012196 |

ACUTE MYELOGENOUS LEUKEMIA

# Vysis D7S522/CEP 7 FISH Probe Kit




## PRODUCT DESCRIPTION

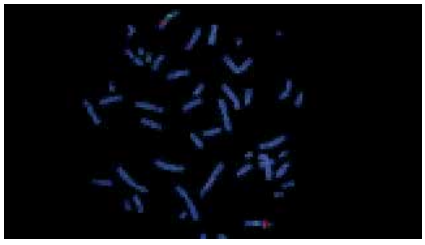
The Vysis D7S522/CEP7 FISH Probe Kit is intended to detect the copy number of the LSI D7S522 and CEP 7 probe targets located at chromosome 7q31 and 7p11.1-q11.1, respectively.

Monosomy 7 and loss of chromosome 7q are observed in a variety of myeloid malignancies such as myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML). In some instances, these abnormalities are associated with patient outcome. The Vysis LSI D7S522 SpectrumOrange/CEP 7 SpectrumGreen Probes have been used to detect copy number abnormalities of the LSI D7522 and CEP7 probe targets in both AML and MDS.

The Vysis LSI D7S522 SpectrumOrange/CEP 7 SpectrumGreen Probes are a mixture of a SpectrumOrange D7S522 probe (7q31) and a SpectrumGreen CEP 7 probe (7p11.1-q11.1). The LSI D7S522 probe target is approximately 224 Kb in length. The CEP 7 probe targets the D7Z1 alpha satellite sequence at the centromere of chromosome 7.

## RESULTS OF HYBRIDIZATION

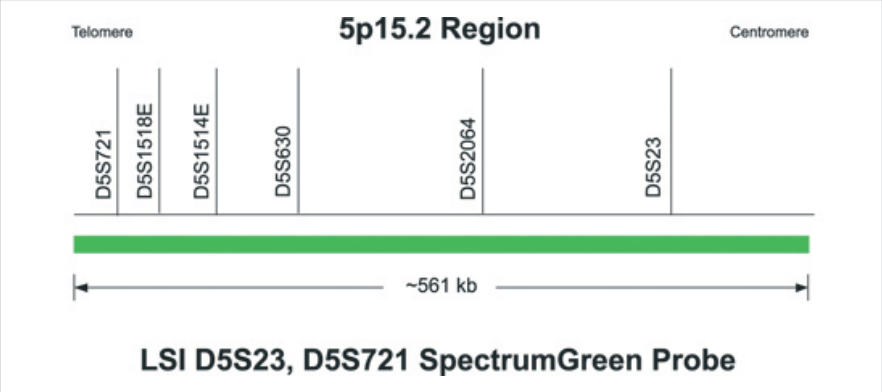
In a normal cell hybridized with the LSI D7S522/CEP 7 Probe, the expected pattern is the two orange, two green signal pattern. In an abnormal cell containing the deletion, the one orange, two green signal pattern will be observed.

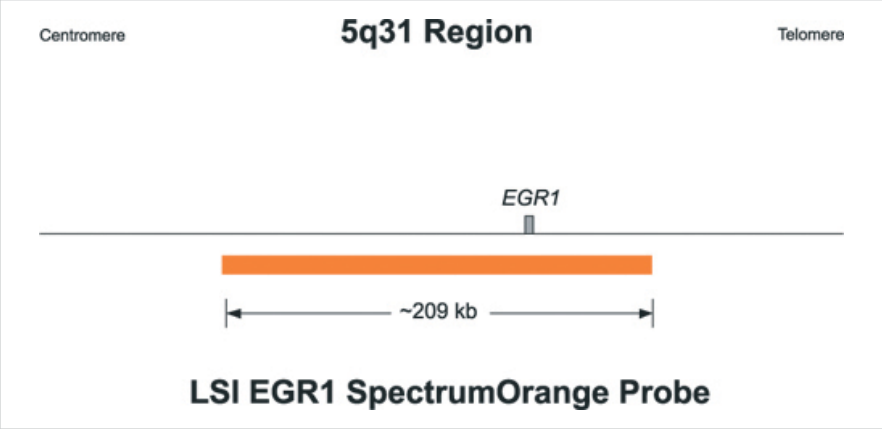


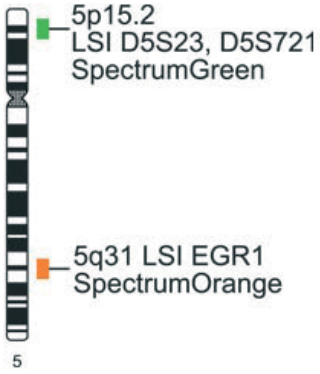
**Normal hybridization:** LSI D7S522/CEP 7 Dual Color Probe hybridized to a normal metaphase cell showing the two orange, two green signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D7S522/Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N08-020 | 00884999014374 |
| Vysis LSI D7S522 SpectrumOrange / CEP 7 SpectrumGreen Probes **(ASR)** | 20 µL | 05J85-001 | 00884999012752 |

# Vysis EGR1 FISH Probe Kit - SC (Specimen Characterization)

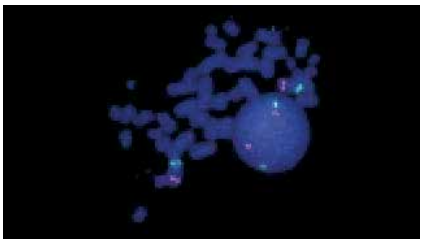



## PRODUCT DESCRIPTION

The Vysis EGR1 FISH Probe Kit – SC (Specimen Characterization) detects the LSI EGR1 probe target on chromosome 5q in bone marrow specimens. The Vysis EGR1 FISH Probe Kit – SC assay results characterize bone marrow specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted by a qualified pathologist or cytogeneticist. This device is not intended for high-risk uses such as selecting therapy, predicting therapeutic response or disease screening. The use of this product for diagnosis, monitoring or risk assessment has not been established.



**Normal hybridization:** Vysis LSI EGR1 SpectrumOrange/D5S23, D5S721 SpectrumGreen Probes hybridized to cells showing the two orange, two green (2R2G) signal pattern.

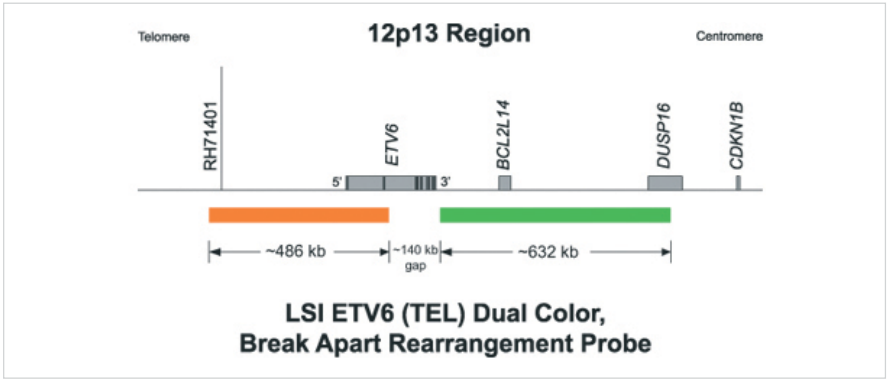
Abnormalities of chromosome 5 are common aberrations in myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML). A commonly deleted segment on chromosome band 5q31 has been identified and the early growth response (EGR1) gene is among the candidate genes in this segment. A study suggests that haploinsufficiency of EGR1 may play a role in leukemogenesis. The Vysis locus-specific identifier (LSI) EGR1 SpectrumOrange/ D5S23, D5S721 SpectrumGreen Probes, components of the Vysis EGR1 FISH Probe Kit – SC, have been used in several studies to detect EGR1 deletions. A study comparing the Vysis LSI EGR1 SpectrumOrange/ D5S23, D5S721 SpectrumGreen Probes to metaphase cytogenetics to detect loss of 5q, in both MDS and AML, concluded while cytogenetics detected most instances of del (5q), fluorescence in situ hybridization (FISH) was especially useful in cases with suboptimal growth, and EGR1 FISH detects del(5q) in a broad variety of myeloid neoplasms. A study investigating whether monosomy 5, identified by G-banded karyotyping, truly existed in 28 cases of MDS or AML, found del(5q) in 24 cases and monosomy 5 in only 3 cases. This study concluded EGR1 FISH, using the Vysis LSI EGR1 SpectrumOrange/D5S23, D5S721 SpectrumGreen Probes, can complement conventional cytogenetics and improve the karyotype definition. A study, conducted as part of an Eastern Cooperative Oncology Group (ECOG) clinical trial, showed that FISH detection of specific aberrations using several Vysis FISH probe sets including the Vysis LSI EGR1 SpectrumOrange/D5S23, D5S721 SpectrumGreen Probes, was highly correlated to cytogenetic discovery of these same aberrations in AML patients. The Vysis EGR1 FISH Probe Kit – SC uses FISH DNA probe technology to detect the probe target for LSI EGR1, and the LSI D5S23, D5S721 probe serves as a control.

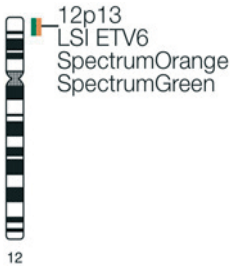
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis EGR1 FISH Probe Kit - SC (Specimen Characterization) **(CE)** | 20 µL | 04N37-001 | 00884999038165 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

ACUTE MYELOGENOUS LEUKEMIA

# Vysis ETV6 Break Apart FISH Probe Kit




## PRODUCT DESCRIPTION

The LSI ETV6 fluorescence in situ hybridization (FISH) probe set is intended to detect rearrangements of the ETV6 gene locus in the chromosome 12p13 region.

Rearrangements of the short arm of chromosome 12 are frequently recurring abnormalities found in a variety of hematologic malignancies of both myelocytic and lymphoid origin. They include balanced and unbalanced translocations which prevalently involve band 12p13. The ETV6 (TEL) gene is the most common target found to be rearranged with more than 40 chromosome bands. ETV6-RUNX1 (AML1) gene fusion resulting from a t(12;21) has been characterized as the most common genetic lesion in pediatric acute lymphoblastic leukemia (ALL) and is associated with a favorable outcome.

The Vysis LSI ETV6 Dual Color Break Apart Rearrangement Probe has successfully been used in disease and therapy monitoring of different poor prognosis AML cases.

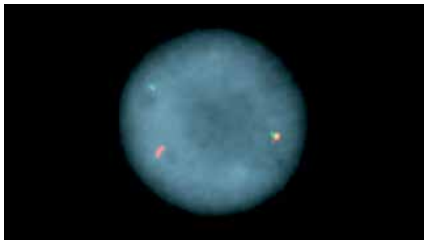
The Vysis LSI ETV6 (TEL) (12p13) Dual Color Break Apart Rearrangement Probe is a mixture of two probes. The 632 kb SpectrumGreen probe begins about 6 kb proximal to the ETV6 (TEL) gene and extends to toward the centromere. The SpectrumOrange probe begins within ETV6 intron 2 and extends toward the 12p telomere for approximately 490 kb. There is a gap between the two probes of about 140 kb.

## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals.

The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 12 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

**Normal hybridization:** Normal cell hybridization using the LSI ETV6 (TEL) (12p13) Dual Color, Break Apart Rearrangement Probe.

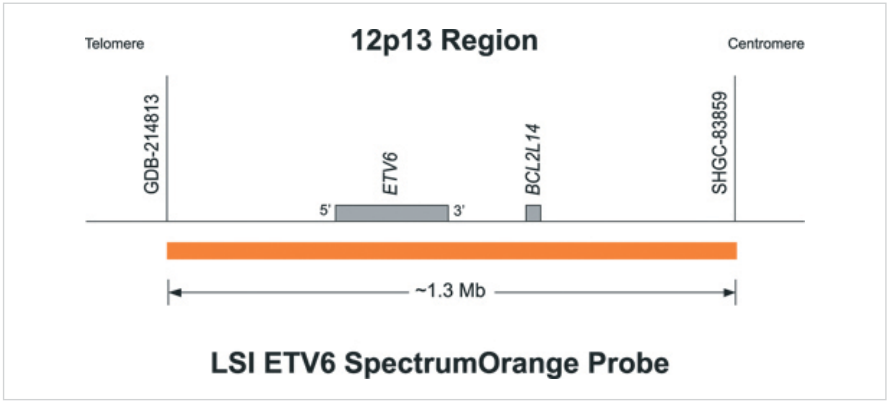


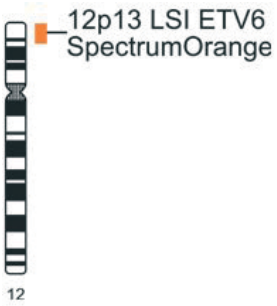
**Abnormal hybridization:** Abnormal cell hybridization using the LSI ETV6 (TEL) (12p13) Dual Color, Break Apart Rearrangement Probe.

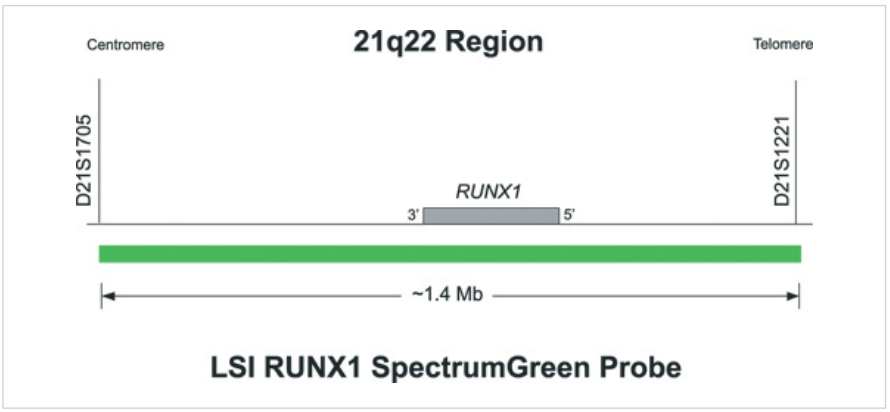
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ETV6 Break Apart FISH Probe Kit **(CE)** | 20 µL | 04N09-020 | 00884999007932 |

ACUTE LYMPHOCYTIC LEUKEMIA

# Vysis ETV6/RUNX1 DF FISH Probe Kit





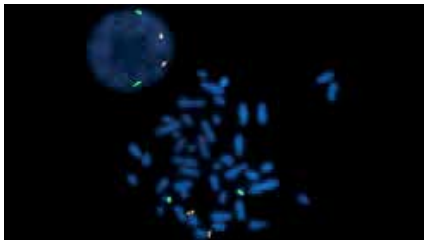
## PRODUCT DESCRIPTION

The Vysis ETV6/RUNX1 DF FISH Probe Kit is intended to detect the t(12;21)(p13;q22) translocation between the ETV6 gene and the RUNX1 gene using the fluorescence in situ hybridization (FISH) technique.

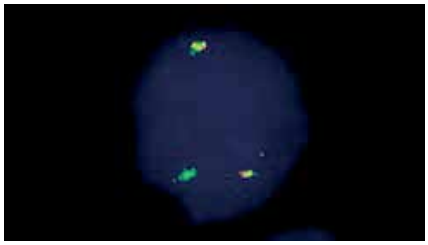
The t(12;21)(p13;q22) chromosomal translocation is the most common chromosomal rearrangement in childhood acute lymphocytic leukemia (ALL). Although not detectable by classical cytogenetics, the t(12;21) resulting in the fusion of the 5' section of the ETV6 (TEL) gene on chromosome 12p13 to almost the entire RUNX1 (AML1) gene located on chromosome 21q22 occurs in about 25% of childhood ALL. The Vysis ETV6/RUNX1 DF FISH Probe Kit uses a dual-color, dual-fusion probe design to detect the t(12;21) by fluorescence in situ hybridization.

## HYBRIDIZATION RESULTS

Two lymphocyte cells, one in interphase (upper left) next to chromosomes from a metaphase cell (lower right), that have been hybridized with the LSI ETV6/RUNX1 Dual Color Dual Fusion Probe. Both cells show the two orange (RUNX1), two green (ETV6) signal pattern.

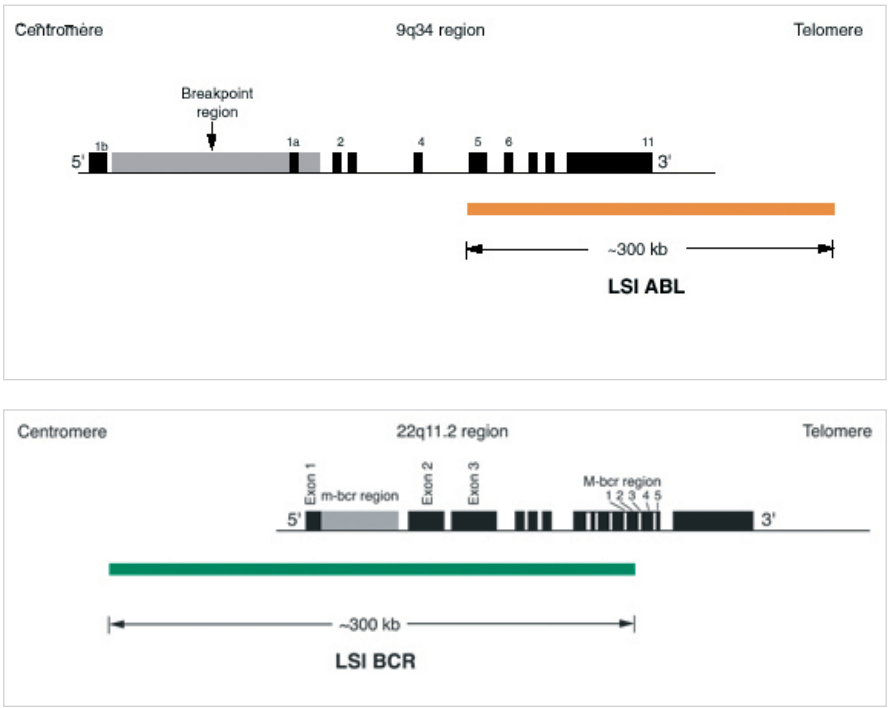


A bone marrow cell in interphase hybridized with the LSI ETV6/RUNX1 Dual Color Dual Fusion Probe. The cell in this image shows the one orange (RUNX1), one green (ETV6), two fusion (der (12) and der (21)) signal pattern.



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ETV6/RUNX1 DF FISH Probe Kit **(CE)** | 10 µL | 05N96-010 | 00884999015487 |

# Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit



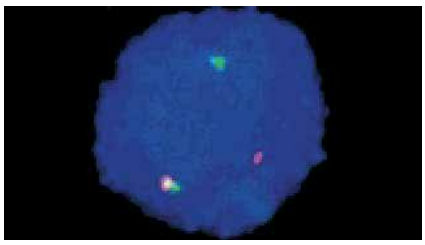


## PRODUCT DESCRIPTION

The LSI BCR/ABL Dual Color, Single Fusion Translocation Probe is a mixture of the LSI ABL probe labeled with SpectrumOrange and the LSI BCR probe labeled with SpectrumGreen. The ABL probe begins between exons 4 and 5 and continues for about 300 kb toward the telomere of chromosome 9. The LSI BCR probe begins between BCR exons 13 and 14 (M-bcr exons 2 and 3) and extends toward the centromere on chromosome 22 for approximately 300 kb, extending well beyond the m-bcr region.

## RESULTS OF HYBRIDIZATION

A nucleus lacking the t(9;22) will exhibit the two orange, two green (2O2G) signal pattern. In a cell harboring the t(9;22), one orange, one green, and one orange/green (yellow) fusion signal pattern (1O1G1F) will be observed. This simple probe design detects the 5' BCR/3' ABL gene fusion and is useful for detecting samples with a high percentage of cells possessing this translocation.

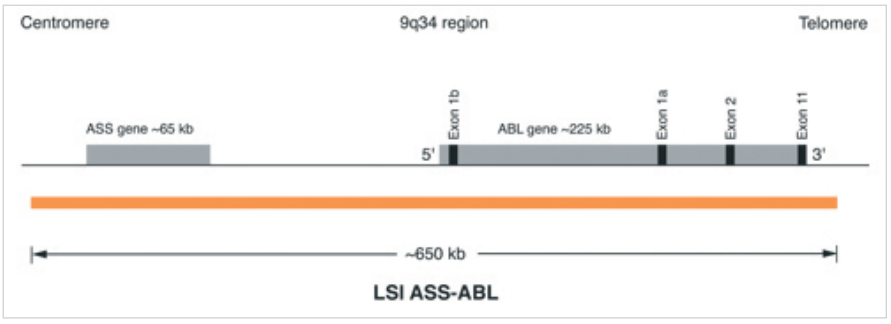


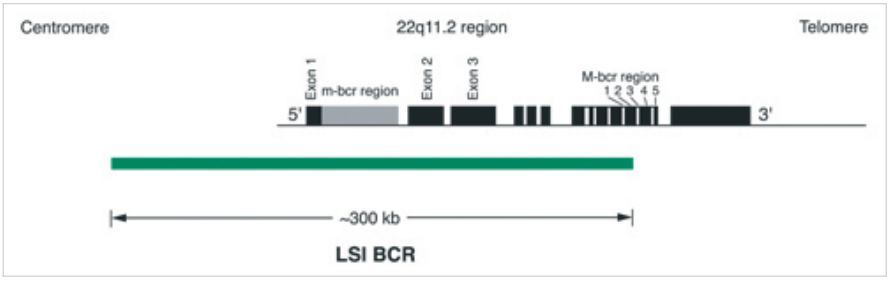
LSI BCR/ABL Dual Color, Single Fusion Translocation Probe hybridized to a nucleus containing the t(9;22). One orange, one green and one fusion (IOIGIF) signal pattern is observed.

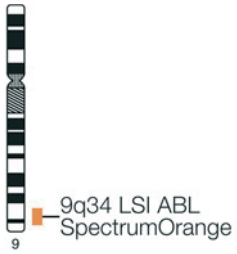
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L56-050 | 00884999031463 |

ACUTE MYELOGENOUS LEUKEMIA

# Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit



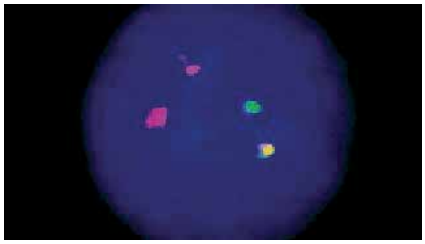


## PRODUCT DESCRIPTION

The BCR/ABL ES Dual Color Translocation Probe is a mixture of the LSI ABL probe labeled with SpectrumOrange and the LSI BCR probe labeled with SpectrumGreen. The spanning ABL probe is approximately 650 kb extending from an area centromeric of the ASS gene to well telomeric of the last ABL exon. The SpectrumGreen BCR probe is approximately 300 kb beginning between BCR exons 13 and 14 (M-bcr exons 2 and 3) and extending well beyond the m-bcr region.

## RESULTS OF HYBRIDIZATION

A nucleus lacking the t(9;22) will exhibit a two orange, two green(2O2G) signal pattern. In a nucleus possessing the t(9;22) involvingthe M-bcr, one green (native BCR), one large orange (native ABL), onesmaller orange (ES), and one fused orange/green signal (5' BCR/3' ABL),(2O1G1F) will be observed. Minor breakpoint (m-bcr) signal patterns mayappear as one orange, one green, and two fusion signals. In some cellsa deletion may occur 5' of the ABL breakpoint that may reduce the ESpattern to a single fusion pattern.



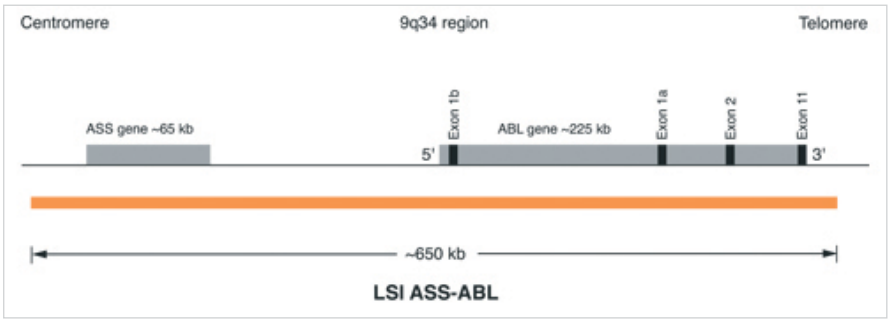
**Abnormal hybridization:** LSI BCR/ ABL ES Dual Color Translocation Probe hybridized to a nucleuscontaining the t(9;22) showing one green (native BCR), one large orange(native ABL), one smaller orange (ES) and one fused orange/ green(20IGIF) signal pattern.

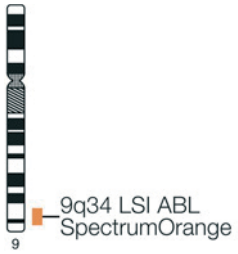
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L55-020 | 00884999031456 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe **(ASR)** | 20 µL | 05J78-001 | 00884999012479 |

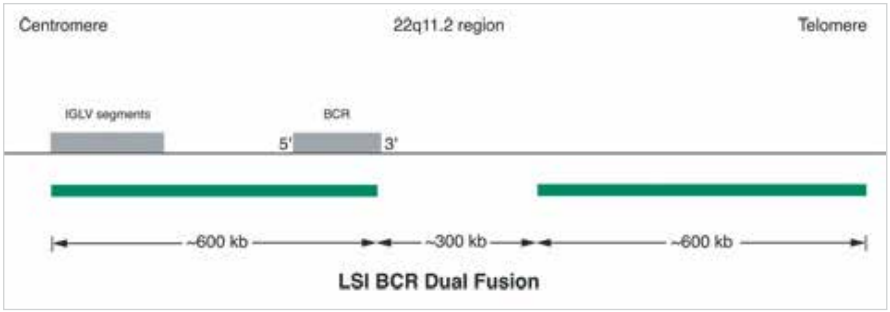
 Please note some products may not be for sale in all markets. Contact your local representative for availability.

ACUTE MYELOGENOUS LEUKEMIA

# Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit



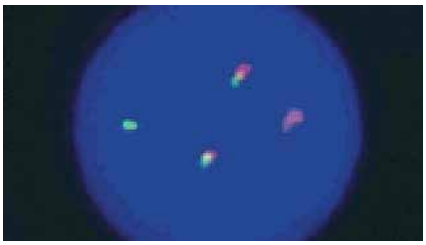


## PRODUCT DESCRIPTION

The LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe is a mixture of the LSI BCR probe labeled with SpectrumGreen and the LSI ABL probe labeled with SpectrumOrange. The spanning ABL probe has a genomic target of approximately 650 kb extending from an area centromeric of the argininosuccinate synthetase gene (ASS) to well telomeric of the last ABL exon. The BCR probe target spans a genomic distance of about 1.5 Mb. The BCR probe begins within the variable segments of the immunoglobulin lambda light chain locus (IGLV), extends along chromosome 22 through the BCR gene, and ends at a point approximately 900 kb telomeric of BCR. A region of about 300 kb containing low-copy number repeats has been eliminated from the probe which introduces a gap in the coverage of the probe target. Both probes span their respective breakpoints.

## RESULTS OF HYBRIDIZATION

A nucleus lacking the t(9;22) translocation will exhibit the two orange, two green (2O2G) signal pattern. In a nucleus containing a simple balanced t(9;22), one orange and one green signal from the normal 9 and 22 chromosomes and two orange/green (yellow) fusion signals, one each from the derivative 9 and 22 chromosomes, will be observed (1O1G2F). In some instances, deletions may occur 3' of the BCR breakpoint and/or 5' of the ABL breakpoint resulting in either an ES (extra orange or green) signal pattern or a single fusion pattern.

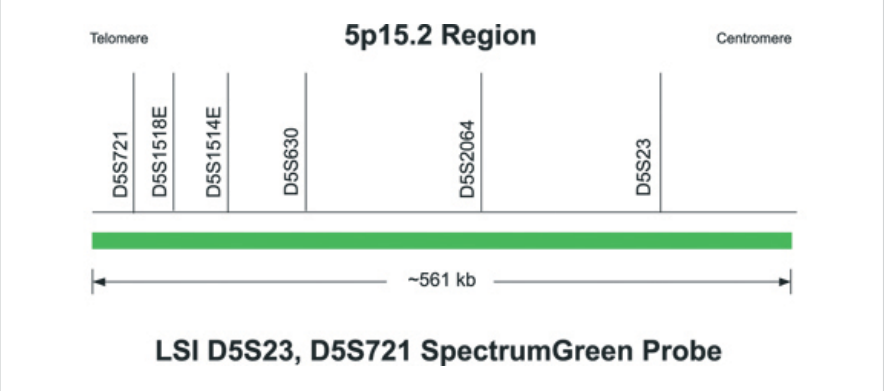


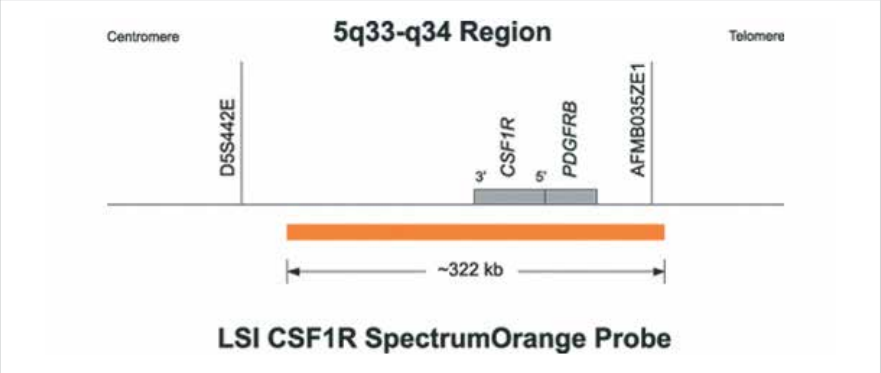
**Abnormal hybridization:** LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe hybridized to a nucleus containing a simple balanced t(9;22). One orange, one green and two orange/green fusion signals are observed (1O1G2F).

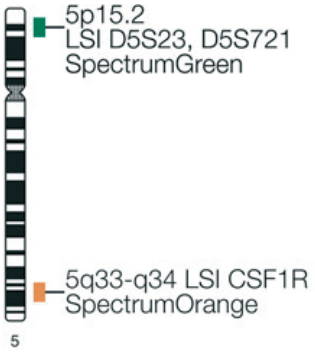
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L10-001 | 00884999031166 |
| | 50 µL | 08L10-002 | 00884999031173 |

ACUTE MYELOGENOUS LEUKEMIA

# Vysis CSF1R/D5S23, D5S721 FISH Probe Kit




## PRODUCT DESCRIPTION

The LSI CSF1R and LSI D5S23, D5S721 fluorescence in situ hybridization (FISH) probes are intended to detect loss of the LSI CSF1R probe target in the chromosome 5q33-q34 region.

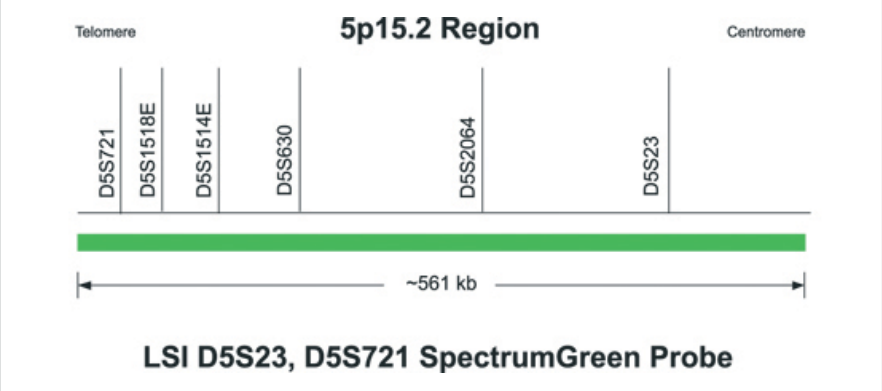
Commonly deleted regions (CDRs) have been defined on chromosome 5q for myeloid malignancies by FISH and other techniques. A 1.5 Mb CDR containing the CSF1R gene has been established for the 5q- syndrome, a specific type of myelodysplastic syndrome. The loss of the hybridization signal from one copy of the LSI CSF1R probe target may be used to establish a deletion within the 5q- syndrome CDR. The Vysis LSI CSF1R/D5S23, D5S721 Dual Color Probe has been used in several studies to determine deletion of the LSI CSF1R probe target.

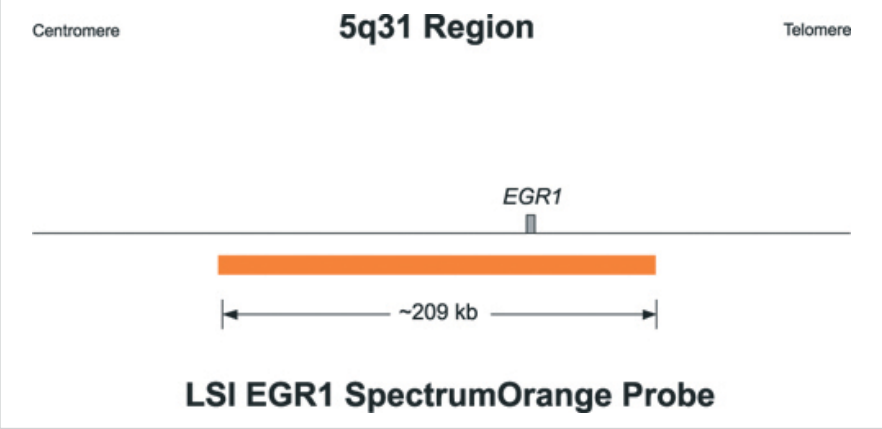
The Vysis LSI CSF1R/D5S23, D5S721 Dual Color probe is a mixture of the approximately 322 kb SpectrumOrange labeled CSF1R probe and the approximately 561 kb SpectrumGreen labeled D5S23, D5S721 probe.

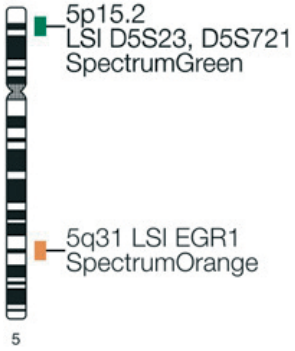
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CSF1R/D5S23, D5S721 Probes **(ASR)** | 20 µL | 05J60-001 | 00884999012189 |
| Vysis CSF1R/D5S23, D5S721 FISH Probe Kit **(CE)** | 20 µL | 05N03-020 | 00884999014336 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit



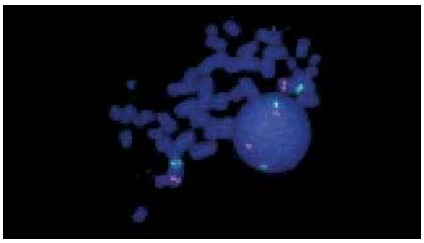




## PRODUCT DESCRIPTION

The LSI EGR1/D5S23, D5S721 Dual Color Probe may be used to detect deletions of 5q31 containing the EGR1 locus. The LSI D5S23, D5S721 probe aids in determining if the deletion is of the whole chromosome 5 (-5) versus 5q-.The LSI EGR1/D5S23, D5S721 Probe is a mixture of the approximately 200 kb SpectrumOrange labeled LSI EGR1 probe and the approximately 450 kb SpectrumGreen labeled LSI D5S23, D5S721 probe.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the LSI EGR1/D5S23, D5S721 probe is the two orange, two green (2O2G) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange, two green (1O2G) signal pattern will be observed.

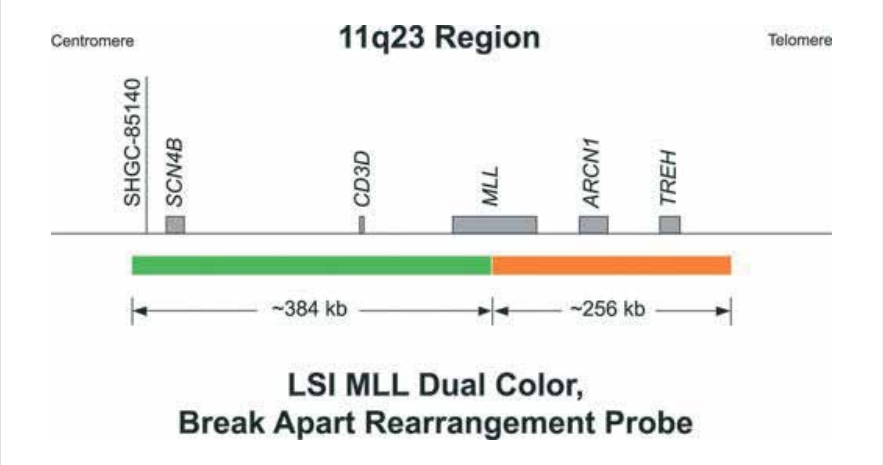


**Normal hybridization:** LSI EGR1/D5S721, D5S23 Dual Color Probe hybridized to normal cells showing the two orange, two green (2O2G) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit **(CE)** | 20 µL | 08L68-020 | 00884999031586 |

ACUTE MYELOGENOUS LEUKEMIA

# Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe Kit





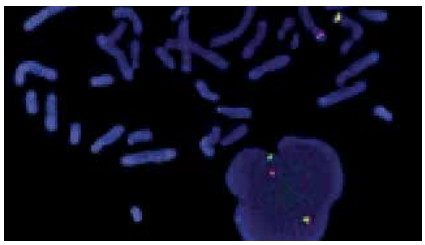
## PRODUCT DESCRIPTION

The LSI MLL Dual Color, Break Apart Rearrangement Probe is designed to detect the 11q23 rearrangement associated with various translocations involving the MLL gene. Translocations disrupting the MLL (ALL-1,HRX) gene are among the most common cytogenetic abnormalities observed in hematopoietic malignancies. Although over 30 variant translocations have been seen involving MLL translocations, the most common abnormalities are t(4;11)(q21;q23), t(9;11)(p22;q23), and t(11;19)(q23;p13).

The LSI MLL Dual Color, Break Apart Rearrangement Probe consists of a 350 kb portion centromeric of the MLL gene breakpoint cluster region (bcr) labeled in SpectrumGreen and approximately 190 kb portion largely telomeric of the bcr labeled in SpectrumOrange. In approximately 25% of 11q23 translocations, a region beginning at the MLL breakpoint and extending distally is deleted. This probe can provide a better indication of the presence of the 11q23 translocation than a single color probe design.

## RESULTS OF HYBRIDIZATION

The signal pattern observed in a cell lacking the MLL rearrangement is expected to show a two orange/green (yellow) fusion signal pattern (2F). In a cell possessing a MLL translocation, the expected pattern is one green/orange (yellow) fusion signal, one orange signal, and one green (1O1G1F) signal. With the MLL Dual Color, Break Apart Rearrangement Probe, a large deletion occurring distally from the MLL breakpoint might weaken or totally eliminate one of the two orange signals, potentially producing a FISH pattern characteristic of concomitant translocation and deletion, i.e., one orange/green fusion and one isolated green signal.



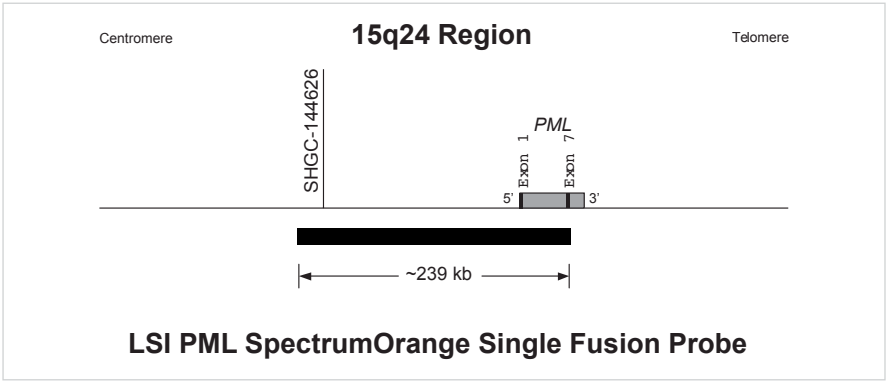
**Abnormal hybridization:** LSI MLL Dual Color, Break Apart Rearrangement Probe hybridized to cells possessing a t(9:11)(p22;q23) and exhibiting the expected one orange, one green and one orange/green fusion signal pattern (1O1G1F).

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L57-020 | 00884999031470 |

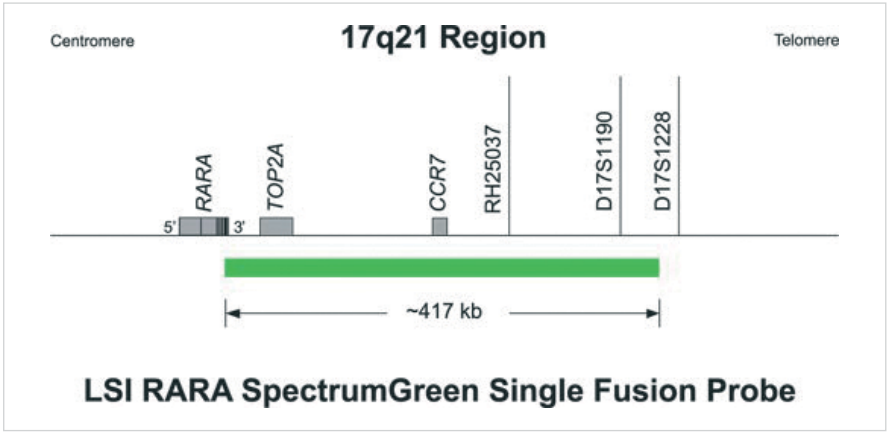
 Please note some products may not be for sale in all markets. Contact your local representative for availability.

ACUTE MYELOGENOUS LEUKEMIA

# Vysis PML/RARA Single Fusion FISH Probe Kit









## PRODUCT DESCRIPTION

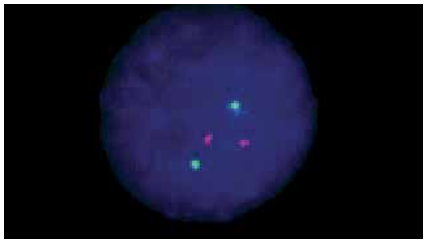
The Vysis PML/RARA SF FISH Probes are intended to detect the t(15;17)(q22;q21.1) reciprocal translocation involving the PML and RARA gene regions.

The vast majority of cases of acute promyelocytic leukemia (APL) have a t(15;17)(q22;q21.1) translocation which fuses the promyelocytic leukemia gene (PML) on chromosome 15q22-q24 to the retinoic acid receptor alpha gene. The PML/RARA fusion is associated with a good response to all-trans retinoic acid therapy.

The Vysis PML/RARA Dual Color Translocation Probe Kit was used in a study of 260 acute myeloid leukemia patients and detected 11 positive samples. In the same study, conventional banding analysis resulted in only 7 positive results due to cytogenetic failure and one case of a cryptic translocation.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the LSI PML/RARA probe is a two orange and two green (2O2G) signal pattern. In an abnormal cell containing a PML/RARA fusion, the one green (RARA), one orange (PML), and closely adjacent or fused green/orange (yellow) signal pattern (1O1G1F) is observed.



**Normal hybridization:** LSI PML/RARA Dual Color Translocation Probe hybridized to a normal nucleus, showing a two orange, two green (2O2G) signal pattern.

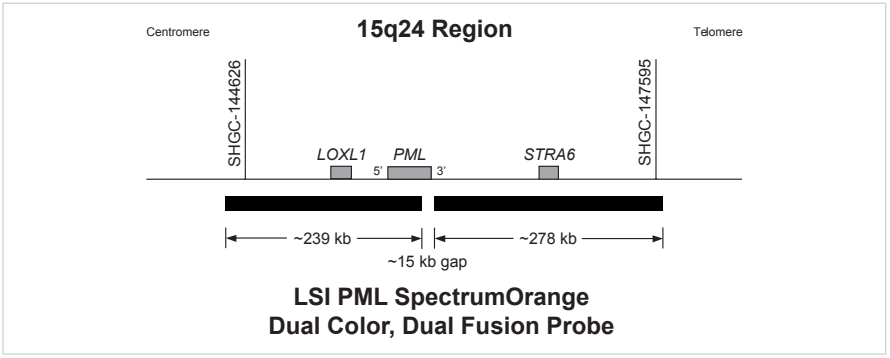
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis PML/RARA Single Fusion FISH Probe Kit **(CE)** | 20 µL | 05N45-020 | 00884999014947 |
| Vysis PML/RARA Single Fusion FISH Probe **(ASR)** | 20 µL | 05J66-001 | 00884999012257 |



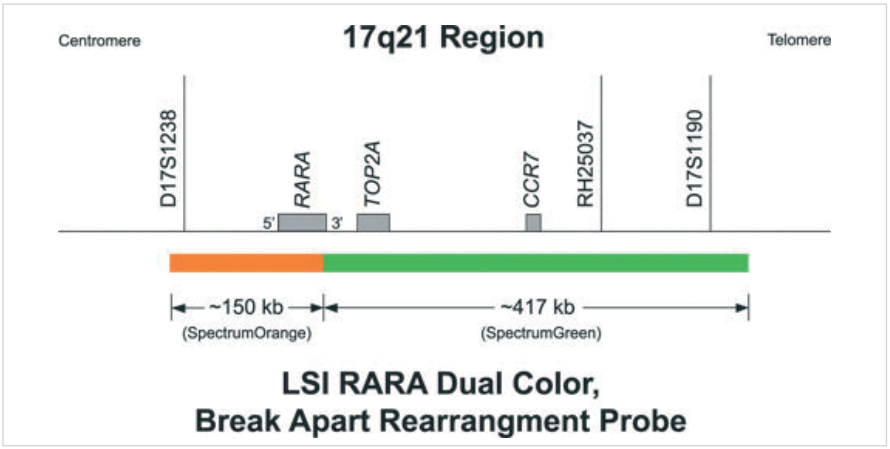
Please note some products may not be for sale in all markets. Contact your local representative for availability.

ACUTE MYELOGENOUS LEUKEMIA

# Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe Kit









## PRODUCT DESCRIPTION

The reciprocal and balanced t(15;17), involving the PML (promyelocytic leukemia) gene on chromosome 15q22 and the RARA (retinoic acid receptor alpha) gene on chromosome 17q12.1 is a characteristic molecular feature of certain types of leukemia. Two gene fusion products result from this translocation, each of which encodes a functional chimeric protein: PML/RARA and RARA/PML.

The breakpoints in the 15q22 region of chromosome 15 occur within a 13 kb region of the PML gene that contains three breakpoint cluster regions (bcr): bcr 3 extends from intron 3 through the 5' end of intron 4, bcr 2 extends from exon 5 to exon 6, and bcr 1 extends from intron 6 into exon 7. Break frequency is highest in bcr 1, followed by bcr 3 and bcr 2. The breakpoints on chromosome 17 occur within the approximately 17 kb intron 2 of the RARA gene.

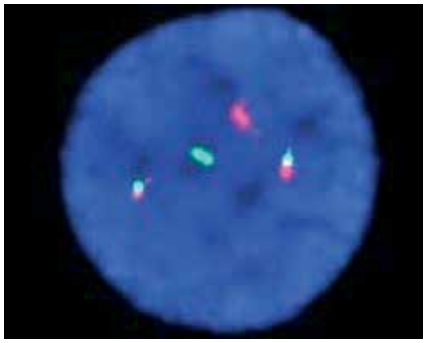
The LSI PML/RARA Dual Color, Dual Fusion Translocation Probe is a mixture of two FISH DNA Probes. The first, LSI PML, is an ~500 kb unique sequence probe that hybridizes to the 15q22 region containing the PML gene and is labeled in SpectrumOrange. The second, LSI RARA, is an ~700 kb unique sequence probe that hybridizes to the 17q21.1 region containing the RARA gene and is labeled in SpectrumGreen.

## RESULTS OF HYBRIDIZATION

In a normal cell that lacks the t(15;17), a two orange and two green signal pattern will be observed reflecting the two intact copies of RARA and PML, respectively.

This probe is provided for those interested in identifying the t(15;17). In an abnormal cell containing the t(15;17), one orange (PML), a one green (RARA), and two fusion (PML/RARA and RARA/PML) signal pattern is observed.

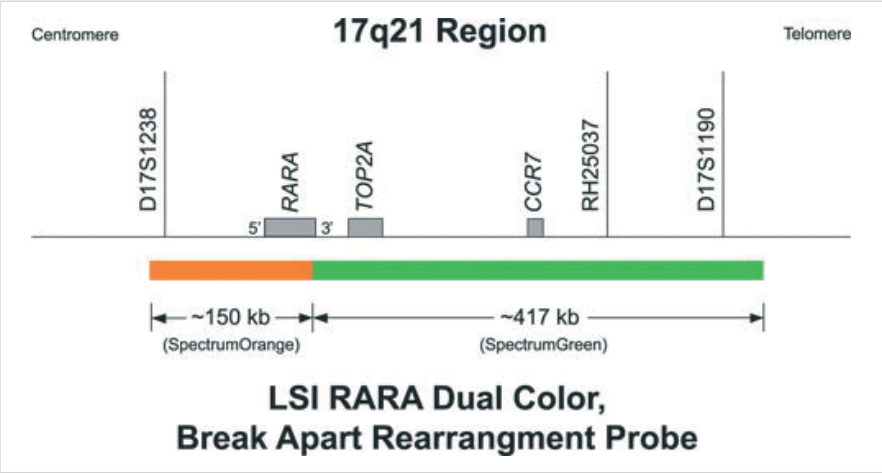
**Normal hybridization:** Result of the hybridization of the LSI PML/RARA Dual Color, Dual Fusion Translocation Probe as observed in a normal interphase cell.



**Abnormal hybridization:** Abnormal cell hybridized with the LSI PML/RARA Dual Color, Dual Fusion Translocation Probe. The cell in this image shows the one orange (PML), one green (RARA), two fusion (PML/RARA and RARA/PML) signal pattern indicative of the t(15;17).

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 01N36-020 | 00884999000780 |
| Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 05J70-001 | 00884999012325 |

# Vysis LSI RARA Dual Color Break Apart Rearrangement Probe





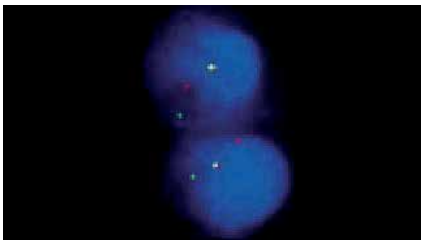
## PRODUCT DESCRIPTION

The Vysis RARA Break Apart FISH Probe is intended to detect chromosomal rearrangements involving the RARA gene region at chromosome 17q21 using the fluorescence in situ hybridization (FISH) technique.

Acute promyelocytic leukemia (APL) is associated with chromosomal rearrangements involving the retinoic acid receptor µ (RARA) gene on chromosome 17q21 and variable partner genes. In the vast majorityof APL cases, the RARA gene fuses with the promyelocytic leukemia gene (PML) located on chromosome 15q22 resulting in a t(15;17) translocation. RARA fusions with promyelocytic leukemia zinc finger (PLZF, 11q13), nucleophosmin (NPM, 5q35), nuclear mitotic apparatus (NuMA,11q23), signal transducer and activator of transcription 5b (STAT5B, 17q21), and PRKAR1A (protein kinase, cAMP-dependent, regulatory, type I, alpha, 17q23-q24) genes are also described. The Vysis RARA Break Apart FISH Probe Kit has been used in several studies to detect chromosome 17q21 rearrangements involving the RARA gene.

## RESULTS OF HYBRIDIZATION

The signal pattern observed in a cell that is lacking a RARA gene rearrangement consists of two orange/green (yellow) fusion signals (2F). The two fusion signals represent the normal (non-rearranged) RARA genes located on both 17 chromosomes. A signal pattern indicative of the RARA gene rearrangement is one orange, one green, and one green/orange (yellow) fusion signal. The separation of orange and green signals from one fusion (1O1G1F) indicates that the RARA gene has split apart. The remaining single fusion signal represents the normal (non-rearranged RARA) gene on the normal chromosome extends approximately 400 kb toward the telomere of chromosome 17.

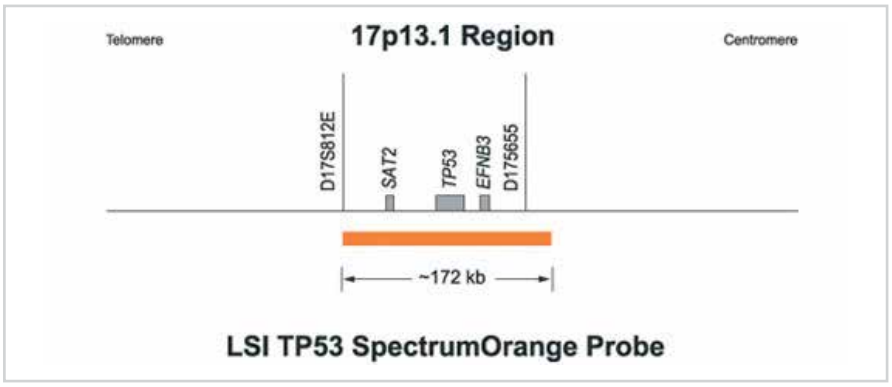


**Abnormal hybridization:** Vysis LSI RARA Dual Color, Break Apart Rearrangement Probe hybridized to nuclei containing one orange, one green and one fusion (1O1G1F) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI RARA Dual Color Break Apart Rearrangement Probe **(CE)** | 20 µL | 05N46-020 | 00884999014954 |

ACUTE MYELOGENOUS LEUKEMIA

# Vysis LSI TP53 SpectrumOrange/ Vysis CEP 17 SpectrumGreen Probe



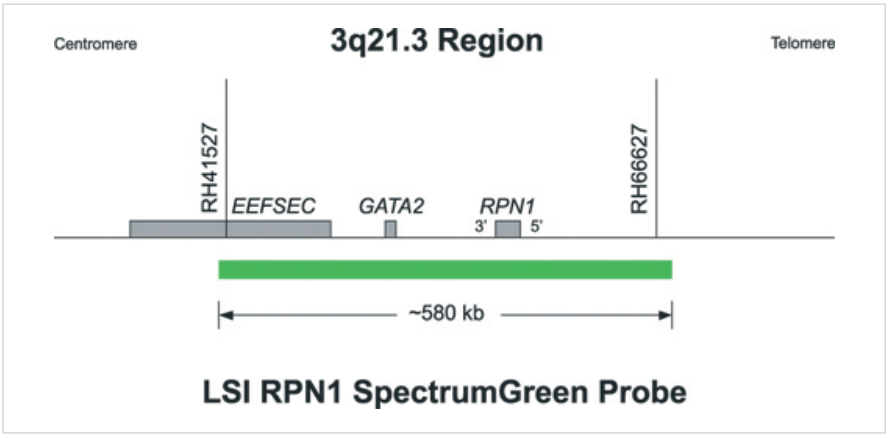


| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TP53 SpectrumOrange/Vysis CEP 17 SpectrumGreen Probe **(ASR)** | 20 µL | 01N17-020 | 00884999000520 |

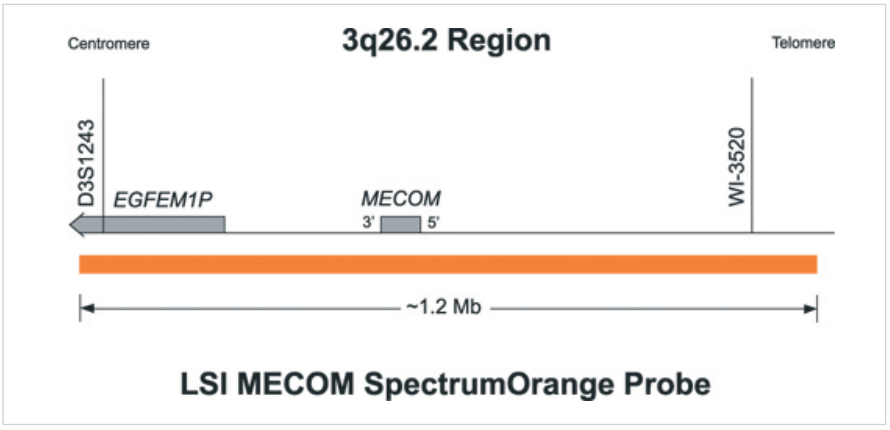
 Please note some products may not be for sale in all markets. Contact your local representative for availability.

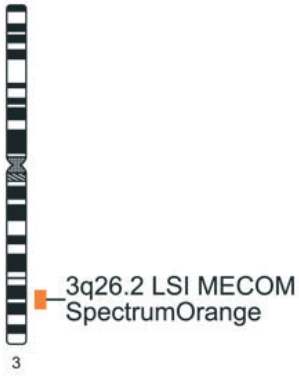
ACUTE MYELOGENOUS LEUKEMIA

# Vysis RPN1/MECOM DF FISH Probe Kit








## PRODUCT DESCRIPTION

The Vysis RPN1/MECOM DF FISH Probe Kit is intended to detect a fusion between the ribophorin I gene (RPN1) and the MDS1 and EVI1 complex locus gene (MECOM) using the fluorescence in situ hybridization (FISH) technique.

Acute myeloid leukemia (AML) with inv(3)(q21;q26.2) or t(3;3) (q21;q26.2) represents 1 to 2% of all AML. It has an aggressive disease course with short survival and poor response to chemotherapy. AML with inv(3)(q21;q26.2) or t(3;3) (q21;q26.2) is associated with an unfavorable prognosis. These abnormalities may also be found in a similar percentage of myelodysplastic syndromes (MDS). Due to the subtle appearance of this rearrangement, particularly inv(3), conventional cytogenetic chromosome analysis may miss these abnormalities.

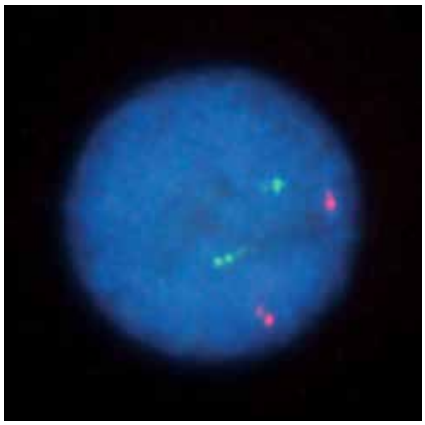
The Vysis RPN1/MECOM DF FISH Probe Kit identifies rearrangements between the RPN1 gene and the MECOM locus by detecting the fusion of the Locus Specific Identifier (LSI) RPN1 SpectrumGreen and LSI MECOM SpectrumOrange probe signals resulting from chromosomal rearrangement between the hybridization targets of the 2 probes.

## RESULTS OF HYBRIDIZATION

The most frequently expected signal pattern of the Vysis LSI RPN1/MECOM Dual Color Dual Fusion Probes in abnormal specimens is 1 orange, 1 green, and 2 orange/green fusion signals. Other signal patterns may occur in abnormal specimens, and metaphase analysis may be helpful in characterization of such patterns.

The most commonly expected signal pattern of the Vysis LSI RPN1/ MECOM Dual Color Dual Fusion Probes in normal specimens is 2 orange and 2 green signals. Due to the proximity of the 2 probes on the q arm of chromosome 3, however, the orange and green signals may sometimes appear as a fusion in a normal nucleus. This effect can produce a pattern of 1 orange, 1 green, and 1 orange/green fusion signal or, more rarely, 2 orange/green fusion signals.

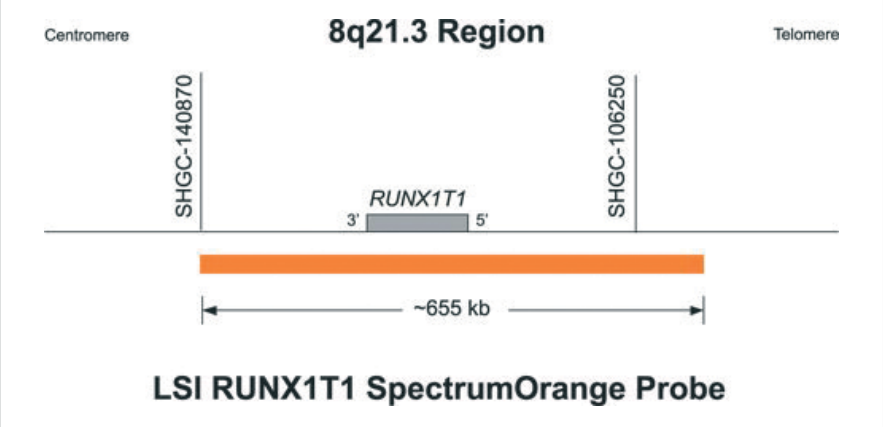
**Abnormal hybridization:** Vysis LSI RPN1/ MECOM Dual Color Dual Fusion Probes hybridized to a nucleus containing a simple balanced t(3;3)(q21.3;q26.2). One orange, one green and two orange/green fusion signals are observed.



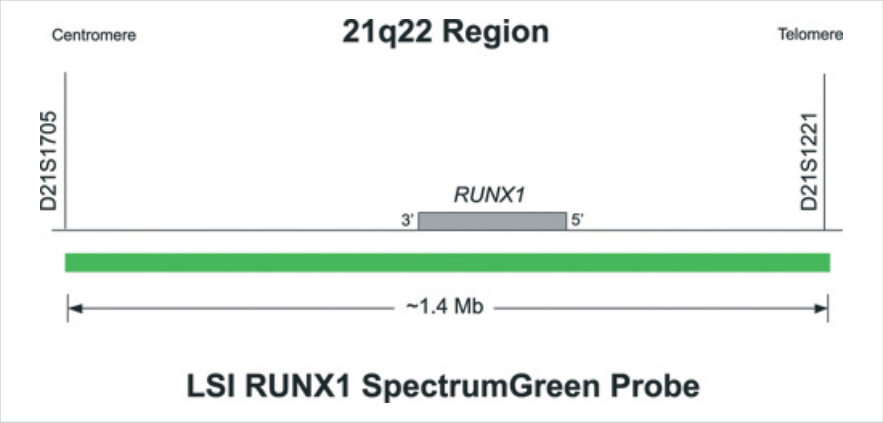
**Normal hybridization:** Vysis LSI RPN1/ MECOM Dual Color Dual Fusion Probes hybridized to a nucleus containing non-rearranged RPN1 and MECOM regions. Two orange and two green signals are observed.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis RPN1/MECOM DF FISH Probe Kit **(CE)** | 10 µL | 06N60-010 | 00884999034914 |

# Vysis RUNX1/RUNX1T1 DF FISH Probe Kit









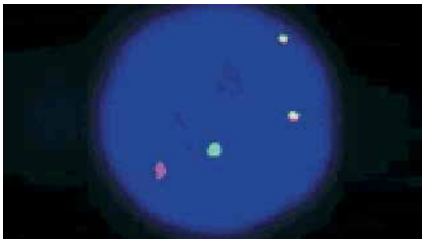
## PRODUCT DESCRIPTION

These fluorescence in situ hybridization (FISH) probes are intended to detect the t(8;21)(q21.3;q22) reciprocal translocation involving the RUNX1 and RUNX1T1 gene regions.

A translocation between chromosomes 8 and 21, t(8;21)(q21.3;q22), is seen in approximately 8% of adult patients and 12% of children with Acute Myeloid Leukemia (AML). Patients with t(8;21) alone have betterrisk status than patients with normal karyotype or with multiple molecular abnormalities. The Vysis LSI RUNX1/RUNX1T1 Dual Color Dual Fusion Probes have been used in several studies to detect t(8;21).

## RESULTS OF HYBRIDIZATION

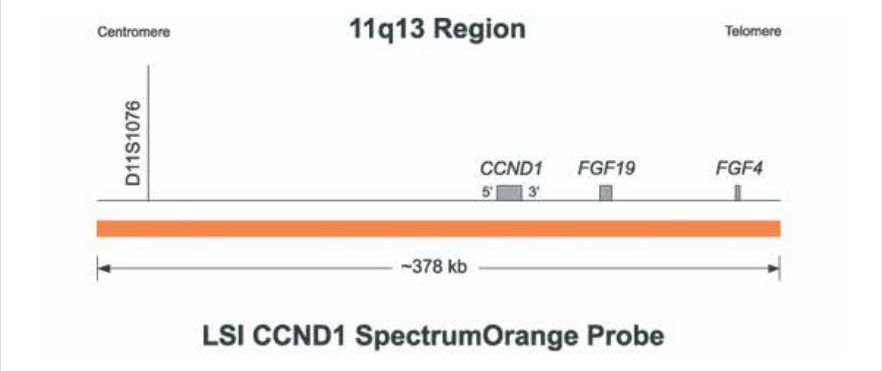
In a normal cell without the RUNX1/RUNX1T1 (also called AML1/ETO) fusion gene, two orange signals representing normal copies of RUNX1T1 and two green signals representing normal copies of RUNX1 are observed. In a cell containing the RUNX1/RUNX1T1 fusion gene, one orange (RUNX1T1), one green (RUNX1), and two orange/green (yellow) fusion signals are observed. The fusion signals represent the juxtaposition of the translocated portions of the two gene regions on the der(8) and the der(21). Variant RUNX1/RUNX1T1 signal patterns other than the most commonly observed one orange, one green, and two fusions (1O1G2F), may also occur.

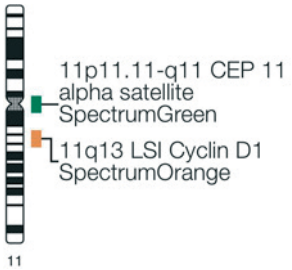


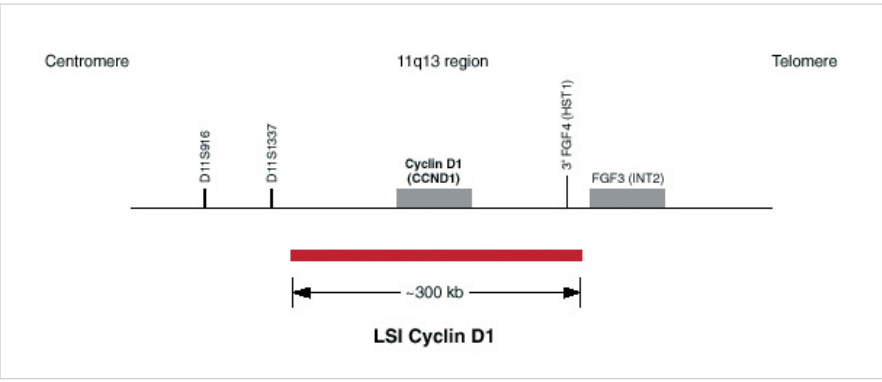
**Abnormal hybridization:** Vysis LSI RUNX1/RUNX1T1 Dual Color Dual Fusion Probes hybridized to an abnormal nucleus showing a one orange, one green and two fusion (1O1G2F) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis RUNX1/RUNX1T1 DF FISH Probe Kit **(CE)** | 20 µL | 08L70-020 | 00884999031609 |

# LSI Cyclin D1 (11q13) SpectrumOrange/ Vysis CEP 11 SpectrumGreen



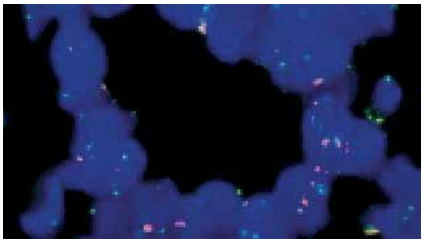




## PRODUCT DESCRIPTION

The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/ CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange signals. Other patterns may be observed if additional genetic alterations are present.

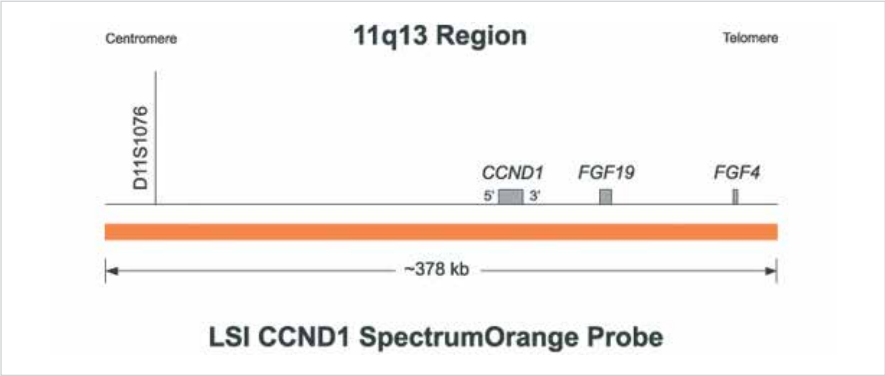


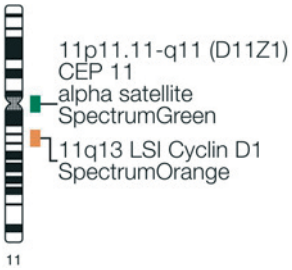
**Normal hybridization:** LSI Cyclin D1 SpectrumOrange and CEP 11 SpectrumGreen hybridization.

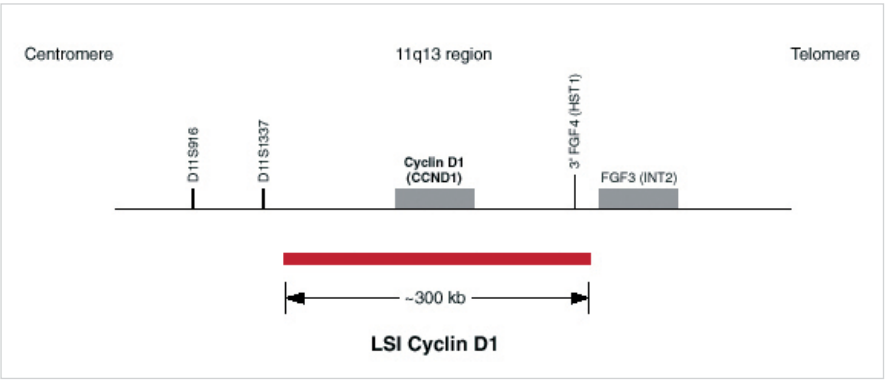
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| LSI Cyclin D1 (11q13) SpectrumOrange/ Vysis CEP 11 SpectrumGreen **(ASR)** | 20 µL | 05J41-001 | 00884999011755 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis CCND1 / CEP 11 FISH Probe Kit




## PRODUCT DESCRIPTION

Amplification of the chromosome 11q13 region, which harbors the Cyclin D1 (CCND1, PRAD1) oncogene, has been reported to occur in up to 15% of breast cancers. CCND1 amplification has been reported to be a prognostic marker.

Several studies used the Vysis CCND1/CEP 11 FISH Probe Kit to detect CCND1 amplification in breast cancer samples. Al-Karaya et al. analyzed a tissue microarray of 2197 breast cancer samples using the probe kit and found CCND1 amplification in 20.1% of cases. CCND1 amplification was associated with high tumor grade and a tendency toward shortened survival. Jirstrom et al. analyzed a tissue microarray of 500 breast cancer specimens from patients treated and not treated with adjuvant tamoxifen. The study found CCND1 amplification to be agonistic to tamoxifen with amplified patients having a significantly higher risk of recurrence.

The Vysis LSI CCND1 SpectrumOrange/CEP11 SpectrumGreen Probes have been applied to cancers other than breast cancer. For example, Katz et al. found elevated CCND1 copy number to be sensitive indicator of mantle cell lymphoma, and could distinguish mantle cell lymphoma from most other B-cell non Hodgkins lymphoma specimens.

The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/ CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange orange signals. Other patterns may be observed if additional genetic alterations are present.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 |

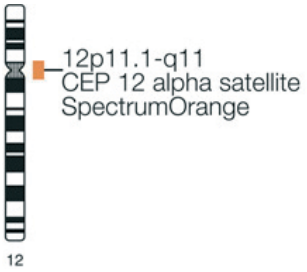
CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit

## PRODUCT DESCRIPTION

CEP 12 DNA Probe is a SpectrumOrange labeled probe specific for the alpha satellite (centromeric) region, 12p11.1-q11.

The CEP 12 DNA Probe Kit which is available for in vitro diagnostic use and may be used as an adjunct to standard karotyping to identify and enumerate chromosome 12 in nuclei of cells obtained from peripheral blood lymphocytes in patients with B-cell chronic lymphocytic leukemia (B-CLL). In multi-site clinical trials, the CEP 12 analysis of interphase nuclei was 100% sensitive and 91% specific as compared to traditional cytogenetic analysis when adequate metaphase preparations could be produced. Results are available within 3 hours or less. Trisomy 12 is the most commonly reported chromosome aberration in CLL. Chromosomal aberrations, determined by cytogenetic analysis are present in up to 55% of all B-CLL cases.




## MATERIALS PROVIDED

Materials provided with the CEP 12 DNA Probe Kit:

- CEP 12 DNA probe pre-denatured in hybridization buffer (220 µL)
- NP-40 (detergent for wash solution: 1000 µL)
- DAPI II counterstain (300 µL)
- 20X SSC (66 g)

Control slides for the CEP 12 kit are also sold separately. See Order No. 30-805000, Order No. 30-805002.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for CEP 12 is the two orange (2O) signal pattern. In an abnormal cell containing trisomy 12, the expected pattern will be the three orange (3O) signal pattern.

**Normal hybridization:** CEP 12 SpectrumOrange hybridized to a normal cell showing two orange signals indicating two copies of chromosome 12.

## INTENDED USE

The CEP 12 SpectrumOrange DNA Probe Kit is intended to detect AT rich alpha satellite sequences in the centromere region of chromosome 12 in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosome 12 via fluorescence in situ hybridization (FISH) in interphase nuclei of cells obtained from peripheral blood lymphocytes in patients with B-cell chronic lymphocytic leukemia (CLL). It is not intended to be used as a stand alone assay for test reporting; FISH results are intended to be reported and interpreted only in conjunction with results of standard cytogenetic analysis, performed concurrently, utilizing the same patient specimen. The CEP 12 assay has not been validated for purposes other than those described above. It is not intended for use with test matrices other than peripheral blood lymphocytes from subjects with CLL, to screen for chromosome 12 aneuploidy, e.g., in asymptomatic individuals, or to monitor patients for residual disease.

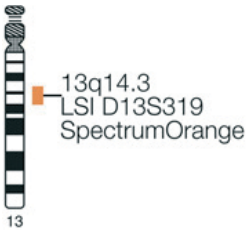
## LIMITATIONS

1. The CEP 12 DNA Probe Kit has been optimized only for identifying chromosome 12 in interphase nuclei from peripheral blood specimens from patients with B-cell chronic lymphocytic leukemia.
2. The clinical interpretation of any abnormality or its absence by FISH should be done in conjunction with standard cytogenetic analysis and proper controls, and should be evaluated within the context of the patient's medical history and past diagnostic laboratory test results.
3. Clinical specimens with >2.0% tri-signaled nuclei are considered to have an abnormal trisomy 12 clone. Those with ≤ 2.0% tri-signaled nuclei should be considered normal, although the presence of trisomy 12 is not completely excluded. When the percentage of tri-signaled interphase nuclei are near the cutoff point (1.5-2.5%), the results should be interpreted with caution.
4. The CEP 12 assay has been validated only for use with peripheral blood lymphocytes obtained from patients with B-cell CLL leukemia. It is not intended to be used for chromosome 12 enumeration in other patient populations or with other test matrices such as amniocytes, chorionic villi, fibroblasts, tumor cells, long term cultures, among others.
5. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate; the CEP 12 DNA Probe Kit has been optimized for archived peripheral blood specimens stored only at -20°C or -80°C, as recommended.
6. The CEP 12 DNA Probe Kit has not been validated for monitoring disease status.
7. It is possible that some individuals may have target sequences at an alternate chromosomal location that may hybridize with CEP 12. This has not been investigated for this device; the user should assess this in metaphase spreads from each subject tested.
8. The CEP 12 assay is intended only to aid in the enumeration of chromosome 12 centromeres; it is not designed to detect chromosome 12 structural abnormalities.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-012 | 00884999027084 |
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-012 | 00884999027015 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis D13S319 (13q14.3) Probe


## PRODUCT DESCRIPTION

The LSI D13S319 Probe may be used to identify deletions of the LSI D13S319 locus at 13q14.3. D13S319 located between RB1 and the D13S25 loci is a commonly deleted marker. A candidate tumor suppressor gene resides telomeric of the RB1 gene at 13q14.LSI D13S319 Probe is an approximately 130 kb SpectrumOrange labeled probe.

## RESULTS OF HYBRIDIZATION

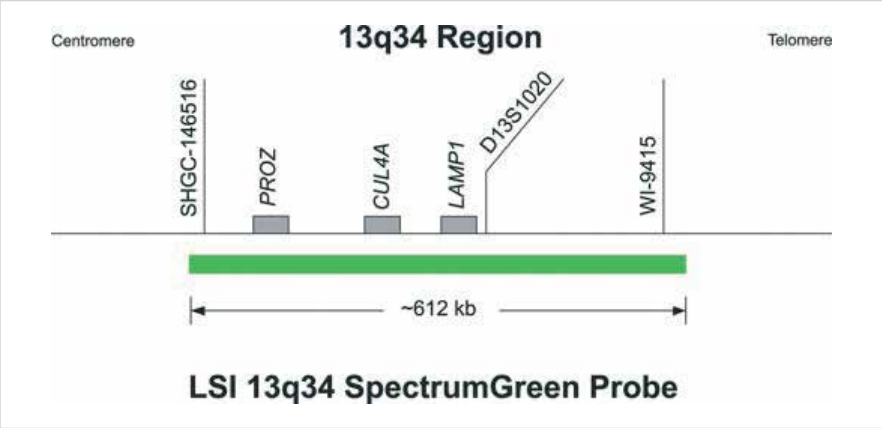
In a normal cell, the expected pattern for the LSI D13S319 probe is the two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.

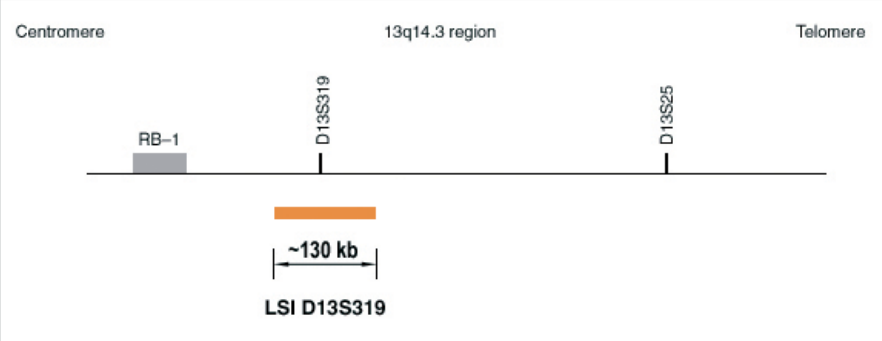
LSI D13S319 Single Color Probe hybridized to a normal metaphase showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D13S319 (13q14.3) Probe **(ASR)** | 20 µL | 05J86-001 | 00884999012769 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis D13S319/13q34 FISH Probe Kit



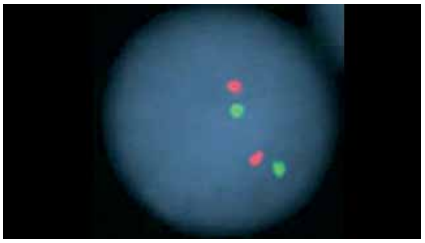





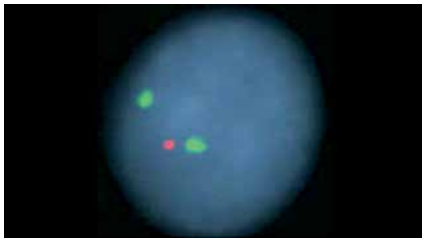
## PRODUCT DESCRIPTION

The Vysis D13S319/LSI13q34 FISH Probe Kit is intended to detect the copy number of the LSI D13S319 probe target located at chromosome 13q14 and the copy number of the LSI13q34 probe target located at chromosome 13q34.

Loss 13q or all of chromosome 13 occurs commonly in multiple myeloma. Avet-Loiseau et al utilized the Vysis D13S319 probe in alarge study to demonstrate the negative effects of the loss of 13q on event-free survival and overall survival in myeloma patients.



**Normal hybridization:** Nucleus showing the two green and two orange signals.

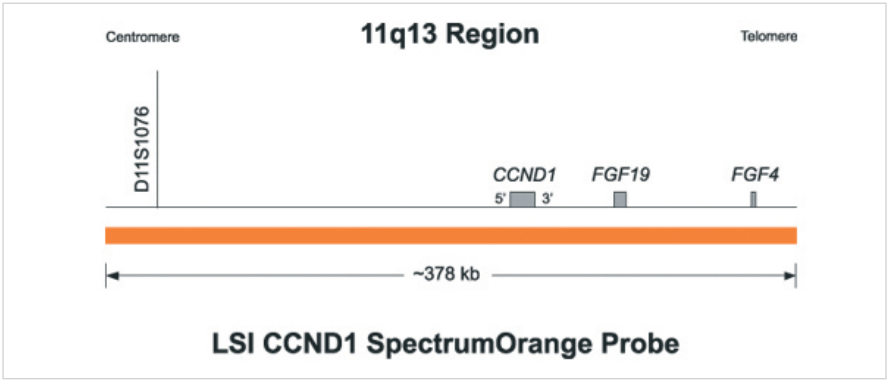


**Abnormal hybridization:** Nucleus showing the two green and one orange signal.

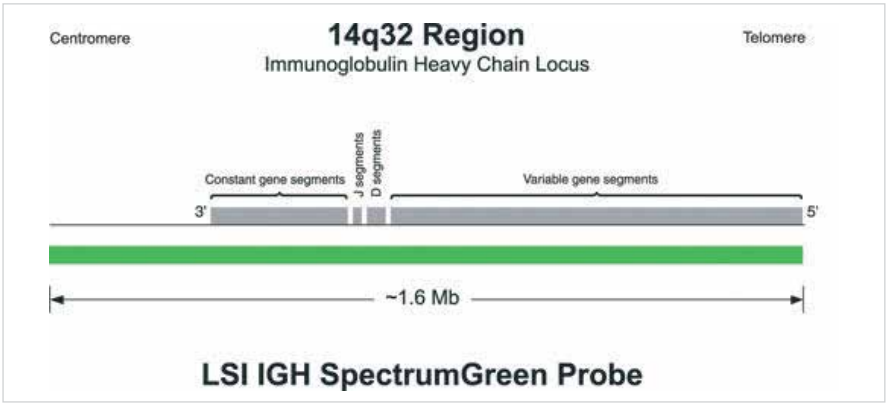
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D13s319/13q34 FISH Probe Kit **(CE)** | 20 µL | 05N37-020 | 00884999014893 |

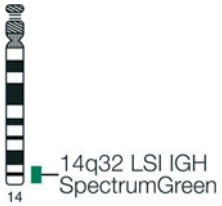
CHRONIC LYMPHOCYTIC LEUKEMIA

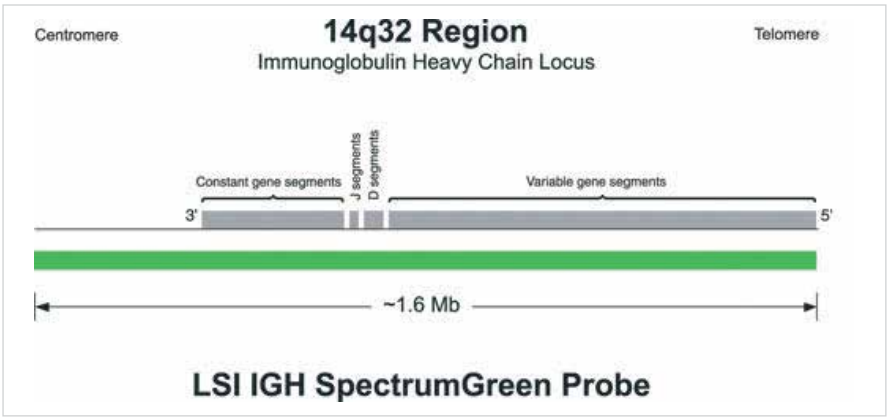
# Vysis IGH/CCND1 DF FISH Probe Kit








## PRODUCT DESCRIPTION

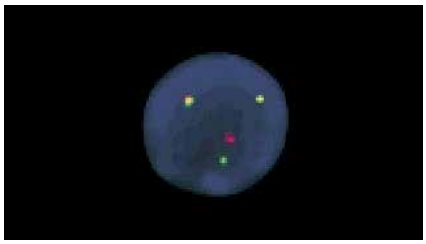
These fluorescence in situ hybridization (FISH) probes are intended to detect the t(11;14)(q13;q32) reciprocal translocation involving the IGH and CCND1 gene regions.

Mantle cell lymphoma is commonly associated with the balanced translocation t(11;14)(q13;q32). Mantle cell lymphoma has the most aggressive clinical course among the small cell lymp`homas. FISH has emerged as an important aid in the diagnosis of mantle cell lymphoma. The Vysis LSI IGH/CCND1 Dual Color Dual Fusion Probes have been used in publications to detect t(11;14) in Mantle Cell Lymphoma.

## RESULTS OF HYBRIDIZATION

LSI IGH/CCND1 hybridized to a cell containing t(11;14) with breakpoints at the MTC on 11q13 and at the IGH J region on 14q32 is expected to result in a signal pattern of two orange/green (yellow) fusions, one on each of the abnormal chromosomes 11 and 14 and single orange and green signals from the normal chromosomes.

Due to the gap between the two probes in the IGH probe set, the normal IGH loci may sometimes appear as two slightly separated green signals. This gap may also cause a slight separation of the orange and green signals on the der(11) chromosome, in some instances. Analysis of t(11;14) samples suggests that due to variation in breakpoint location on 11q13 loss of V segments within the LSI IGH probe target, some samples containing t(11;14) might display signal patterns different than 1O1G2F.

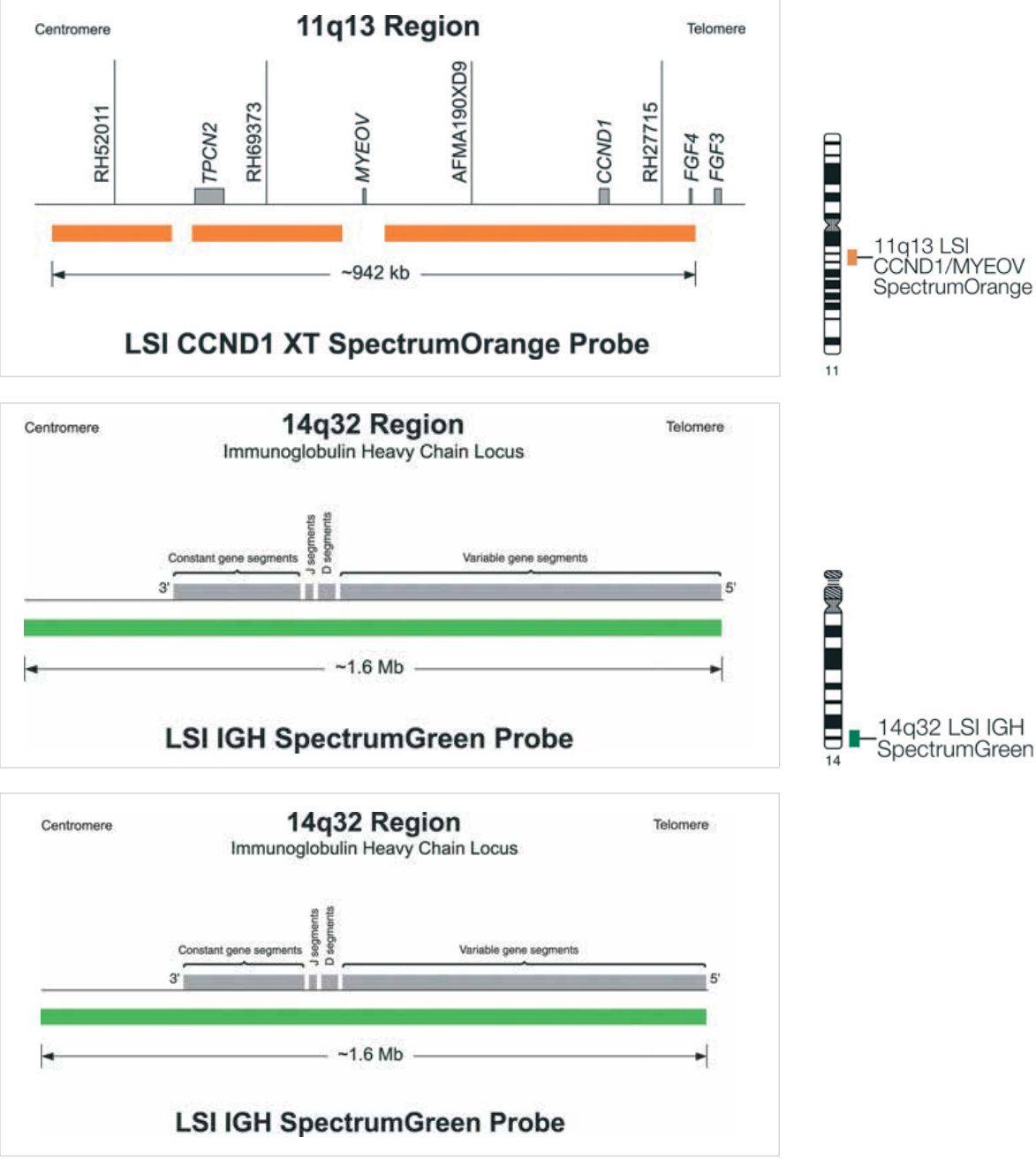


**Abnormal hybridization:** LSI IGH/CCND1 Dual Color, Dual Fusion Translocation Probe hybridized to an abnormal nucleus showing the common 1O1G2F signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis IGH/CCND1 DF FISH Probe Kit **(CE)** | 20 µL | 08L58-020 | 00884999031487 |
| Vysis LSI IGH/CCND1 Dual Color Dual Fusion Probes **(ASR)** | 20 µL | 05J69-001 | 00884999012301 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis IGH/CCND1 XT DF FISH Probe Kit



## PRODUCT DESCRIPTION

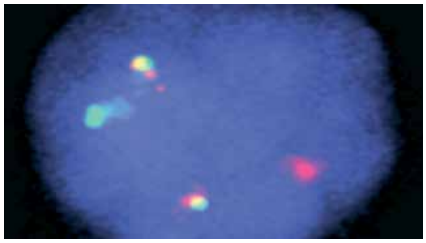
These fluorescence in situ hybridization (FISH) probes are intended to detect t(11;14)(q13;q32) reciprocal translocation involving the IGH and CCND1 gene regions.

The t(11;14)(q13;q32) is the most common translocation detected in myeloma. Patients with t(11;14) have been reported to have a bettersurvival and response to treatment particularly high dose therapy and stem cell support. The Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes have been used in publications to detect t(11;14).

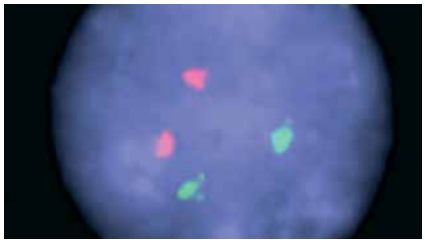
## RESULTS OF HYBRIDIZATION

In an abnormal cell containing the t(11;14), one orange (CCND1/MYEOV), one green (IGH), and two fusion signal pattern (der (11) and der (14)) may be observed. Some samples containing the t(11;14) may display signal patterns different than one orange, one green, and two fusions.

In a normal cell that lacks the t(11;14), a two orange and two green signal pattern will be observed reflecting the two intact copies of CCND1/MYEOV and IGH respectively.



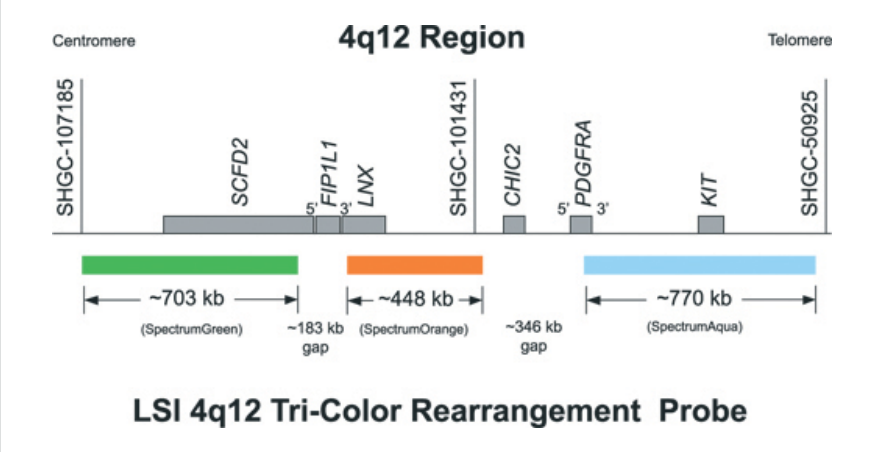
**Abnormal hybridization:** An abnormal interphase cell hybridized with the Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes. The cell in this image shows the one orange (CCND1/MYEOV), one green (IGH), two fusion (der (11) and der (14)) signal pattern indicative of a t(11;14).



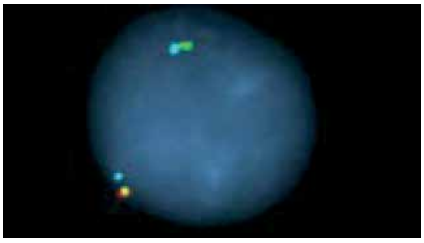
**Normal hybridization:** A normal interphase cell hybridized with the Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes. The cell shows the expected two orange (CCND1/MYEOV), two green (IGH) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis IGH/CCND1 XT DF FISH Probe Kit **(CE)** | 20 µL | 05N33-020 | 00884999014862 |
| Vysis LSI IGH/CCND1 XT Dual Color, Dual Fusion Translocation Probes **(ASR)** | 20 µL | 05J72-001 | 00884999012370 |

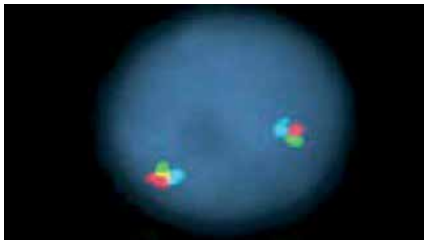
# Vysis LSI 4q12 Tricolor, Rearrangement Probe







**Abnormal hybridization:** Nucleus showing the one tricolor green/orange/aqua fusion signal and one green/aqua fusion signal.



**Normal hybridization:** Nucleus showing the two tricolor green/orange/aqua fusion signals.

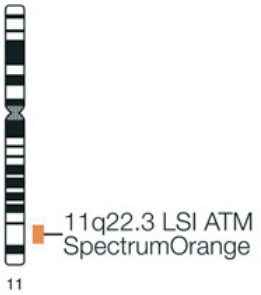
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 4q12 Tricolor, Rearrangement Probe **(ASR)** | 20 µL | 01N79-020 | 00884999001039 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI ATM (11q22.3) SpectrumOrange Probe

## PRODUCT DESCRIPTION

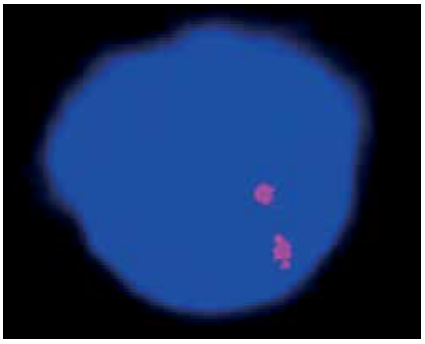
The LSI ATM probe is a ~500 kb unique sequence probe that hybridizes to the 11q22.3 region of chromosome 11. This probe spans the entire ~184 kb Ataxia telangiectasia mutated (ATM) gene and several others.



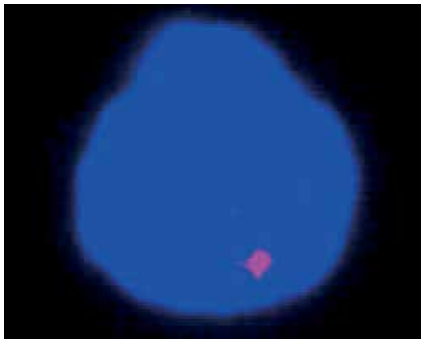

## RESULTS OF HYBRIDIZATION

This probe set allows status assessment of the ATM gene region on chromosome 11q22.3. In a normal cell with two intact copies of the ATM gene region, a two orange signal pattern will be observed.

This probe set allows status assessment of the ATM gene region on chromosome 11q22.3. In an abnormal cell with a deletion in the ATM gene region, fewer than two orange signals will be observed.



**Normal hybridization:** Result of the hybridization of the LSI ATM (11q22.3) Probe as observed in a normal interphase cell.

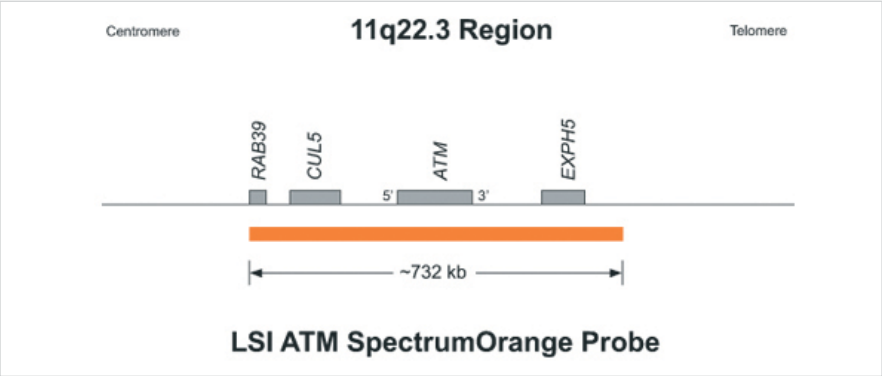


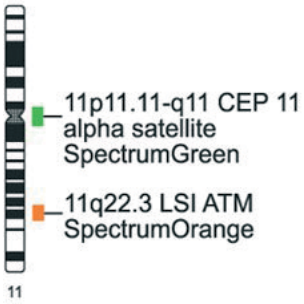
**Abnormal hybridization:** Abnormal cell hybridized with the LSI ATM (11q22.3) Probe. The cell in this image shows the one orange signal pattern indicative of a deletion of one copy of the ATM gene region on chromosome 11q22.3.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI ATM (11q22.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N33-020 | 00884999000759 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI ATM/CEP 11 FISH Probe Kit

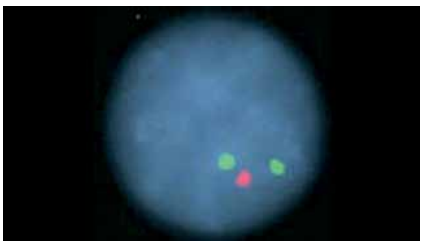


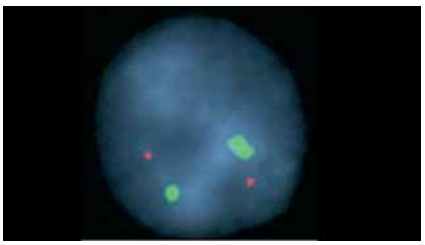

## PRODUCT DESCRIPTION

The Vysis ATM/CEP 11 FISH Probe Kit is intended to detect the copy number of the LSI ATM probe target located at chromosome 11q22.3.

A common deletion that occurs in chronic lymphocytic leukemia (CLL) is the loss of the 11q22 region. Loss of ATM in CLL is associated with aggressive disease. The LSI ATM/CEP 11 probe combination has been used to detect the loss of 11q in several CLL studies.



**Abnormal hybridization:** Nucleus showing the two green and one orange signal.

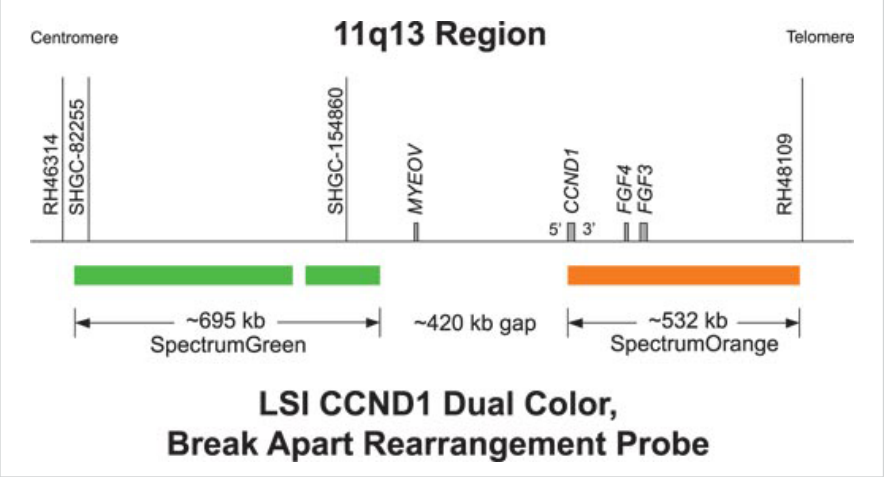


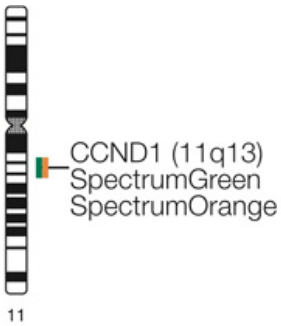
**Normal hybridization:** Nucleus showing the two green and two orange signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI ATM/CEP 11 FISH Probe Kit **(CE)** | 20 µL | 05N55-020 | 00884999015043 |
| Vysis LSI ATM SpectrumOrange/Vysis CEP 11 SpectrumGreen Probes **(ASR)** | 20 µL | 01N18-020 | 00884999000537 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit




## PRODUCT DESCRIPTION

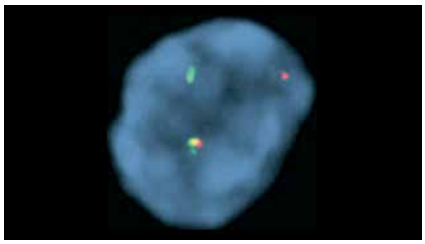
The CCND1 Dual Color Break Apart Rearrangement FISH probe is intended to detect chromosomal rearrangements involving the Cyclin D1 (CCND1) gene region at chromosome 11q13.

Mantle cell lymphoma (MCL) is an aggressive B-cell lymphoma and is commonly characterized by over-expression of CCND1 resulting from the t(11;14)(q13;q32) translocation. Over-expression of CCND1, which can result from chromosomal anomalies such as translocations or gain of the involved area, have been found to occur in multiple myeloma (MM) and MCL. The CCND1 Dual Color Break Apart Rearrangement Probe has been used to help identify rearrangement in the CCND1 breakpoint region in MCL.

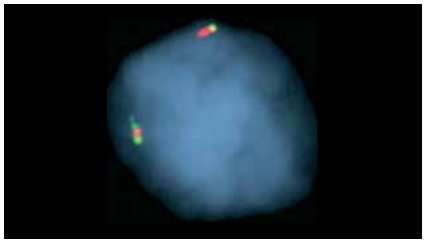
## RESULTS OF HYBRIDIZATION

The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 11 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals.



**Abnormal hybridization:** Abnormal cell hybridization using the LSI CCND1 (11q13) Dual Color Break Apart Rearrangement Probe.



**Normal hybridization:** Normal cell hybridization using the LSI CCND1 (11q13) Dual Color Break Apart Rearrangement Probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 05N38-020 | 00884999014909 |
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J96-001 | 00884999013445 |

# Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe

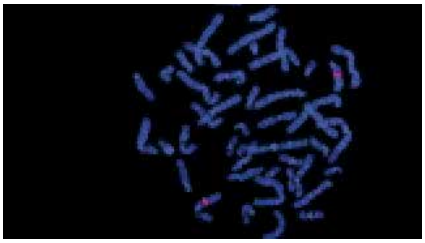
## PRODUCT DESCRIPTION

The LSI D13S25 Probe may be used to identify deletions in the 13q14.3 region. A candidate tumor suppressor gene may reside telomeric of the RB1 gene at 13q14. Deletion of the locus D13S25 at 13q14.3 occurs in a substantial number of cases without deletion of the RB1 gene.

The LSI D13S25 Probe is an approximately 160 kb SpectrumOrange labeled probe.


## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the LSI D13S25 probe is the two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange (1O) signal pattern will be observed.

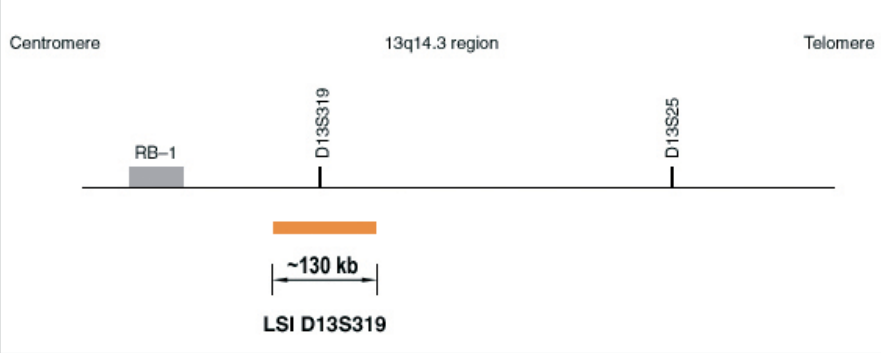


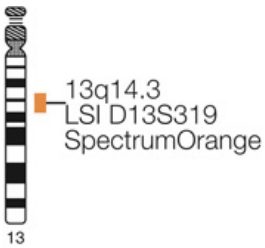
**Normal hybridization:** LSI D13S25 Single Color Probe hybridized to a normal metaphase showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N37-020 | 00884999000797 |
| Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe **(ASR)** | 20 µL | 05J81-001 | 00884999012578 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI D13S319 (13q14.3) SpectrumOrange Probe




## PRODUCT DESCRIPTION

The LSI D13S319 Probe may be used to identify deletions of the LSI D13S319 locus at 13q14.3. D13S319 located between RB1 and the D13S25 loci is a commonly deleted marker. A candidate tumor suppressor gene resides telomeric of the RB1 gene at 13q14.LSI D13S319 Probe is an approximately 130 kb SpectrumOrange labeled probe.

## RESULTS OF HYBRIDIZATION

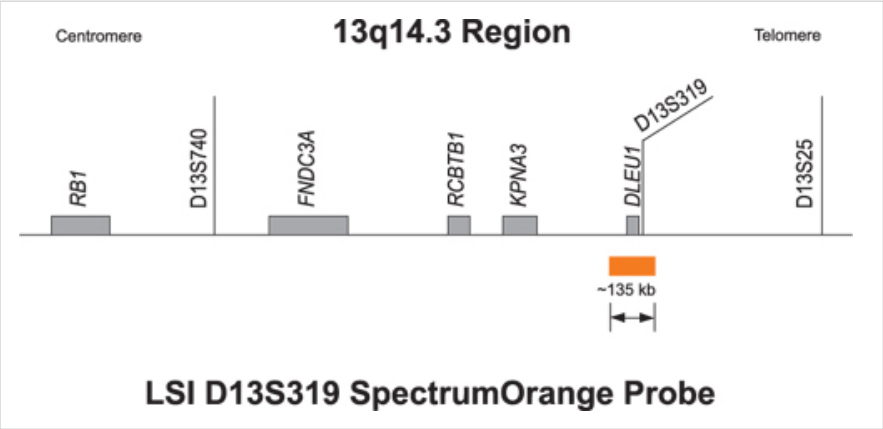
In a normal cell, the expected pattern for the LSI D13S319 probe is the two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.

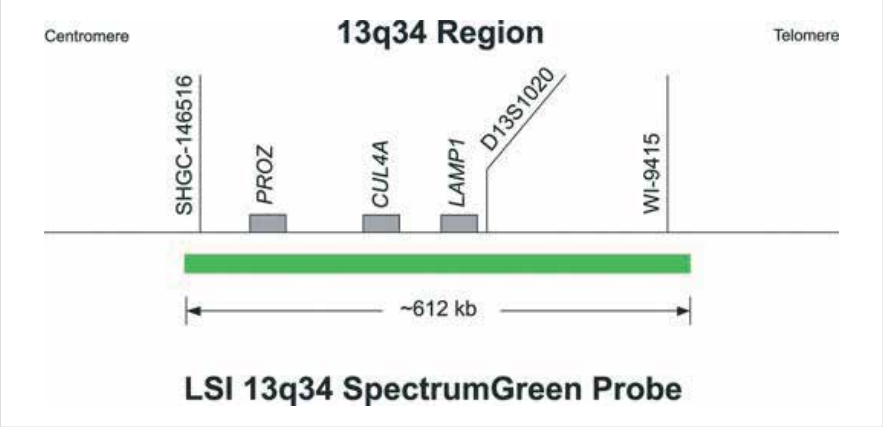
**Abnormal hybridization:** LSI D13S319 Single Color Probe hybridized to a normal metaphase showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI D13S319 (13q14.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N34-020 | 00884999000766 |

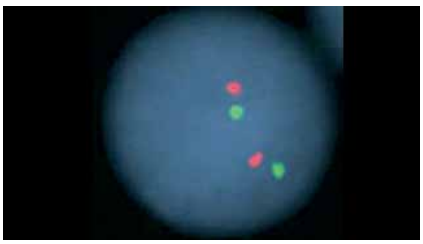
CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI D13S319 SpectrumOrange/ 13q34 SpectrumGreen Probes







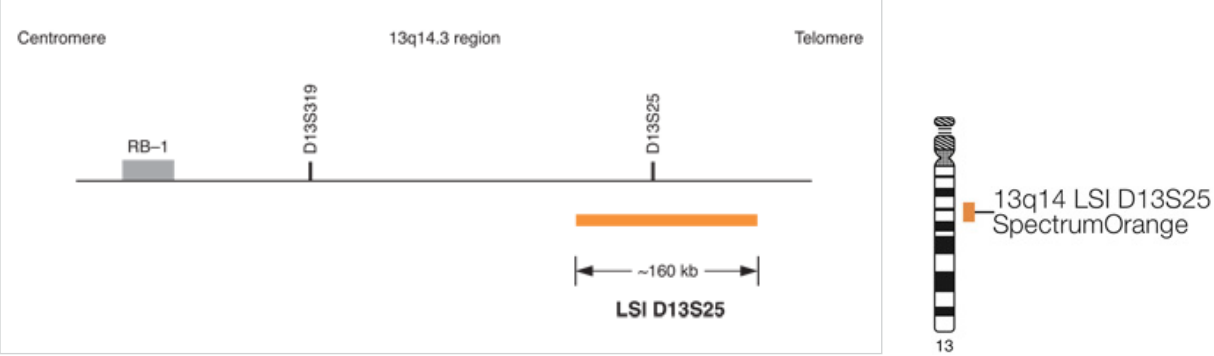
**Normal hybridization:** Nucleus showing the two green and two orange signals.

**Abnormal hybridization:** Nucleus showing the two green and one orange signal.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI D13S319 SpectrumOrange/ 13q34 SpectrumGreen Probes **(ASR)** | 20 µL | 01N20-020 | 00884999000544 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe





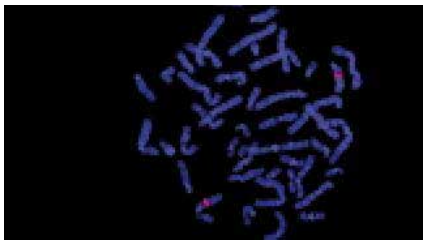


## PRODUCT DESCRIPTION

The LSI D13S25 Probe may be used to identify deletions in the 13q14.3 region. A candidate tumor suppressor gene may reside telomeric of the RB1 gene at 13q14. Deletion of the locus D13S25 at 13q14.3 occurs in a substantial number of cases without deletion of the RB1 gene. The LSI D13S25 Probe is an approximately 160 kb SpectrumOrange labeled probe.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the LSI D13S25 probe is the two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange (1O) signal pattern will be observed.

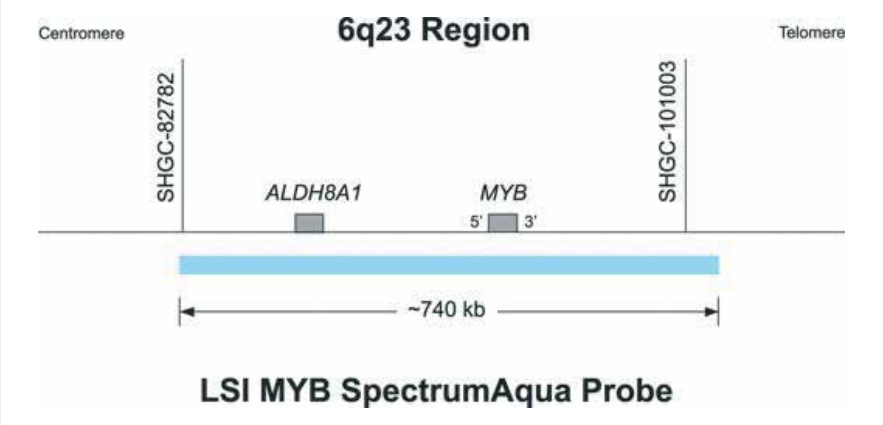


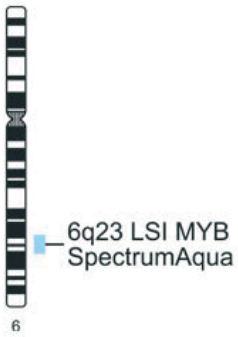
**Normal hybridization:** LSI D13S25 Single Color Probe hybridized to a normal metaphase showing the two orange (2O) signal pattern

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI D13S319 (13q14.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N34-020 | 00884999000766 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI MYB SpectrumAqua Probe Kit




## PRODUCT DESCRIPTION

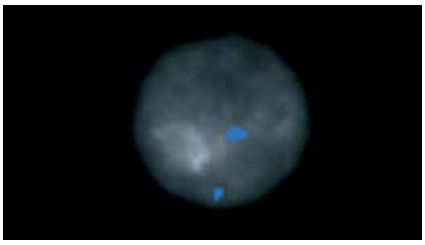
This Vysis MYB SpectrumAqua FISH Probe is intended to detect the copy number of the LSI MYB probe target located at chromosome 6q23.

The Vysis LSI MYB SpectrumAqua Probe was used to detect deletion of its target at 6q23 in a study of 143 chronic lymphocytic leukemia patients. In this study, approximately 5% of patients were found to have this deletion.

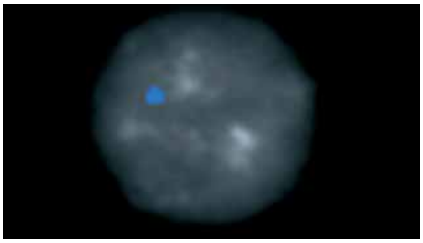
## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase and metaphase nuclei of normal cells is expected to be seen as two aqua signals. The anticipated signal pattern in individuals with a deletion of the 6q23 region would be seen as a single aqua signal. Other patterns may be observed if additional genetic alterations are present.

Hybridization of this probe to interphase and metaphase nuclei of normal cells is expected to be seen as two aqua signals. The anticipated signal pattern in individuals with a deletion of the 6q23 region would be seen as a single aqua signal. Other patterns may be observed if additional genetic alterations are present.



**Normal hybridization:** Normal cell hybridization using the Vysis LSI MYB (6q23) Probe.

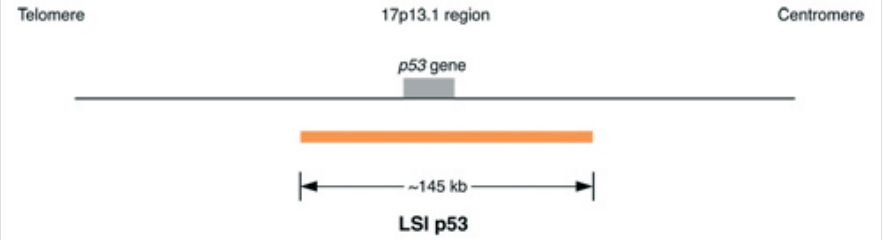


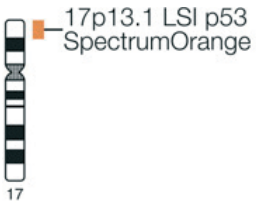
**Abnormal hybridization:** Abnormal cell hybridization using the Vysis LSI MYB (6q23) Probe.

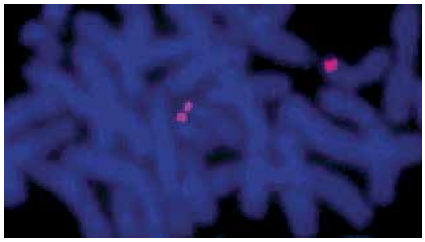
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYB SpectrumAqua Probe Kit **(CE)** | 20 µL | 05N40-020 | 00884999014916 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI p53 (17p13.1) SpectrumOrange Probe



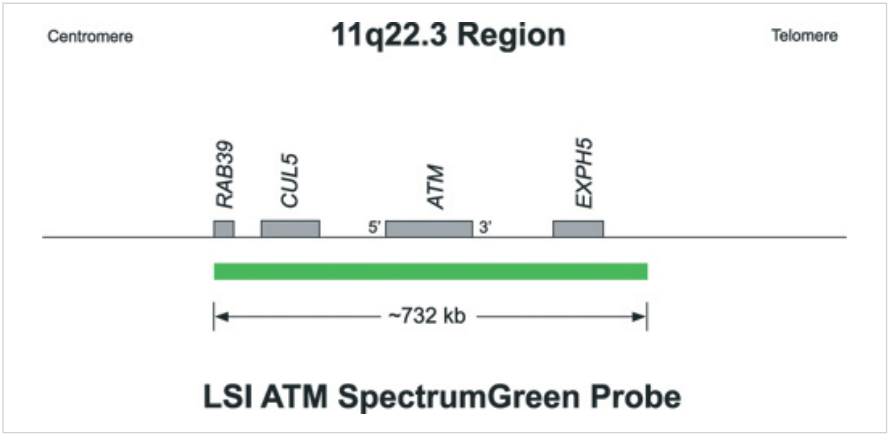



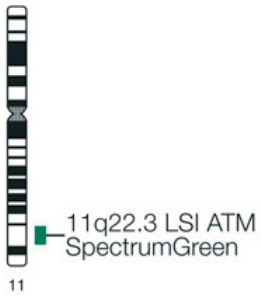



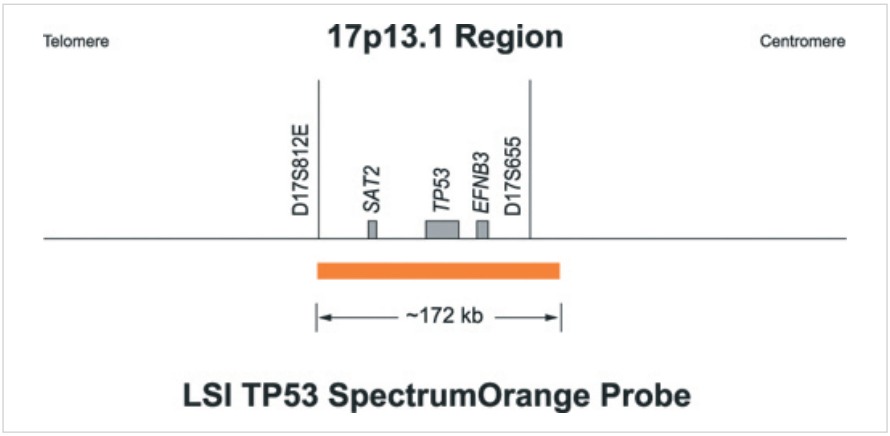
**Normal hybridization:** LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI p53 (17p13.1) SpectrumOrange Probe **(ASR)** | 20 µL | 05J52-001 | 00884999012028 |

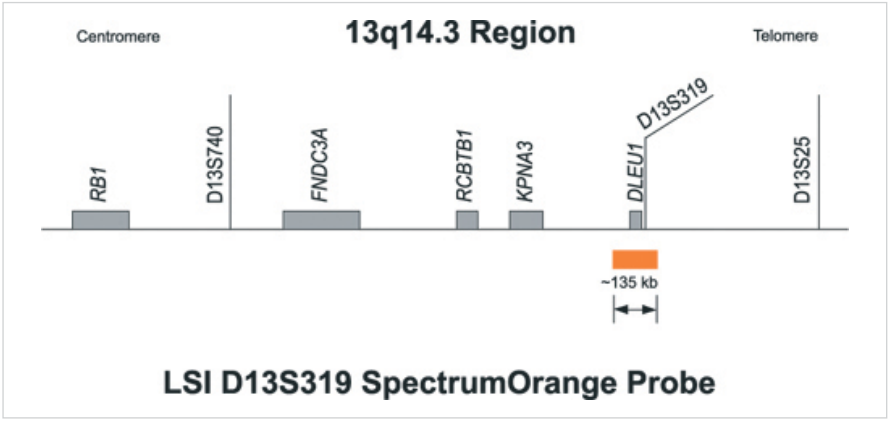
# Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe Kit

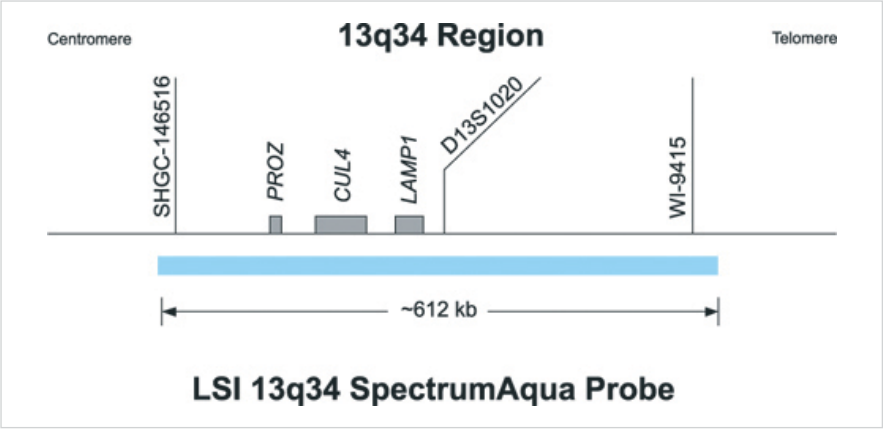


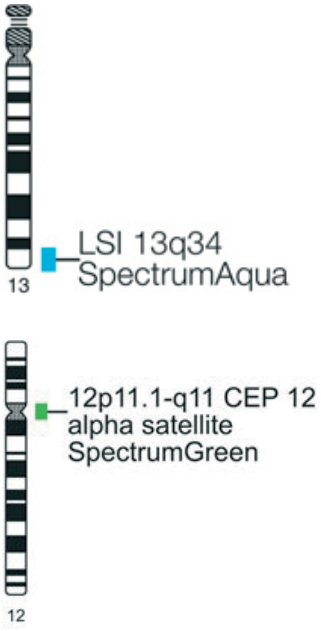








## PRODUCT DESCRIPTION

The leukemias are a diverse group of diseases that are often characterized by multiple genetic aberrations distributed across the genome. In some cases, the same genetic aberrations are shared by different types of leukemia. Trisomy 12 and deletions of chromosomes 13q (primarily the 13q14 region), 17p13.1, and 11q22.32-4, for example, have all been observed in several types of leukemia. Probe vial 1 contains LSI p53 in SpectrumOrange and LSI ATM in SpectrumGreen. Probe vial 2 contains LSI D13S319 in SpectrumOrange, LSI 13q34 in SpectrumAqua, and CEP 12 in SpectrumGreen.

The LSI p53 (17p13.1) probe is a ~145 kb unique sequence probe that is labeled in SpectrumOrange.

The LSI ATM probe is a ~500 kb unique sequence probe that hybridizes to the 11q22.3 region of chromosome 11. This probe spans the entire ~184 kb Ataxia telangiectasia mutated (ATM) gene and several others. The probe is labeled in SpectrumGreen.

The LSI D13S319 probe is a ~130 kb unique sequence probe that is labeled in SpectrumOrange.

The LSI 13q34 probe is a ~550 kb unique sequence probe that hybridizes to the 13q34 region containing the Lysosomal-associate Membrane Protein (LAMP1) gene and several others. The probe is labeled in SpectrumAqua.

The CEP 12 DNA probe hybridizes to the alpha satellite (centromeric) region (12p11.1-q11) of chromosome 12. The probe is labeled in SpectrumGreen.

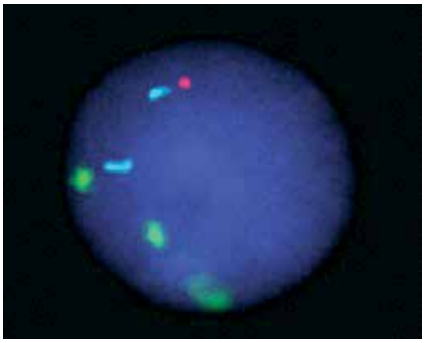
## RESULTS OF HYBRIDIZATION

This multi-color probe set is provided in a two-mixture format.

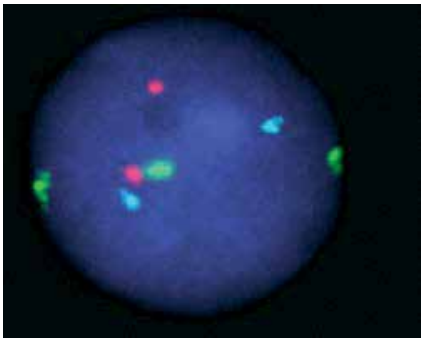
## PROBE 2

This probe allows status assessment of the following three chromosome regions: 13q14.3 (D13S319), 13q34, and 12p11.1-q11. In a normal cell with two intact copies of chromosome 13 and chromosome 12, a two orange, two aqua, and two green signal pattern will be observed. In an abnormal cell with chromosome 13 aberrations only, more complex signal patterns may be expected depending upon the nature of the aberration. Monosomy 13 or 13q- will both appear as a one orange, one aqua, two green signal pattern. An interstitial deletion of the 13q14.3 region will appear as either a one orange, two aqua, two green signal pattern (hemizygous deletion) or a two aqua, two green signal pattern (homozygous deletion) (data not shown). In an abnormal cell with chromosome 12 copy number changes, one will observe greater or less than two green signals.

This multi-color probe set is provided in a two-mixture format.



**Abnormal hybridization:** An abnormal cell hybridized with Probe Set 2. One copy of chromosome 13 is deleted for the D13S319 region as indicated by the single orange signal (LSI D13S319) and the two aqua signals (LSI 13q34). One extra copy of chromosome 12 (trisomy 12) is present as indicated by the three green signals.

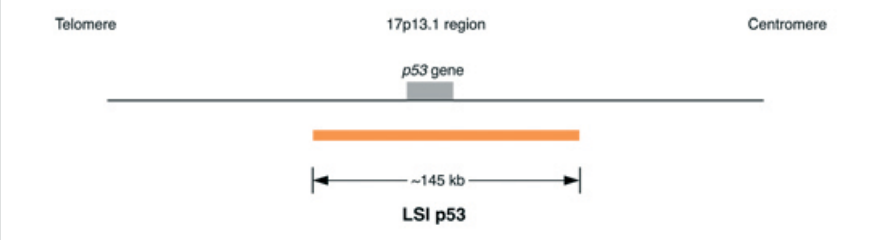


**Abnormal hybridization:** An abnormal cell hybridized with Probe Set 2. Both copies of chromosome thirteen and its q arm are intact as indicated by the two orange (LSI D13S319) and two aqua (LSI 13q34) signals. One extra copy of chromosome 12 (trisomy 12) is present as indicated by the three green signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe **(CE)** | 20 µL | 08L53-020 | 00884999031432 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe **(ASR)** | 20 µL | 05J83-001 | 00884999012622 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis LSI TP53 (17p13.1) SpectrumOrange Probe



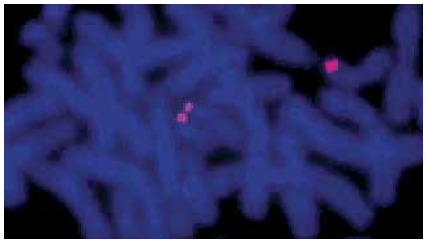


## PRODUCT DESCRIPTION

The LSI TP53 (previously designated as p53) Probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene. The ability to use FISH probes such as the LSI p53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the p53 locus.The LSI p53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.

## RESULTS OF HYBRIDIZATION

In a cell containing a deletion of the LSI p53 locus, one orange LSI p53 signal will be observed (1O signal pattern). In a cell harboring amplification of the p53 locus multiple copies of the orange signal will be observed. In a normal cell the two orange (2O) signal pattern is observed.

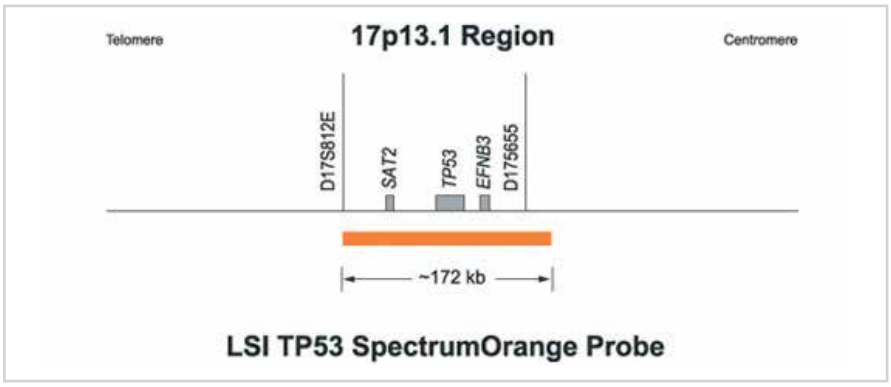


**Normal hybridization:** LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis TP53 / CEP 17 FISH Probe Kit

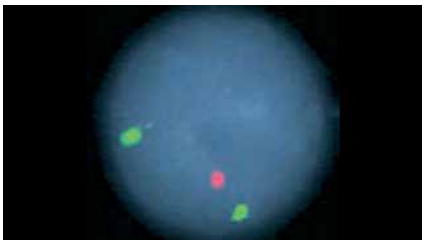




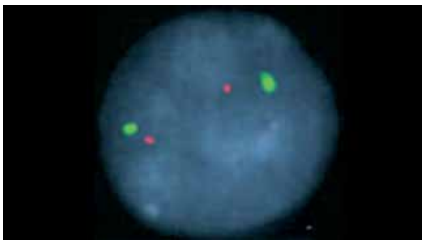
## PRODUCT DESCRIPTION

The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma. The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.



**Abnormal hybridization:** Nucleus showing the two green and one orange signal.

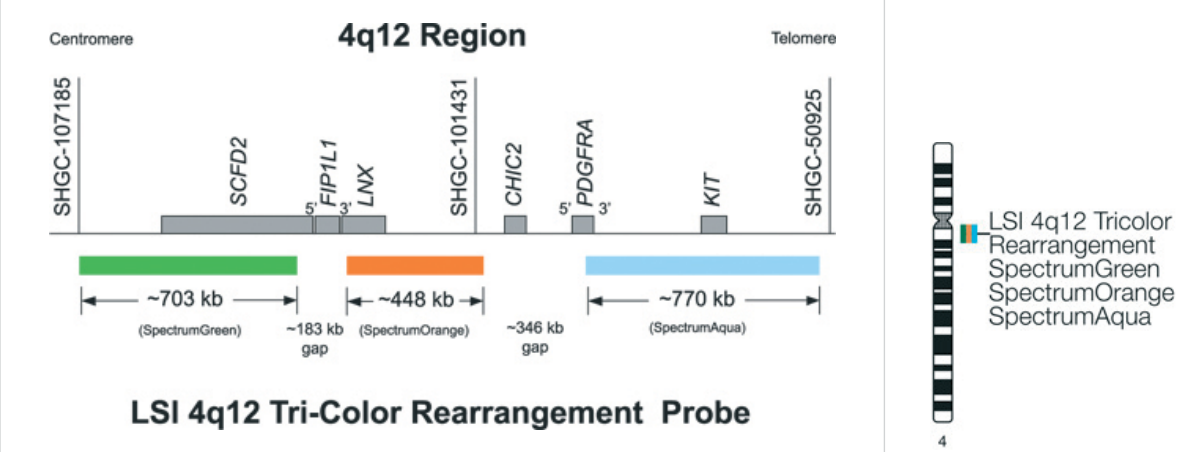


**Normal hybridization:** Nucleus showing the two green and two orange signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 |

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis 4q12 Tri-Color Rearrangement FISH Probe Kit







## PRODUCT DESCRIPTION

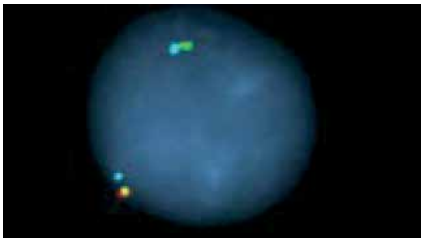
The Vysis 4q12 Tri-Color Rearrangement FISH Probe Kit is intended to detect rearrangements in chromosome 4q12 involving the FIP1L1-PDGFRA region, using FISH.

Chronic Eosinophilic Leukemia (CEL) is described by the World Health Organization (WHO) as a neoplasm in which clonal proliferation of eosinophil precursors results in prolonged eosinophilia. The chromosomal anomaly, del(4)(q12q12), results in a fusion of FIP1L1 and PDGFRA and is found in 40-60% of CEL patients. The Vysis LSI 4q12 Tri-Color Rearrangement Probe has been used to detect an approximately 800 kb deletion containing LNX and CHIC2 and subsequent fusion of FIP1L1 and PDGFRA. The current WHO classification system places myeloproliferative neoplasms with eosinophilia and abnormalities of PDGFRA, PDGFRB, or FGFR1 into their own diagnostic category, while CEL lacking aberrations of these and several other genes falls into the CEL, not otherwise specified classification.

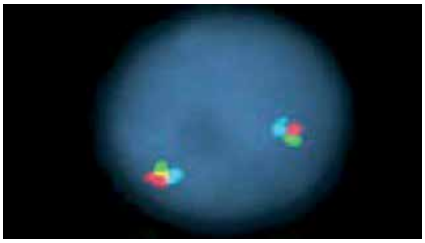
## RESULTS OF HYBRIDIZATION

FISH signal patterns in nuclei having interstitial deletions of the orange probe target on one chromosome 4 homolog should be observed as one tri-color fusion and one green/aqua fusion lacking an orange signal. If the intervening orange probe target is not deleted, but relocated to another separate chromosomal location, the expected pattern would be one tri-color fusion, one green/aqua fusion and one lone orange signal. In instances of translocations involving the PDGFRA gene with loci on other chromosomes, the expected signal pattern would be one tri-color fusion, one orange/green fusion, and one separate aqua signal.

In interphase nuclei of normal cells, the probe is expected to appear as two tri-color (green, orange,aqua) fusions. In these fusions, overlapping orange and green signals may be perceived as yellow fusion signals with appropriate filters.



**Abnormal hybridization:** Abnormal nucleus showing the one tricolor green/orange/aqua fusion signal and one green/aqua fusion signal with the orange signal deleted.

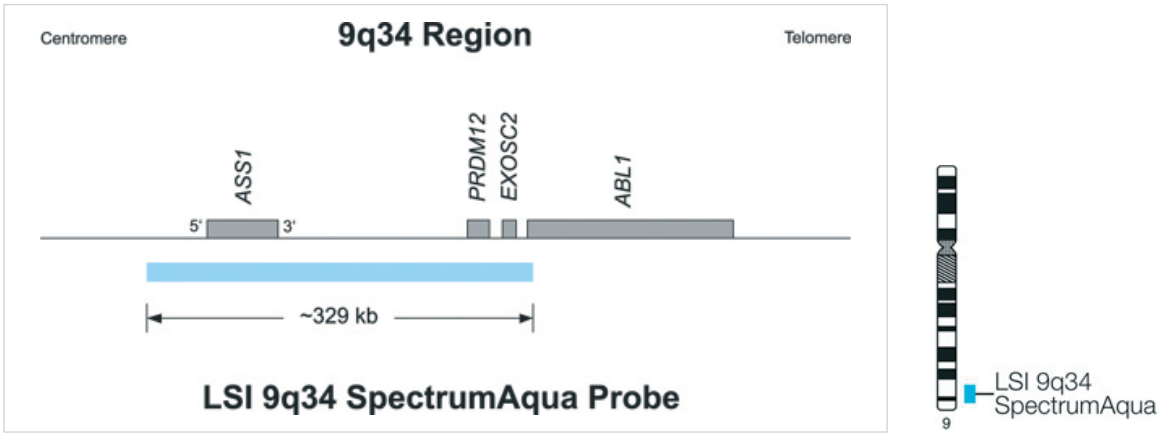


**Normal hybridization:** Normal nucleus showing the two tricolor green/orange/aqua fusion signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis 4q12 Tri-Color Rearrangement FISH Probe Kit **(CE)** | 20 µL | 05N52-020 | 00884999015005 |

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis 9q34 SpectrumAqua Probe Kit







## PRODUCT DESCRIPTION

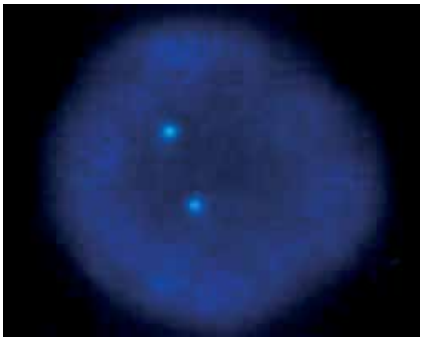
The Vysis 9q34 SpectrumAqua FISH Probe Kit is intended to detect deletion of the Vysis 9q34 probe target region using the fluorescence in situ hybridization (FISH) technique.

Chronic myelogenous leukemia (CML) has a characteristic t(9;22) (q34;q11.2) that results in fusion of the BCR and ABL1 genes. Among a small sub set of patients, there is an associated deletion of a region of 9q34 proximal to the ABL1 breakpoint which includes the arginosuccinate synthetase gene (ASS1). In two different studies of CML patients, the Vysis 9q34 SpectrumAqua probe has been shown to detect deletions of this 9q34 region.

## RESULTS OF HYBRIDIZATION

This probe is provided for those interested in assessing the deletion status of the 9q34 region of chromosome 9. In a normal cell with two intact copies of chromosome 9, two aqua signals will be observed. In an abnormal cell that has lost the 9q34 region of chromosome 9, fewer than two aqua signals will be observed.

This probe is provided for those interested in assessing the deletion status of the 9q34 region of chromosome 9. In a normal cell with two intact copies of chromosome 9, two aqua signals will be observed. In an abnormal cell that has lost the 9q34 region of chromosome 9, fewer than two aqua signals will be observed.



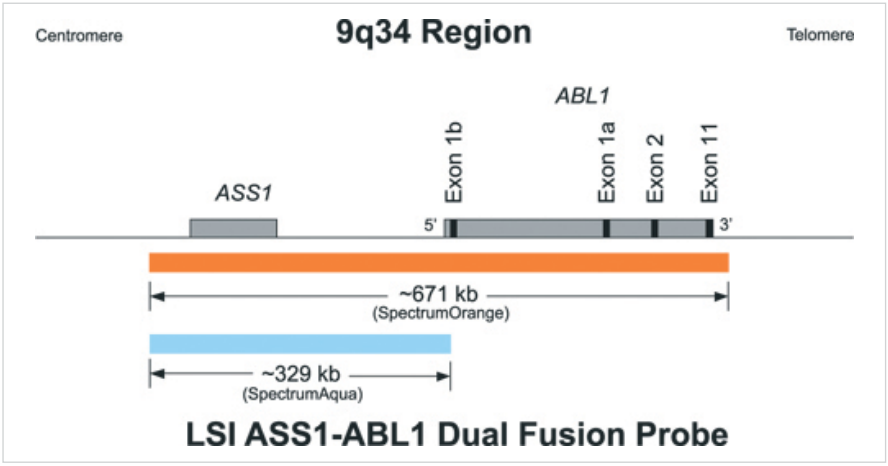
**Normal hybridization:** Result of the hybridization of the LSI 9q34 Probe as observed in a normal interphase cell.

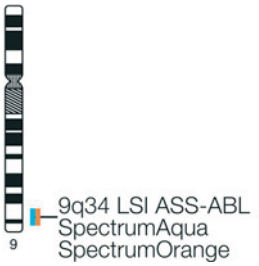
**Abnormal hybridization:** Abnormal cell hybridized with the LSI 9q34 Probe. The cell in this image shows deletion of one copy of the 9q34 region of chromosome 9 as indicated by the single aqua signal.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis 9q34 SpectrumAqua FISH Probe Kit **(CE)** | 20 µL | 05N53-020 | 00884999015012 |
| Vysis LSI 9q34 SpectrumAqua Probe **(ASR)** | 20 µL | 05J79-011 | 00884999012530 |

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit





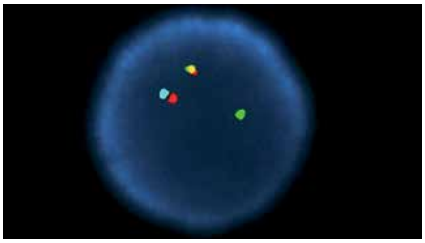

## PRODUCT DESCRIPTION

The Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit is intended to detect the t(9;22)(q34;q11.2) reciprocal translocation involving the BCR and ABL1 gene regions using the fluorescence in situ hybridization (FISH) technique.

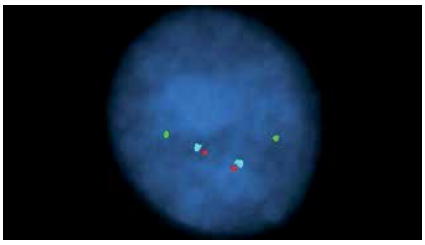
The t(9;22) translocation which fuses the BCR gene on chromosome 22q11.2 and the ABL1 gene on chromosome 9q34 is observed by cytogenetics in greater than 80% of patients with chronic myelogenous leukemia (CML). In CML cases lacking a cytogenetically detectable translocation, the BCR/ABL1 fusion can still almost always be detected by FISH or other molecular techniques. BCR/ABL1 fusions also occur in a portion of acute lymphocytic leukemia cases and more rarely in acute myeloid leukemia. In about 15 to 20 percent of CML cases, the t(9;22) results in the loss of genetic material flanking the BCR and/or ABL1 breakpoints on the derivative 9 chromosome. This loss can prevent the production of the highly specific two-fusion signal patterns expected of dual fusion probes and balanced translocations. If both BCR and ABL1 targets are deleted on the der(9) chromosome, low-level random overlap of orange and green signals

within normal cells (producing a 1 orange, 1 green, 1 fusion pattern) cannot be discriminated from low-level true BCR/ABL1 fusions producing the same pattern. The Tri-Color design of this test uses a probe in a third color (aqua) on the centromeric side of the ABL1 breakpoint, which co-localizes with the orange signal in a random orange/green signal fusion, but is absent from a true BCR/ABL1 molecular fusion on the der(22) chromosome. The probes in this kit have been used in published papers to detect low levels of positive cells in CML patients who were undergoing therapy and had deletions of FISH signals on the derivative chromosome 9.



**Abnormal hybridization:** Nucleus showing the one aqua/orange, one green, and one orange/green fusion (yellow) signal pattern.



**Normal hybridization:** Nucleus showing the two aqua/orange and two green signal pattern.

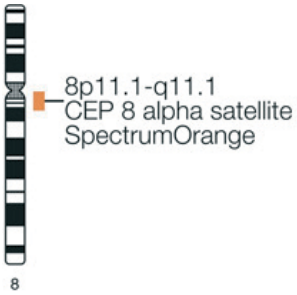
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 20 µL<br>50 µL | 05N54-020<br>05N54-050 | 00884999015029<br>00884999015036 |

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit

## PRODUCT DESCRIPTION

CEP 8 is a SpectrumOrange labeled probe specific for the alpha satellite (centromeric) region, 8p11.1-q11.1.




The CEP 8 DNA Probe Kit which is available for in vitro diagnostic use and may be used as an adjunct to standard karotyping to identify and enumerate chromosome 8 in cells obtained from bone marrow. In multi-site clinical trials, the CEP 8 DNA Probe Kit for interphase analysis was 96% sensitive and 98% specific as compared to traditional cytogenetic analysis. A close association has been made between trisomy 8 and both myeloid blast crisis and basophilia. Trisomy 8 is a prevalent genetic aberration in several specific diseases:

- Chronic Myelogenous Leukemia (CML)
- Acute Myeloid Leukemia (AML)
- Myeloproliferative disorders (MPD)
- Myelodysplastic Syndrome (MDS)
- Other hematologic disorders not specified (HDNOS)

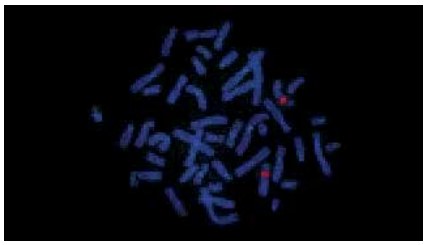
## CEP 8 SPECTRUMORANGE DNA PROBE KIT CONTENT

Components of the CEP 8 SpectrumOrange DNA Probe Kit include:

- CEP 8 SpectrumOrange alpha satellite DNA for centromere region 8p11.1-q11.1 predenatured in hybridization buffer (220 µL)
- NP-40 (detergent for wash solution: 1000 µL)
- DAPI II counterstain (300 µL)
- 20X SSC (66 g)
- Control slides for the CEP 8 kit are also sold separately. See Order No. 30-805000 and Order No. 30-805002.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the CEP 8 probe is a two orange (2O) signal pattern. In an abnormal cell containing trisomy 8, the expected pattern will be a three orange (3O) signal pattern.



**Normal hybridization:** CEP 8 SpectrumOrange hybridized to a normal cell showing two orange signals indicating two copies of chromosome 8.

## INTENDED USE

The CEP 8 SpectrumOrange DNA Probe Kit is intended to detect AT rich alpha satellite sequences in the centromere region of chromosome 8 in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosome 8 via fluorescence in situ hybridization (FISH) in interphase nuclei and in metaphase spreads of cells obtained from bone marrow in patients with myeloid disorders [Chronic myelogenous leukemia (CML), Acute myeloid leukemia (AML), Myeloproliferative disorder (MPD), Myelodysplastic syndrome (MDS), and Hematological disorders not otherwise specified (HDNOS)]. It is not intended to be used as a stand alone assay for test reporting. It is not intended for use in long term cell cultured materials such as amniocytes, fibroblasts and tumor cells.

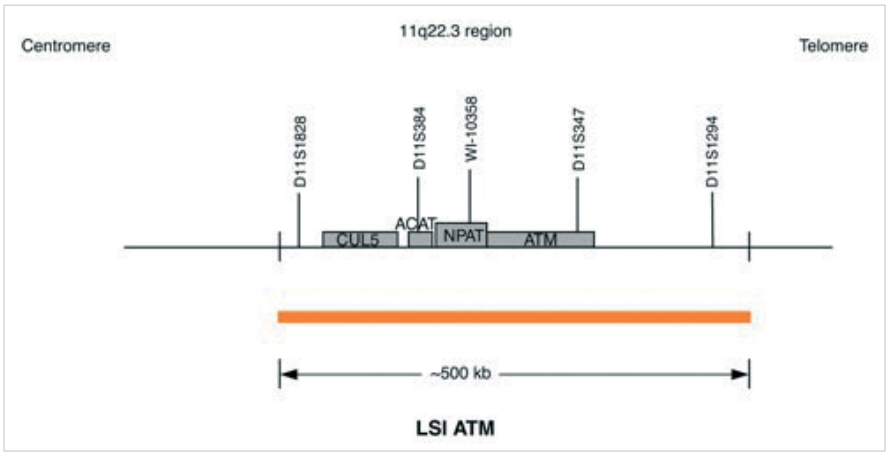
## LIMITATIONS

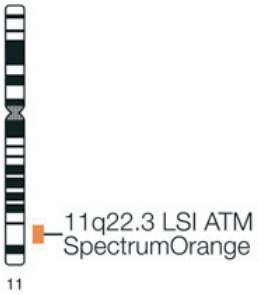
- The CEP 8 SpectrumOrange DNA Probe Kit has been characterized only for identifying chromosomes in nuclear preparations or metaphase spreads from bone marrow specimens.
- The clinical interpretation of any test results should be done in conjunction with standard cytogenetic analysis and should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
- Clinical specimens with >2.2% tri-signaled nuclei are considered to have an abnormal trisomy 8 clone. Those with ≤ 2.2% tri-signaled nuclei should be considered normal, although the presence of trisomy 8 is not completely excluded.
- The CEP 8 SpectrumOrange DNA Probe Kit is not intended for long term cell cultured materials such as amniocytes, fibroblasts and tumor cells.
- FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
- If significant peripheral blood contamination is present in the bone marrow specimen, the blood may dilute the specimen; it is important to recognize the potential effects this dilution effect may have on the FISH assay results.
- It is possible that patients may have chromosome polymorphism which may hybridize with CEP 8 probe. FISH metaphase analysis should be done in addition to FISH interphase analysis. Polymorphism was not investigated in the clinical trials.
- This assay will not detect the presence of other chromosome abnormalities frequently associated with hematological disorders.
- The efficacy of this assay for monitoring of trisomy 8 or disease progression has not been demonstrated.

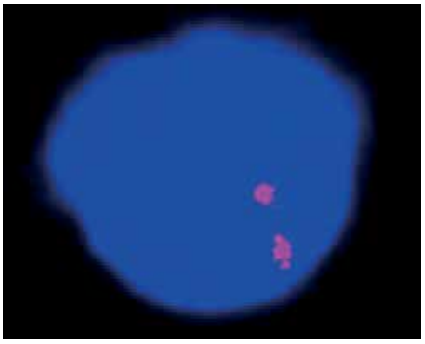
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 |

CHRONIC MYELOGENOUS LEUKEMIA

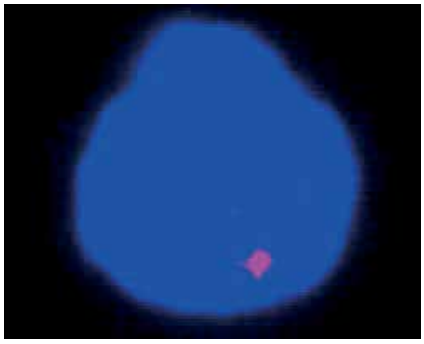
# Vysis LSI ATM (11q22.3) SpectrumOrange Probe



**Normal hybridization:** Result of the hybridization of the LSI ATM (11q22.3) Probe.



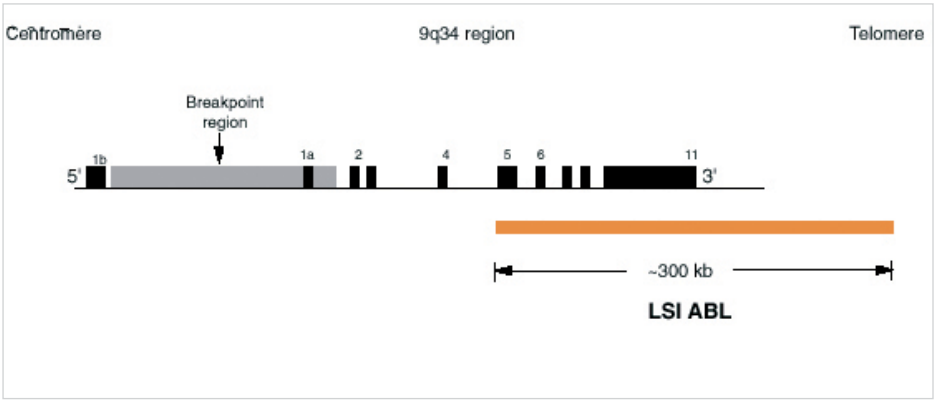
**Abnormal hybridization:** Cell hybridized with the LSI ATM (11q22.3) Probe. The cell in this image shows the one orange signal pattern.

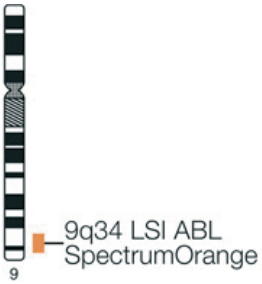
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI ATM (11q22.3) SpectrumOrange Probe **(ASR)** | 20 µL | 05J64-001 | 00884999012226 |

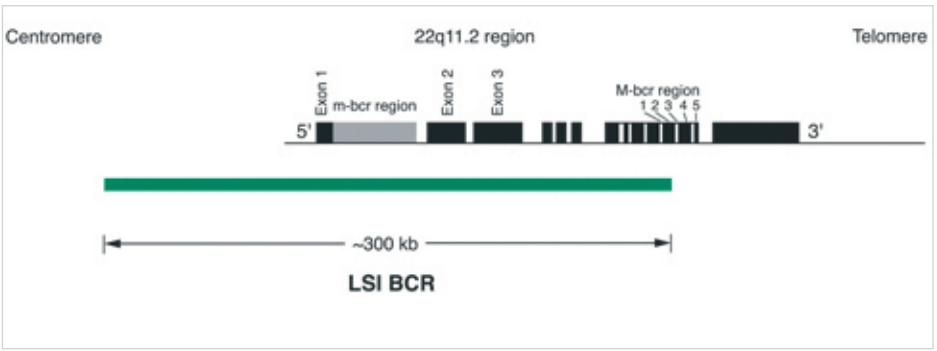
 Please note some products may not be for sale in all markets. Contact your local representative for availability.

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit





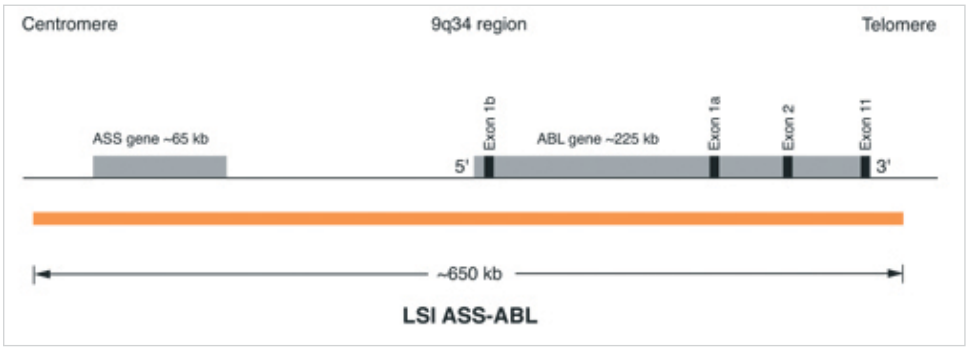
## PRODUCT DESCRIPTION

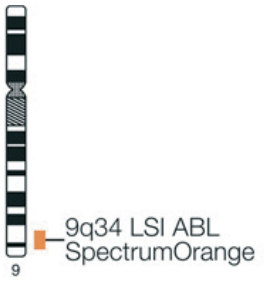
The LSI BCR/ABL Dual Color, Single Fusion Translocation Probe is a mixture of the LSI ABL probe labeled with SpectrumOrange and the LSI BCR probe labeled with SpectrumGreen. The ABL probe begins between exons 4 and 5 and continues for about 300 kb toward the telomere of chromosome 9. The LSI BCR probe begins between BCR exons 13 and 14 (M-bcr exons 2 and 3) and extends toward the centromere on chromosome 22 for approximately 300 kb, extending well beyond the m-bcr region.

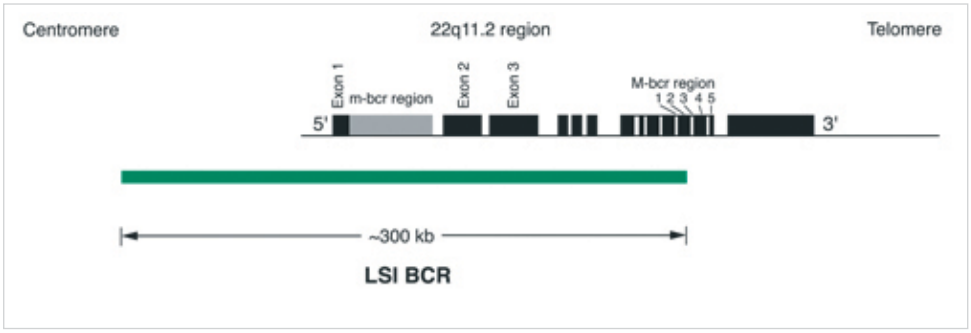
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L56-050 | 00884999031463 |

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit



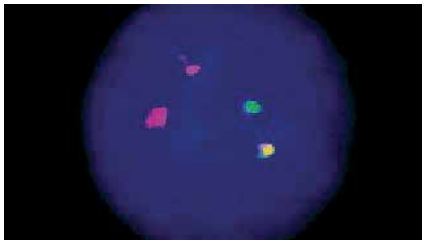


## PRODUCT DESCRIPTION

The BCR/ABL ES Dual Color Translocation Probe is a mixture of the LSI ABL probe labeled with SpectrumOrange and the LSI BCR probe labeled with SpectrumGreen. The spanning ABL probe is approximately 650 kb extending from an area centromeric of the ASS gene to well telomeric of the last ABL exon. The SpectrumGreen BCR probe is approximately 300 kb beginning between BCR exons 13 and 14 (M-bcr exons 2 and 3) and extending well beyond the m-bcr region.

## RESULTS OF HYBRIDIZATION

A nucleus lacking the t(9;22) will exhibit a two orange, two green(2O2G) signal pattern. In a nucleus possessing the t(9;22) involvingthe M-bcr, one green (native BCR), one large orange (native ABL), onesmaller orange (ES), and one fused orange/green signal (5' BCR/3' ABL),(2O1G1F) will be observed. Minor breakpoint (m-bcr) signal patterns mayappear as one orange, one green, and two fusion signals. In some cellsa deletion may occur 5' of the ABL breakpoint that may reduce the ESpattern to a single fusion pattern.



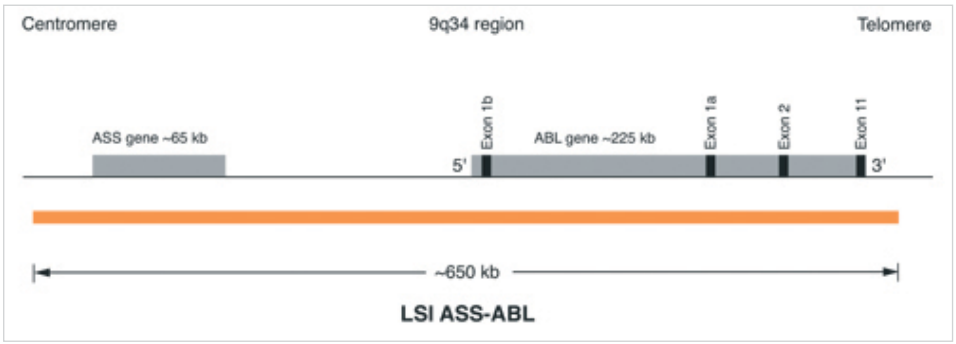
**Abnormal hybridization:** LSI BCR/ ABL ES Dual Color Translocation Probe hybridized to a nucleuscontaining the t(9;22) showing one green (native BCR), one large orange(native ABL), one smaller orange (ES) and one fused orange/ green(20IGIF) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 05J78-001 | 00884999012479 |

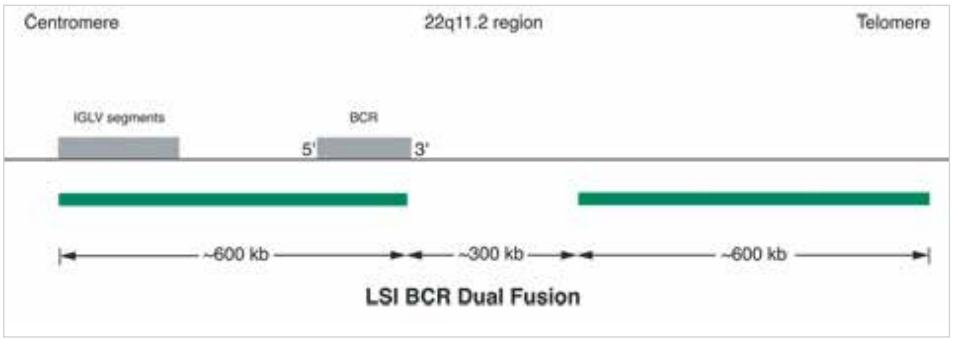
 Please note some products may not be for sale in all markets. Contact your local representative for availability.

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit







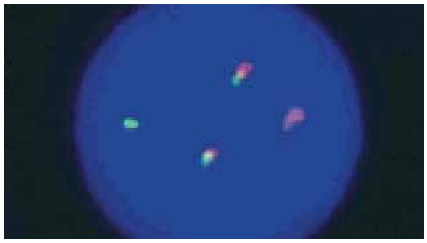


## PRODUCT DESCRIPTION

The LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe is a mixture of the LSI BCR probe labeled with SpectrumGreen and the LSI ABL probe labeled with SpectrumOrange. The spanning ABL probe has a genomic target of approximately 650 kb extending from an area centromeric of the argininosuccinate synthetase gene (ASS) to well telomeric of the last ABL exon. The BCR probe target spans a genomic distance of about 1.5 Mb. The BCR probe begins within the variable segments of the immunoglobulin lambda light chain locus (IGLV), extends along chromosome 22 through the BCR gene, and ends at a point approximately 900 kb telomeric of BCR. A region of about 300 kb containing low-copy number repeats has been eliminated from the probe which introduces a gap in the coverage of the probe target. Both probes span their respective breakpoints.

## RESULTS OF HYBRIDIZATION

A nucleus lacking the t(9;22) translocation will exhibit the two orange, two green (2O2G) signal pattern. In a nucleus containing a simple balanced t(9;22), one orange and one green signal from the normal 9 and 22 chromosomes and two orange/green (yellow) fusion signals, one each from the derivative 9 and 22 chromosomes, will be observed (1O1G2F). In some instances, deletions may occur 3' of the BCR breakpoint and/or 5' of the ABL breakpoint resulting in either an ES (extra orange or green) signal pattern or a single fusion pattern.



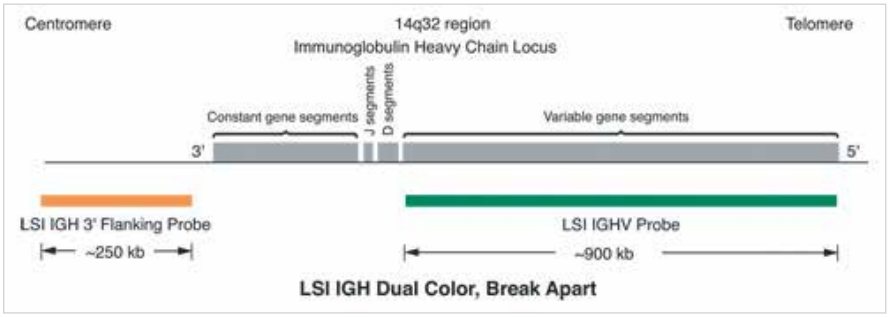
**Abnormal hybridization:** LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe hybridized to a nucleus containing a simple balanced t(9;22). One orange, one green and two orange/green fusion signals are observed (1O1G2F).

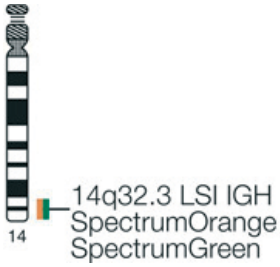
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L10-001 | 00884999031166 |
| | 50 µL | 08L10-002 | 00884999031173 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe



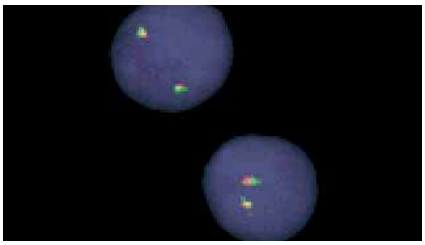

## PRODUCT DESCRIPTION

The LSI IGH Dual Color, Break Apart Rearrangement Probe is designed to detect chromosomal breakage of the immunoglobulin heavy chain (IGH) locus that is associated with 14q32 translocations involving a variety of other loci. Breakpoints within the IGH locus may occur at either the J segments [e.g., breakpoints commonly observed with t(14;18)] or within switch sequences located within the constant gene segments.

The LSI IGH Dual Color, Break Apart Rearrangement Probe is a mixture of two probes that hybridize to opposite sides of the J through constant regions of the IGH locus. The approximately 900 kb SpectrumGreen labeled LSI IGHV probe covers essentially the entire IGH variable region. The hybridization target of the approximately 250 kb SpectrumOrange labeled LSI IGH 3' flanking probe lies completely 3' to the IGH locus. As a result of this probe design, any translocation with a breakpoint at the J segments or within switch sequences should produce separate orange and green signals.

## RESULTS OF HYBRIDIZATION

When hybridized to a normal nucleus, the LSI IGH Dual Color, Break Apart Rearrangement Probe produces a two orange/green (yellow) fusion (2F) signal pattern. As there is no probe targeted to the J or constant regions, a slight gap between the two differently colored probe signals may sometimes be observed in nuclei from normal cells. When the IGH Dual Color, Break Apart Translocation Probe is hybridized to a nucleus containing an IGH translocation, one orange, one green, and one orange/green fusion signal pattern is observed (1O1G1F). This signal pattern indicates that the genomic targets for the LSI IGHV and LSI IGH 3' flanking probes have been physically separated as a result of the translocation. As V(D)J rearrangements may occur on either, or both, of the translocated and non-translocated IGH alleles, the green LSI IGHV probe signal intensity on either, or both, of the alleles may be diminished as a result of probe target deletion in some samples.



**Normal hybridization:** LSI IGH Dual Color, Break Apart Rearrangement Probe hybridized to nuclei exhibiting the expected two fusion (2F) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J73-001 | 00884999012394 |

CHRONIC MYELOGENOUS LEUKEMIA

# Vysis PDGFRB Break Apart FISH Probe Kit


## PRODUCT DESCRIPTION

The Vysis PDGFRB Break Apart FISH Probe Kit is intended to detect chromosomal rearrangements involving the platelet derived growth factor receptor beta (PDGFRB) gene at chromosome 5q32-q33 using the fluorescence in situ hybridization (FISH) technique.

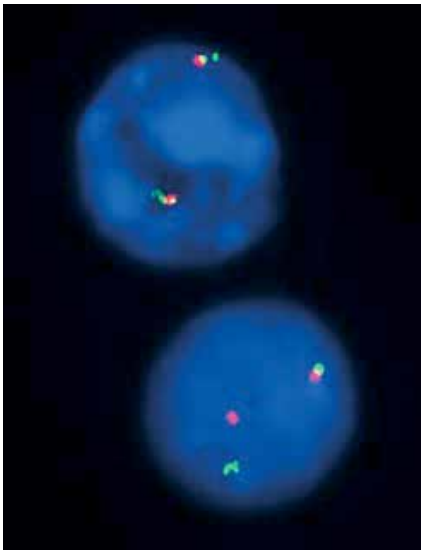
Rearrangement of the PDGFRB gene is a recurring abnormality in the semi-molecular myeloproliferative disease category of myeloid and lymphoid neoplasms with eosinophilia and abnormalities of the PDGFRA, PDGFRB, or FGFR1 genes. A rearrangement of the PDGFRB gene can result from a gene fusion to one of as many as fifteen different known partner genes.

The Vysis PDGFRB Break Apart FISH Probe Kit identifies rearrangements involving the PDGFRB gene by detecting the separation of the LSI PDGFRB SpectrumOrange and LSI PDGFRB SpectrumGreen probe signals resulting from chromosomal breakage between the hybridization targets of the two probes.

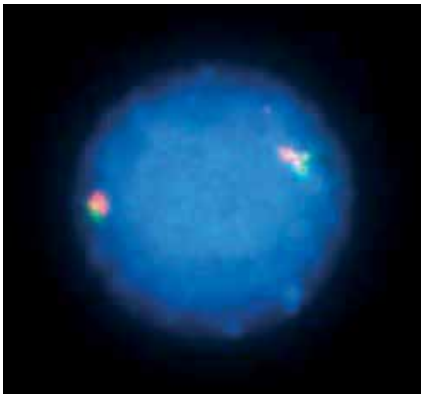
## RESULTS OF HYBRIDIZATION

The expected abnormal pattern of the Vysis LSI PDGFRB Break Apart Rearrangement Probe with a rearrangement involving the PDGFRB gene is one orange, one green, and one fusion signal. Other abnormal signal patterns may occur, and metaphase analysis may be helpful in characterization of such patterns.

The expected normal signal pattern of the Vysis LSI PDGFRB Break Apart Rearrangement Probe is two orange/green fusion signals that may be seen as adjacent orange/green signals slightly separated due to the gap between the two probes.



**Abnormal hybridization:** Vysis LSI PDGFRB Dual Color Break Apart Rearrangement Probe hybridized to abnormal nuclei containing one orange, one green and one fusion (1O1G1F) signal pattern and normal nuclei containing two fusion (2F) signal pattern.

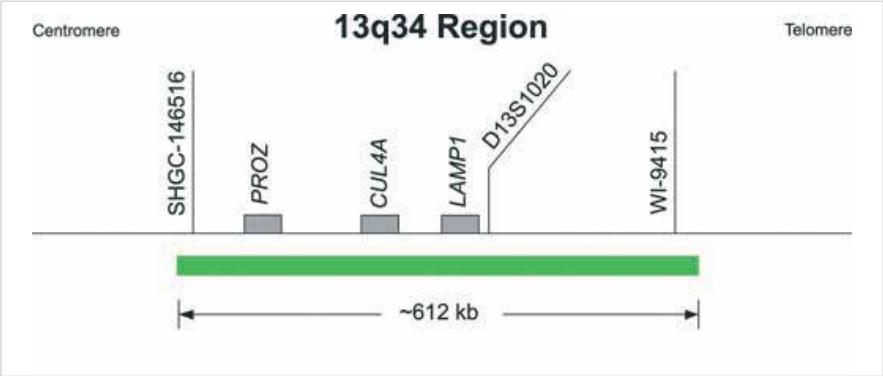


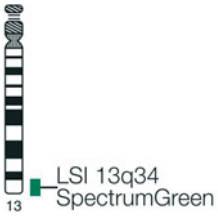
**Normal hybridization:** Vysis LSI PDGFRB Dual Color Break Apart Rearrangement Probe hybridized to normal nuclei containing two fusion (2F) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis PDGFRB Break Apart FISH Probe Kit **(CE)** | 10 µL | 06N24-010 | 00884999025585 |

MULTIPLE MYELOMA

# Vysis 13q34 SpectrumGreen FISH Probe Kit




## PRODUCT DESCRIPTION

This fluorescence in situ hybridization (FISH) probe is intended to detect the copy number of the LSI 13q34 probe target located at chromosome 13q34.

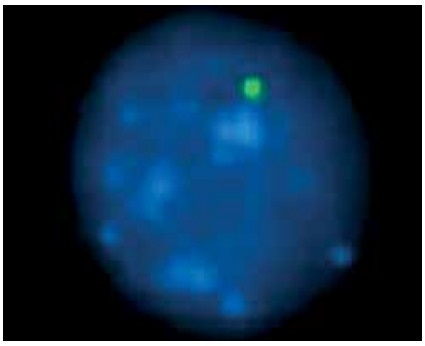
Genetic aberrations of chromosome 13, especially 13q- and monosomy, are common in hematopoietic disorders. Deletions of 13q14 have been detected in 30-50% of multiple myeloma patients. The differentiation of an interstitial deletion from loss of the entire q arm is made difficult for lack of a more telomeric marker. The LSI 13q34 probe is located near the telomere region of the q arm.

The Vysis LSI 13q34 SpectrumGreen Probe has been used to detect copy number abnormalities of the LSI 13q34 probe target in multiple myeloma samples.Results of Hybridization

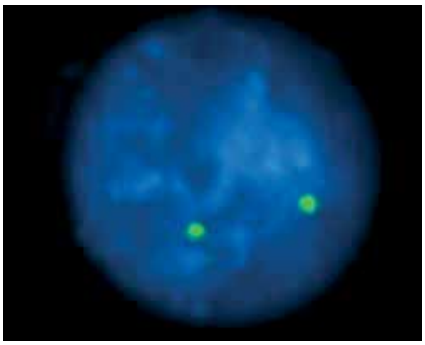
## RESULTS OF HYBRIDIZATION

In an abnormal cell that has lost the 13q34 region of chromosome 13, fewer than two green signals will be observed.

In a normal cell with two intact copies of chromosome 13, two green signals will be observed.



**Abnormal hybridization:** Abnormal cell hybridized with the LSI 13q34 Probe. The cell in this image shows deletion of one copy of the 13q34 region of chromosome 13 as indicated by the single green signal.



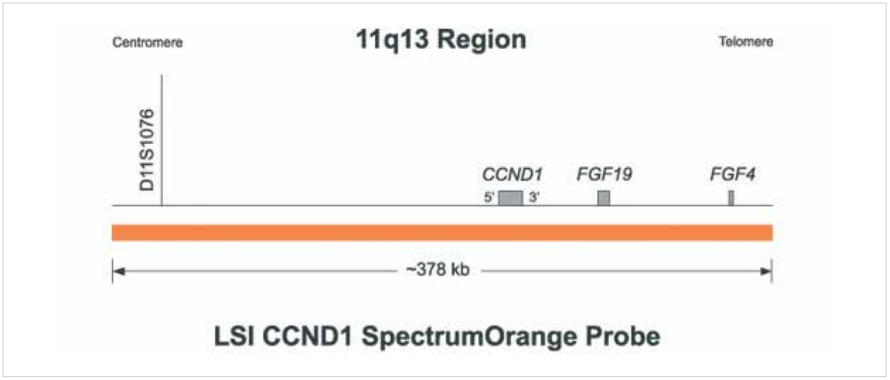
**Normal hybridization:** Result of the hybridization of the LSI 13q34 Probe as observed in a normal interphase cell.

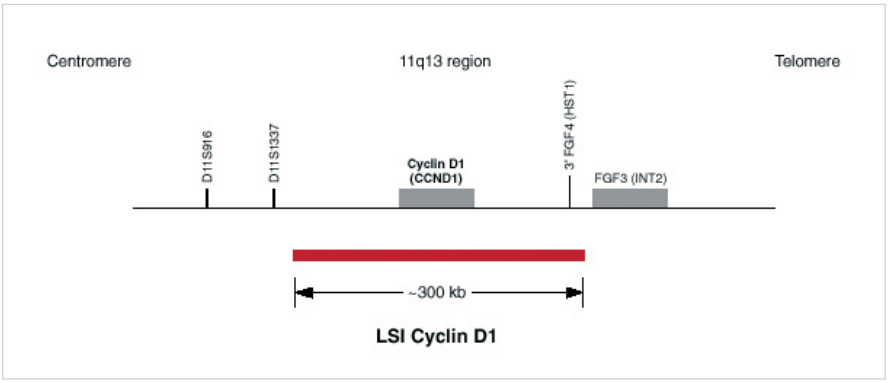
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis 13q34 SpectrumGreen FISH Probe Kit **(CE)** | 20 µL | 05N34-020 | 00884999014879 |

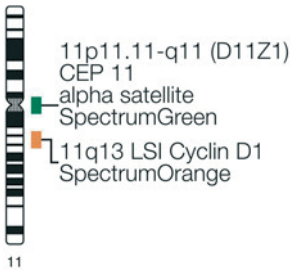
 Please note some products may not be for sale in all markets. Contact your local representative for availability.

MULTIPLE MYELOMA

# Vysis CCND1/CEP 11 FISH Probe Kit




## PRODUCT DESCRIPTION

Amplification of the chromosome 11q13 region, which harbors the Cyclin D1 (CCND1, PRAD1) oncogene, has been reported to occur in up to 15% of breast cancers. CCND1 amplification has been reported to be a prognostic marker.

Several studies used the Vysis CCND1/CEP 11 FISH Probe Kit to detect CCND1 amplification in breast cancer samples. Al-Karaya et al. analyzed a tissue microarray of 2197 breast cancer samples using the probe kit and found CCND1 amplification in 20.1% of cases. CCND1 amplification was associated with high tumor grade and a tendency toward shortened survival. Jirstrom et al. analyzed a tissue microarray of 500 breast cancer specimens from patients treated and not treated with adjuvant tamoxifen. The study found CCND1 amplification to be agonistic to tamoxifen with amplified patients having a significantly higher risk of recurrence.

The Vysis LSI CCND1 SpectrumOrange/CEP11 SpectrumGreen Probes have been applied to cancers other than breast cancer. For example, Katz et al. found elevated CCND1 copy number to be sensitive indicator of mantle cell lymphoma, and could distinguish mantle cell lymphoma from most other B-cell non Hodgkins lymphoma specimens.

The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/ CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

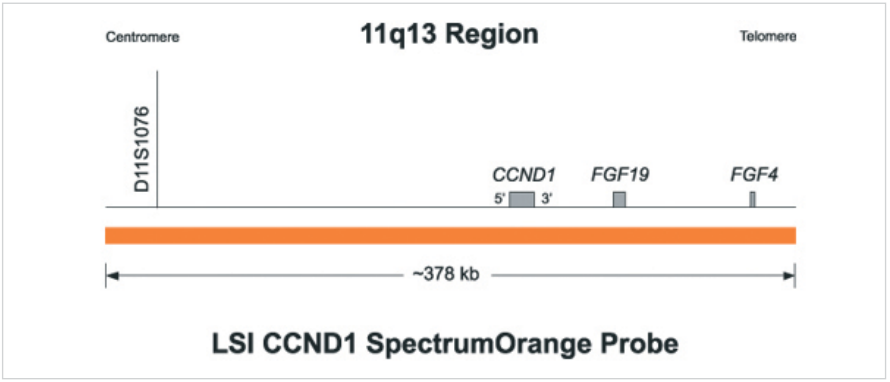
## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange orange signals. Other patterns may be observed if additional genetic alterations are present.

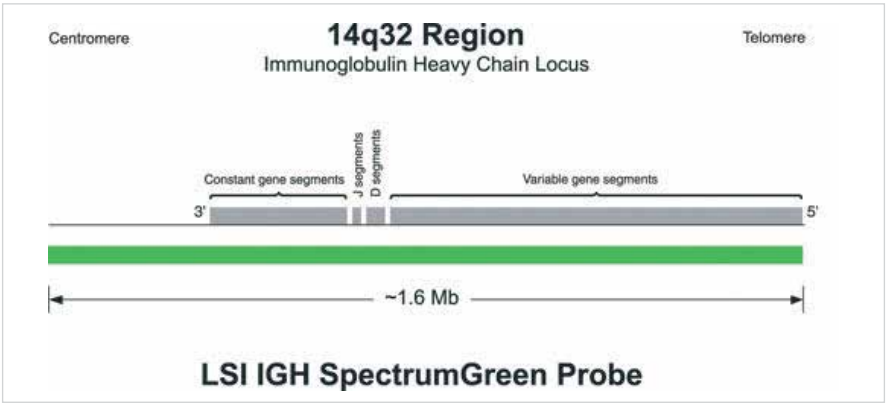
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 |

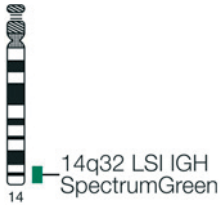
MULTIPLE MYELOMA

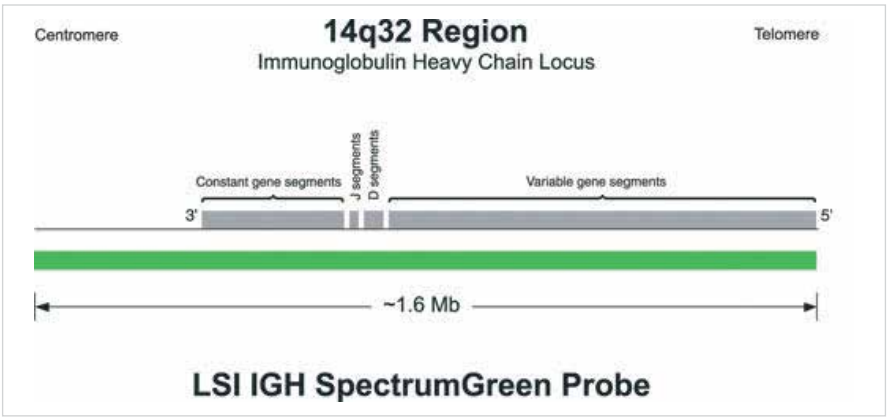
# Vysis IGH/CCND1 DF FISH Probe Kit








## PRODUCT DESCRIPTION

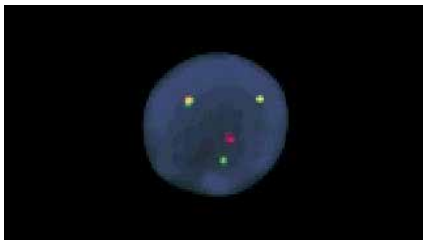
These fluorescence in situ hybridization (FISH) probes are intended to detect the t(11;14)(q13;q32) reciprocal translocation involving the IGH and CCND1 gene regions.

Mantle cell lymphoma is commonly associated with the balanced translocation t(11;14)(q13;q32). Mantle cell lymphoma has the most aggressive clinical course among the small cell lymphomas. FISH has emerged as an important aid in the diagnosis of mantle cell lymphoma. The Vysis LSI IGH/CCND1 Dual Color Dual Fusion Probes have been used in publications to detect t(11;14) in Mantle Cell Lymphoma.

## RESULTS OF HYBRIDIZATION

LSI IGH/CCND1 hybridized to a cell containing t(11;14) with breakpoints at the MTC on 11q13 and at the IGH J region on 14q32 is expected to result in a signal pattern of two orange/green (yellow) fusions, one on each of the abnormal chromosomes 11 and 14 and single orange and green signals from the normal chromosomes.

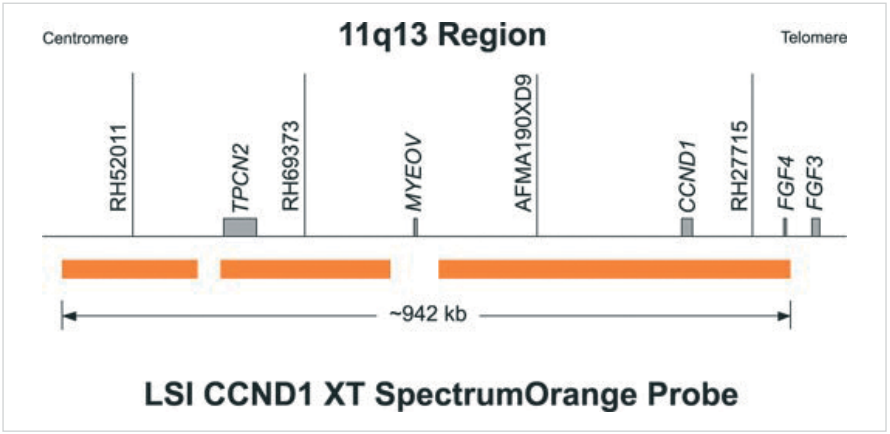
Due to the gap between the two probes in the IGH probe set, the normal IGH loci may sometimes appear as two slightly separated green signals. This gap may also cause a slight separation of the orange and green signals on the der(11) chromosome, in some instances. Analysis of t(11;14) samples suggests that due to variation in breakpoint location on 11q13 loss of V segments within the LSI IGH probe target, some samples containing t(11;14) might display signal patterns different than 1O1G2F.



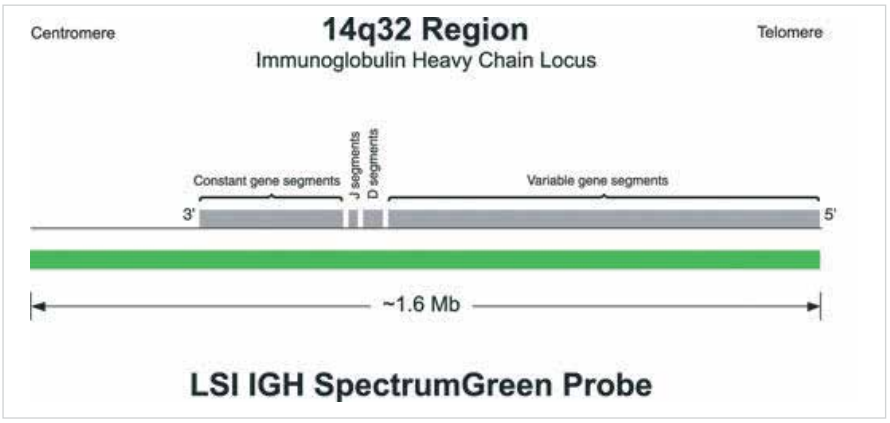
**Abnormal hybridization:** LSI IGH/CCND1 Dual Color, Dual Fusion Translocation Probe hybridized to an abnormal nucleus showing the common 1O1G2F signal pattern.

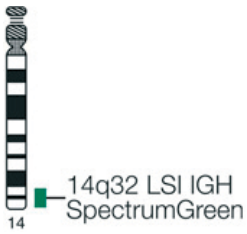
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis IGH/CCND1 DF FISH Probe Kit **(CE)** | 20 µL | 08L58-020 | 00884999031487 |

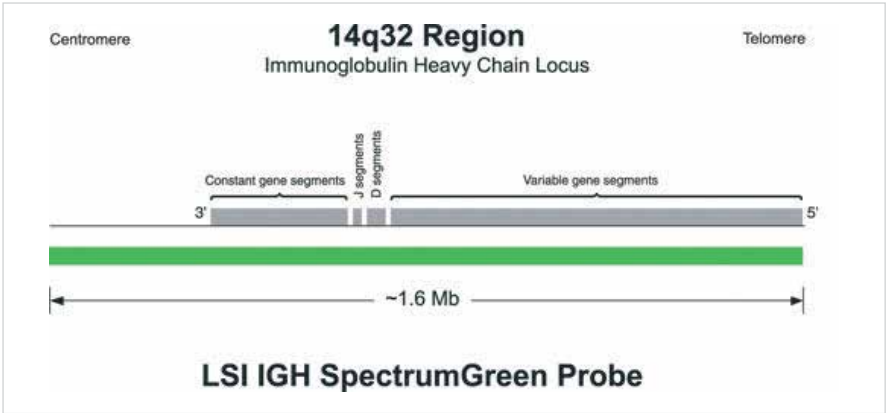
# Vysis IGH/CCND1 XT DF FISH Probe Kit







## PRODUCT DESCRIPTION

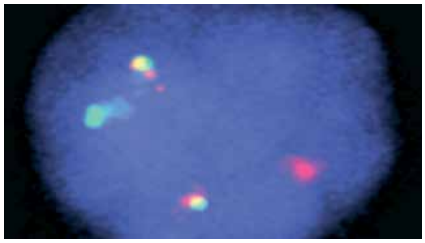
These fluorescence in situ hybridization (FISH) probes are intended to detect t(11;14)(q13;q32) reciprocal translocation involving the IGH and CCND1 gene regions.

The t(11;14)(q13;q32) is the most common translocation detected in myeloma. Patients with t(11;14) have been reported to have a bettersurvival and response to treatment particularly high dose therapy and stem cell support. The Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes have been used in publications to detect t(11;14).

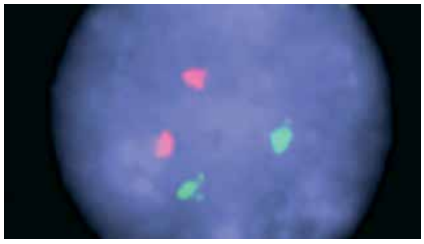
## RESULTS OF HYBRIDIZATION

In an abnormal cell containing the t(11;14), one orange (CCND1/MYEOV), one green (IGH), and two fusion signal pattern (der (11) and der (14)) may be observed. Some samples containing the t(11;14) may display signal patterns different than one orange, one green, and two fusions.

In a normal cell that lacks the t(11;14), a two orange and two green signal pattern will be observed reflecting the two intact copies of CCND1/MYEOV and IGH respectively.



**Abnormal hybridization:** An abnormal interphase cell hybridized with the Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes. The cell in this image shows the one orange (CCND1/MYEOV), one green (IGH), two fusion (der (11) and der (14)) signal pattern indicative of a t(11;14).

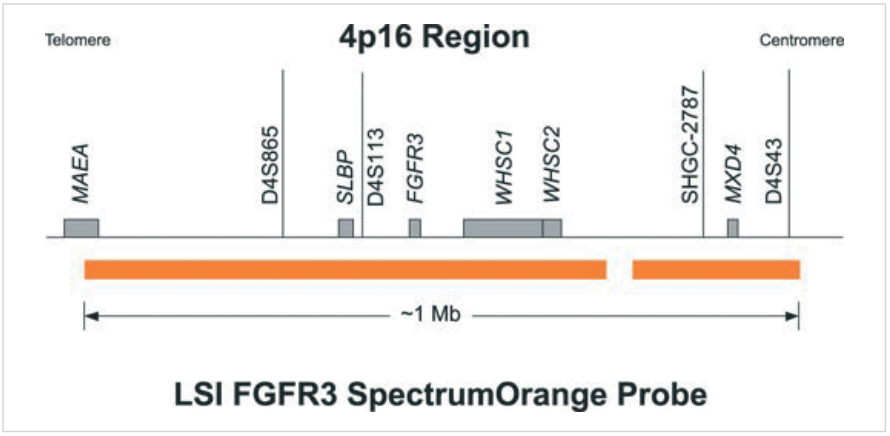


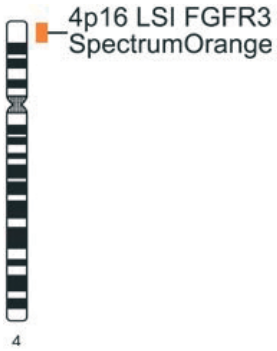
**Normal hybridization:** A normal interphase cell hybridized with the Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes. The cell shows the expected two orange (CCND1/MYEOV), two green (IGH) signal pattern.

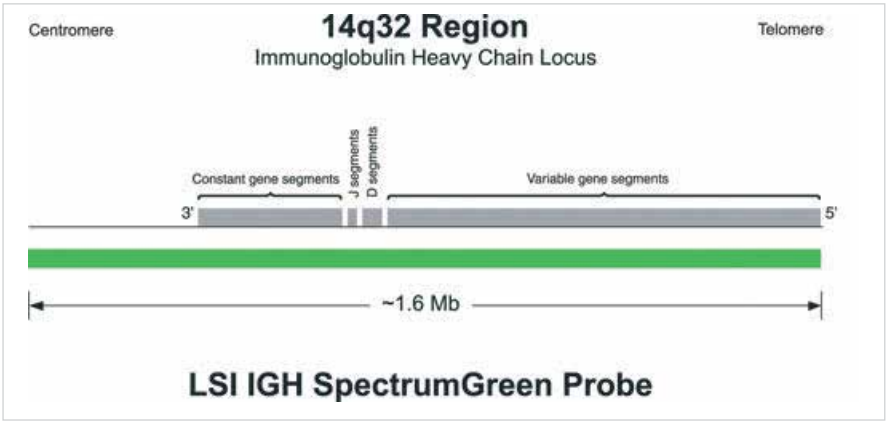
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis IGH/CCND1 XT DF FISH Probe Kit **(CE)** | 20 µL | 05N33-020 | 00884999014862 |

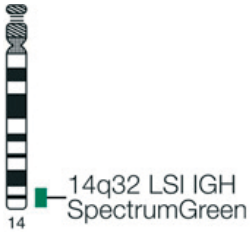
MULTIPLE MYELOMA

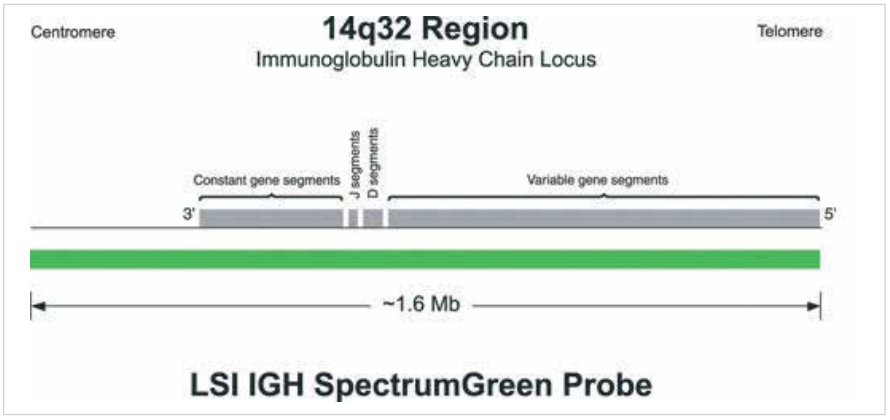
# Vysis IGH/FGFR3 DF FISH Probe Kit



## PRODUCT DESCRIPTION

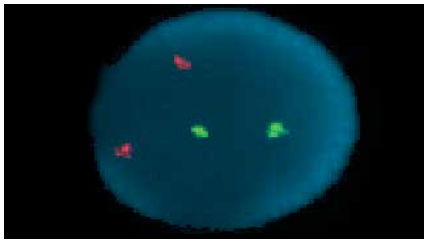
The Vysis IGH/FGFR3 DF FISH Probe Kit is intended to detect the t(4;14) (p16;q32) reciprocal translocation involving the FGFR3 and IGH gene regions.

The t(4;14)(p16;q32) is a common translocation in multiple myeloma (MM), but often missed by cytogenetics due to the telomeric chromosomal location of the regions involved in the translocation. The IFM99 trial demonstrates that the t(4;14) negatively impacted both event-free survival and overall survival in newly diagnosed symptomatic myeloma patients. FISH testing for t(4;14)( p16;q32) has been indicated as one of the minimum clinical tests during MM diagnosis and treatment determination.

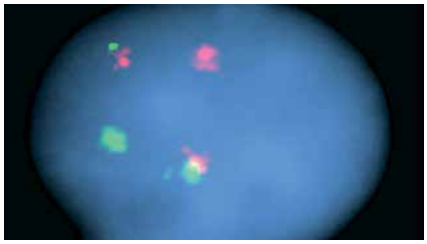
## RESULTS OF HYBRIDIZATION

In a normal cell that lacks the t(4;14), a two orange and two green signal pattern will be observed reflecting the two intact copies of the FGFR3 and IGH regions respectively.

In an abnormal cell containing the t(4;14), one orange (FGFR3), one green (IGH), and two fusion signalpattern (der (4) and der (14)) may be observed. Some samples containing the t(4;14) may display signal patterns differently than one orange, one green, and two fusions.



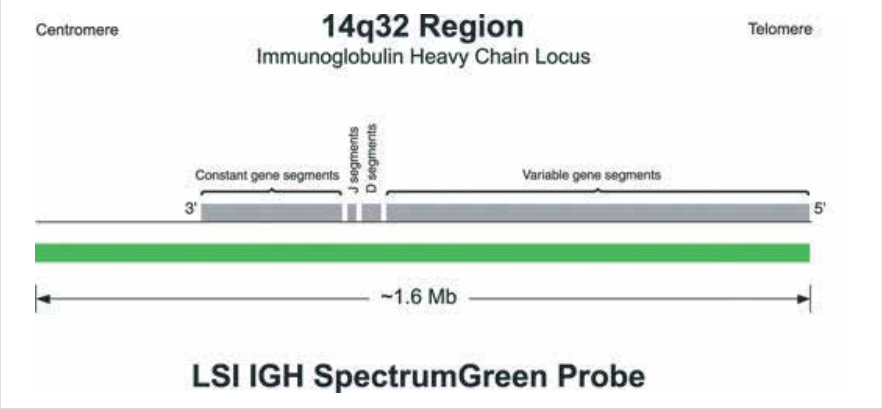
**Normal hybridization:** An interphase cell hybridized with the LSI IGH/FGFR3 Dual Color Dual Fusion Probe. The cell shows the two orange (FGFR3),two green (IGH) signal pattern.

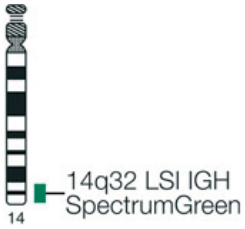


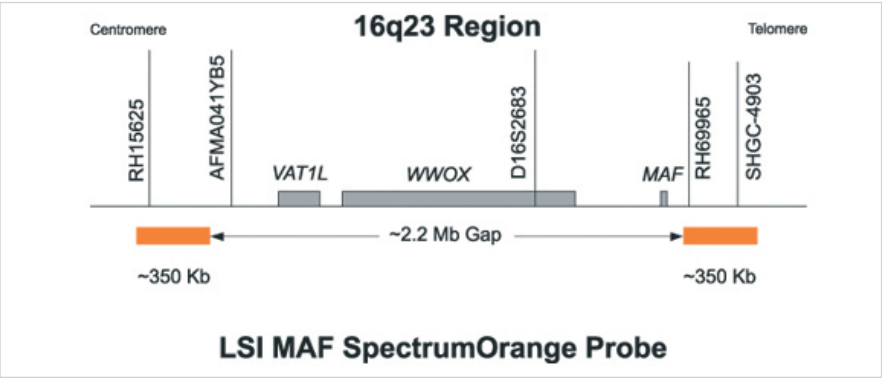
**Abnormal hybridization:** An interphase cell hybridized with the LSI IGH/FGFR3 Dual Color, Dual Fusion Probe. The cell in this image shows the one orange(FGFR3), one green (IGH), two fusion (der (4) and der (14)) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis IGH/FGFR3 DF FISH Probe Kit **(CE)** | 20 µL | 01N69-020 | 00884999000834 |
| Vysis LSI IGH/FGFR3 Dual Color Dual Fusion Probes **(ASR)** | 20 µL | 05J74-001 | 00884999012417 |

# Vysis IGH/MAF DF FISH Probes



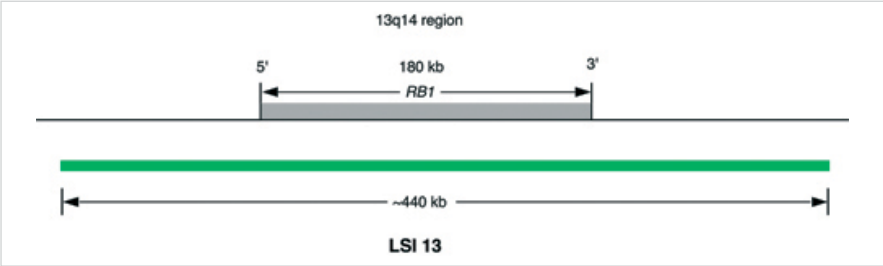



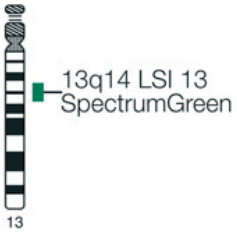


| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis IGH/MAF DF FISH Probes **(ASR)** | 20 µL | 05J84-004 | 00884999012691 |

MULTIPLE MYELOMA

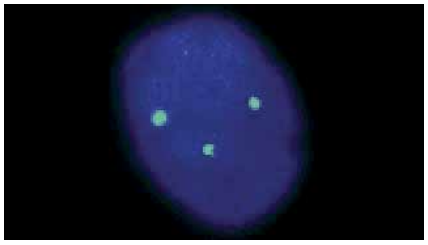
# Vysis LSI 13 (13q14) SpectrumGreen Probe




## PRODUCT DESCRIPTION

LSI 13 (13q14) consists of a set of overlapping clones that contain the RB1 gene and flanking regions. The RB1 gene is 180 kb. The probe extends beyond the gene for 110-170 kb in the 5' direction and approximately 120 kb in the 3' direction. The entire probe is approximately 440 kb in size.

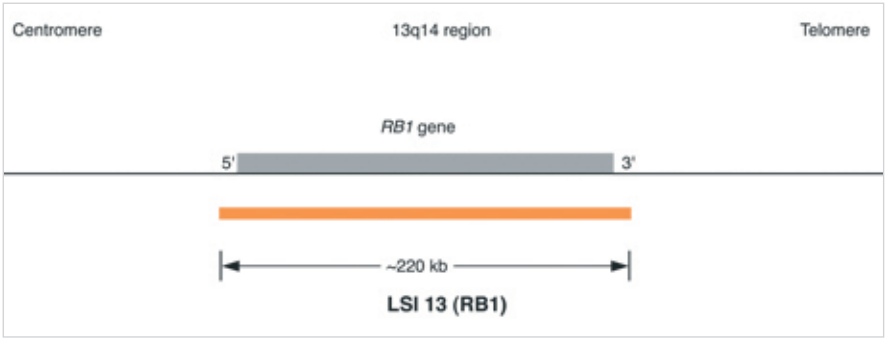


**Normal hybridization:** LSI 13 (13q14) SpectrumGreen hybridized to an amniocyte. Three green signals indicate three copies of chromosome 13

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 13 (13q14) SpectrumGreen Probe **(CE)** | 20 µL | 08L67-020 | 00884999031579 |

MULTIPLE MYELOMA

# Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe Kit





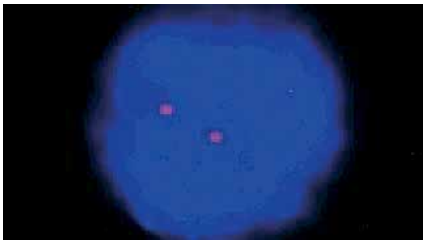
## PRODUCT DESCRIPTION

The LSI 13 (RB1) 13q14 SpectrumOrange Probe contains unique DNA sequences specific to the RB1 gene within the 13q14 region of chromosome 13. The presence or absence of the RB1 gene region may be detected using the LSI 13 (RB1) 13q14 Probe. This probe may be used to detect deletion (not mutation) of the RB1 gene locus.

The LSI 13 (RB1) 13q14 SpectrumOrange Probe is approximately 220 kb and contains sequences that target the entire RB1 gene.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected result for a nucleus hybridized with the LSI 13 (RB1) probe is a two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.

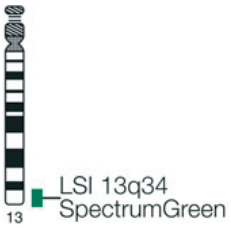


**Normal hybridization:** LSI 13 (RB1) 13q14 Probe hybridized to a normal nucleus showing a two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe **(CE)** | 20 µL | 08L65-020 | 00884999031555 |

MULTIPLE MYELOMA

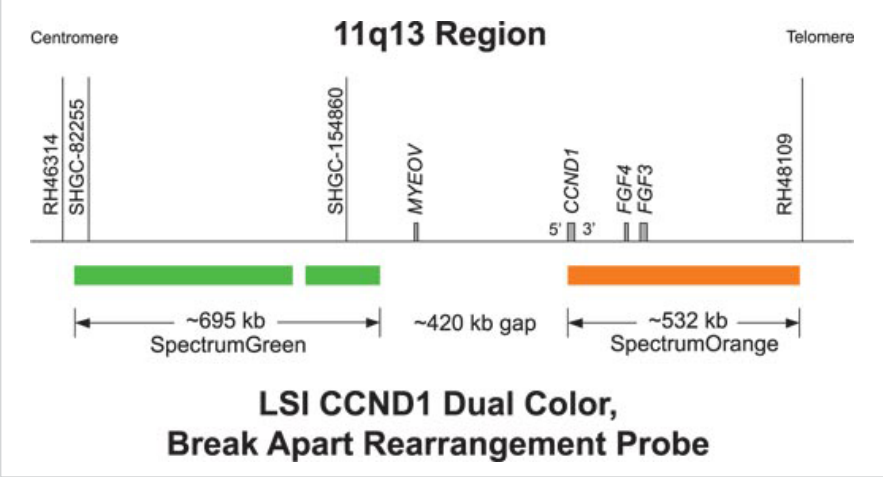
# Vysis LSI 13q34 SpectrumGreen Probe

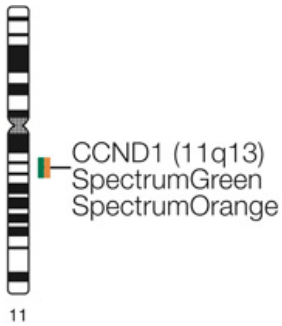



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 13q34 SpectrumGreen Probe **(ASR)** | 20 µL | 05J80-001 | 00884999012547 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit




## PRODUCT DESCRIPTION

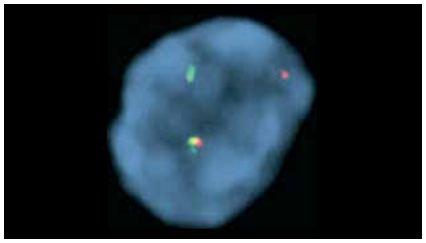
The CCND1 Dual Color Break Apart Rearrangement FISH probe is intended to detect chromosomal rearrangements involving the Cyclin D1 (CCND1) gene region at chromosome 11q13.

Mantle cell lymphoma (MCL) is an aggressive B-cell lymphoma and is commonly characterized by over-expression of CCND1 resulting from the t(11;14)(q13;q32) translocation. Over-expression of CCND1, which can result from chromosomal anomalies such as translocations or gain of the involved area, have been found to occur in multiple myeloma (MM) and MCL. The CCND1 Dual Color Break Apart Rearrangement Probe has been used to help identify rearrangement in the CCND1 breakpoint region in MCL.

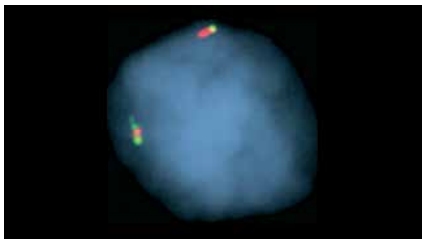
## RESULTS OF HYBRIDIZATION

The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 11 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals.



**Abnormal hybridization:** Abnormal cell hybridization using the LSI CCND1 (11q13) Dual Color Break Apart Rearrangement Probe.



**Normal hybridization:** Normal cell hybridization using the LSI CCND1 (11q13) Dual Color Break Apart Rearrangement Probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 05N38-020 | 00884999014909 |

MULTIPLE MYELOMA

# Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe

## PRODUCT DESCRIPTION

The LSI D13S25 Probe may be used to identify deletions in the 13q14.3 region. A candidate tumor suppressor gene may reside telomeric of the RB1 gene at 13q14. Deletion of the locus D13S25 at 13q14.3 occurs in a substantial number of cases without deletion of the RB1 gene.

The LSI D13S25 Probe is an approximately 160 kb SpectrumOrange labeled probe.

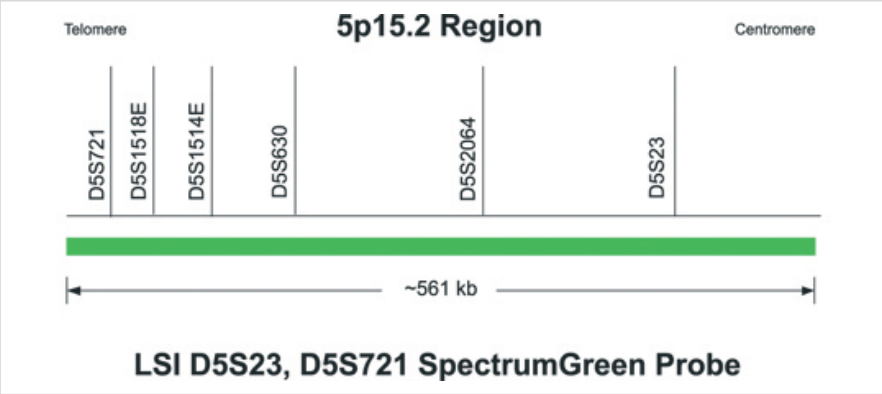

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the LSI D13S25 probe is the two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange (1O) signal pattern will be observed.

**Normal hybridization:** LSI D13S25 Single Color Probe hybridized to a normal metaphase showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI D13S25 (13q14.3) SpectrumOrange Probe **(CE)** | 20 µL | 01N37-020 | 00884999000797 |

# Vysis LSI D5S23, D5S721/CEP 9/CEP 15 FISH Probe Kit





## PRODUCT DESCRIPTION

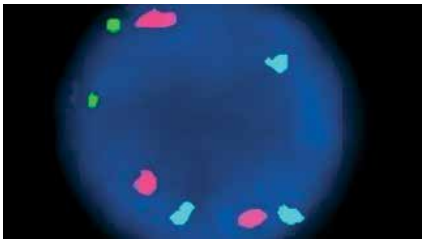
The Vysis D5S23, D5S721/CEP 9/CEP 15 FISH Probe Kit is intended to detect the copy number of the D5S23,D5S721, CEP 9 and CEP 15 probe targets located at5p15.2, 9p11.1-q11.1 and 15p11.1-q11.1, respectively, using FISH.

Hyperdiploidy is one of the cytogenetic subgroups of multiple myeloma (MM) and patients who exhibit hyperdiploidy are reported to have a better outcome than non-hyperdiploid patients. In a study of 205 MM patients, the Vysis D5S23,D5S721/CEP 9/CEP 15 FISH Probe Kit was used to detect hyperdiploidy. Six hundred fifty-seven patients of the IFM99 trial conducted by the Intergroupe Francophone du Mye´lome were also tested for hyperdiploidy using the Vysis D5S23, D5S721/CEP 9/CEP 15 FISH Probe Kit. Of these patients, 39% showed hyperdiploidy.

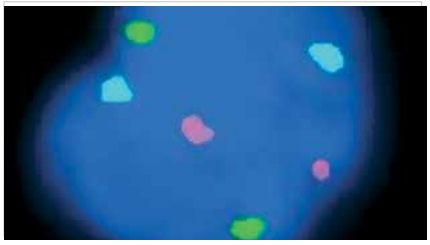
## RESULTS OF HYBRIDIZATION

In an abnormal cell containing hyperdiploidy of either chromosome 5, chromosome 9 or chromosome 15, greater than two signals will be observed for the respective chromosomes.

In a normal cell that lacks hyperdiploidy of chromosome 5, chromosome 9 and chromosome15, a two green, two aqua and two orange signal pattern will be observed reflecting the two copies of each chromosome.



**Abnormal hybridization:** An interphase cell hybridized with the LSI D5S23, D5S721/ CEP 9/CEP 15 Probe. The cell in this image shows a two green (LSI D5S23, D5S721), three aqua (CEP 9) and three orange (CEP 15) signal patterns.

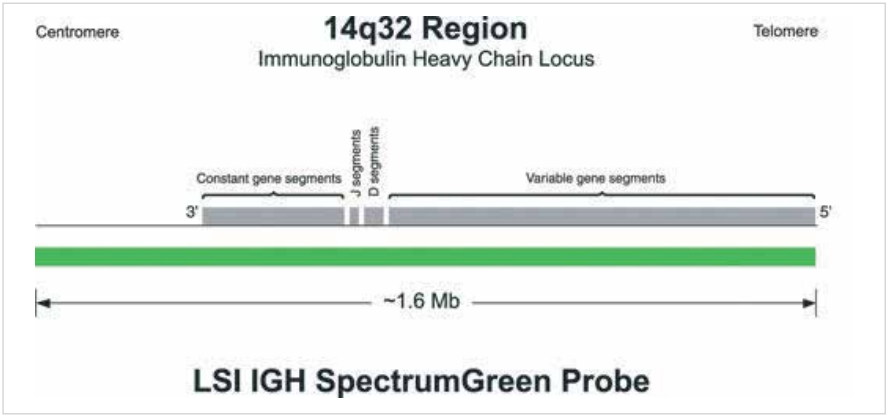


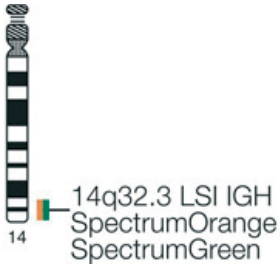
**Normal hybridization:** An interphase cell hybridized with the LSI D5S23, D5S721/ CEP 9/CEP 15 Probe. The cell shows the two green (LSI D5S23, D5S721), two aqua (CEP 9) and two orange (CEP 15) signal patterns.

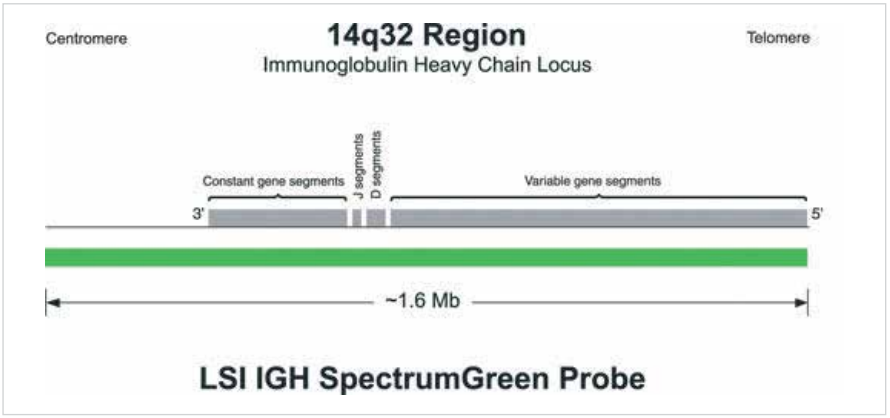
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI D5S23, D5S721/CEP 9/CEP 15 FISH Probe Kit **(CE)** | 20 µL | 05N35-020 | 00884999014886 |
| Vysis LSI D5S23/D5S721, Vysis CEP 9, Vysis CEP 15 Multi-Color Probe **(ASR)** | 20 µL | 05J84-007 | 00884999012721 |

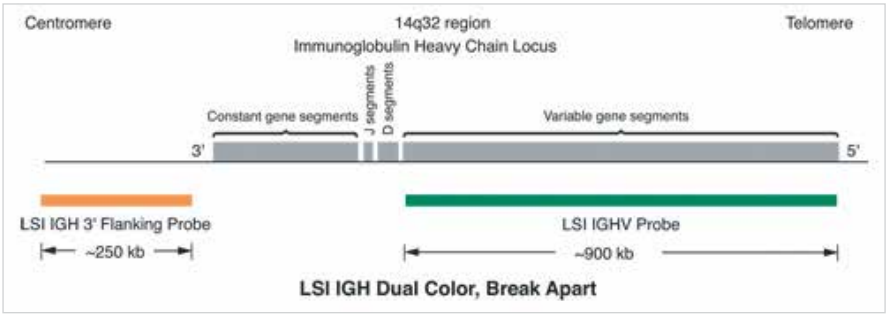
 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe Kit



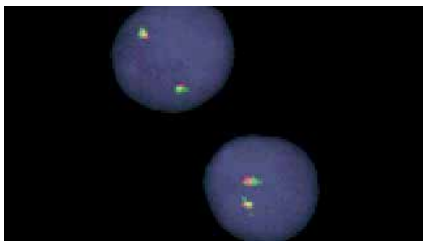
## PRODUCT DESCRIPTION

The LSI IGH Dual Color, Break Apart Rearrangement Probe is designed to detect chromosomal breakage of the immunoglobulin heavy chain (IGH) locus that is associated with 14q32 translocations involving a variety of other loci. Breakpoints within the IGH locus may occur at either the J segments [e.g., breakpoints commonly observed with t(14;18)] or within switch sequences located within the constant gene segments.

The LSI IGH Dual Color, Break Apart Rearrangement Probe is a mixture of two probes that hybridize to opposite sides of the J through constant regions of the IGH locus. The approximately 900 kb SpectrumGreen labeled LSI IGHV probe covers essentially the entire IGH variable region. The hybridization target of the approximately 250 kb SpectrumOrange labeled LSI IGH 3' flanking probe lies completely 3' to the IGH locus. As a result of this probe design, any translocation with a breakpoint at the J segments or within switch sequences should produce separate orange and green signals.

## RESULTS OF HYBRIDIZATION

When hybridized to a normal nucleus, the LSI IGH Dual Color, Break Apart Rearrangement Probe produces a two orange/green (yellow) fusion (2F) signal pattern. As there is no probe targeted to the J or constant regions, a slight gap between the two differently colored probe signals may sometimes be observed in nuclei from normal cells. When the IGH Dual Color, Break Apart Translocation Probe is hybridized to a nucleus containing an IGH translocation, one orange, one green, and one orange/green fusion signal pattern is observed (1O1G1F). This signal pattern indicates that the genomic targets for the LSI IGHV and LSI IGH 3' flanking probes have been physically separated as a result of the translocation. As V(D)J rearrangements may occur on either, or both, of the translocated and non-translocated IGH alleles, the green LSI IGHV probe signal intensity on either, or both, of the alleles may be diminished as a result of probe target deletion in some samples.

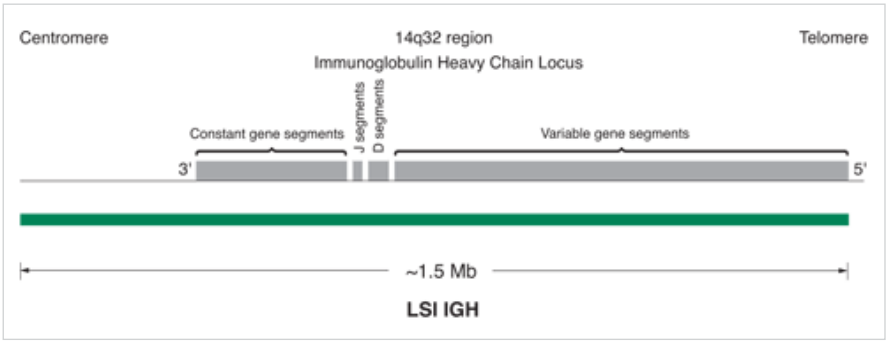


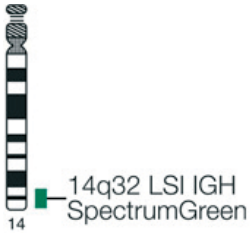
**Normal hybridization:** LSI IGH Dual Color, Break Apart Rearrangement Probe hybridized to nuclei exhibiting the expected two fusion (2F) signal pattern.

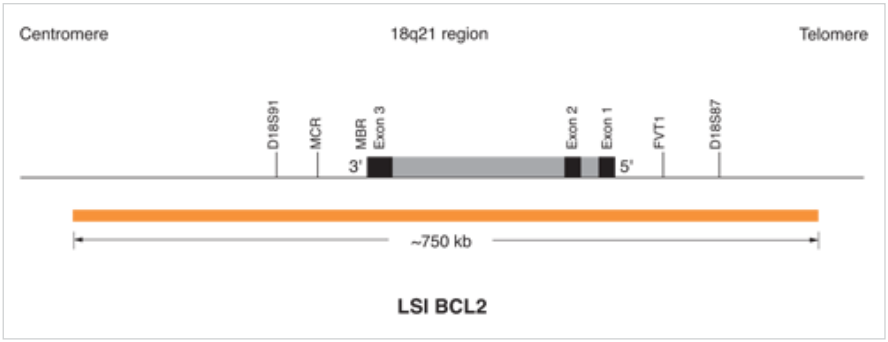
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L63-020 | 00884999031531 |

MULTIPLE MYELOMA

# Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe Kit



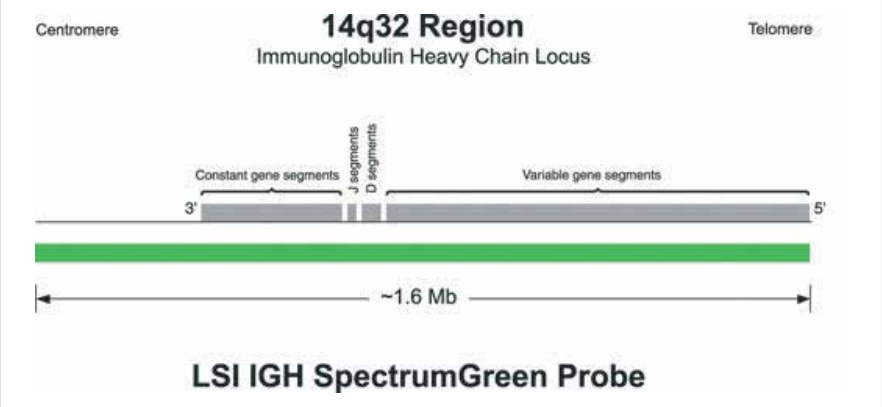



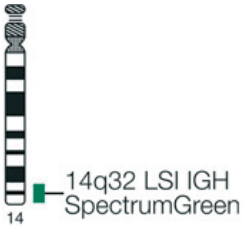


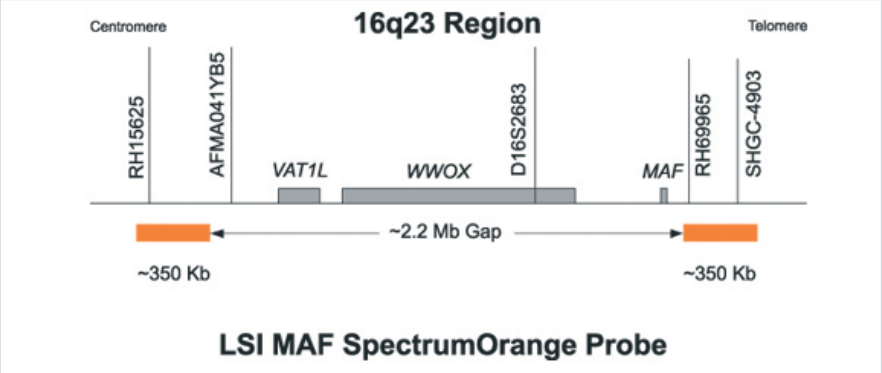
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 05J71-001 | 00884999012356 |

MULTIPLE MYELOMA

# Vysis IGH/MAF DF Probe Kit





## PRODUCT DESCRIPTION

The Vysis IGH/MAF DF FISH Probe Kit is intended to detect the t(14;16)(q32;q23) reciprocal translocation involving the IGH and MAF gene regions.

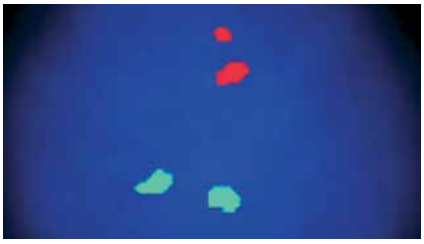
MAF is an oncogene that has been found to be over-expressed in multiple myeloma (MM). Recent studies have analyzed the effect of del(16q), perhaps due to loss of the WWOX gene, on prognosis in newly diagnosed MM and found an association with worse overall survival. Both MAF and WWOX genes are found in tandem on chromosome 16q23. t(14;16)(q32;q23) has been associated with more aggressive forms of MM. Thus, FISH testing for t(14;16)(q32;q23) has been indicated as one of the minimum clinical tests during MM diagnosis and treatment determination.

## RESULTS OF HYBRIDIZATION

In an abnormal cell containing the t(14;16), one green (IGH), one orange (MAF) and two fusion signal pattern (der (14) and der (16)) may be observed. Some samples containing the t(14;16) may display signal patterns different than one orange, one green and two fusions.

In a normal cell that lacks the t(14;16), a two green and two orange signal pattern will be observed reflecting the two intact copies of IGH and the MAF region respectively. Due to the presence of the ~2.2 Mb gap between the two SpectrumOrange labeled MAF probes, signal splitting of the orange probe may be observed in both normal and abnormal cells.

**Abnormal hybridization:** An interphase cell hybridized with the LSI IGH/MAF Dual Color, Dual Fusion Translocation Probe. The cell in this image shows the one green (IGH), one orange (MAF), two fusion (der (14) and der (16)) signal pattern indicative of a y(14;16).

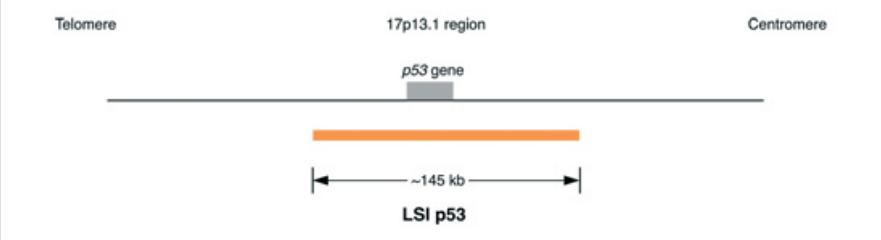


**Normal hybridization:** An interphase cell hybridized with the LSI IGH/MAF Dual Color, Dual Fusion Translocation Probe. The cell shows the two green (IGH), two orange (MAF) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH/MAF DF Probe Kit **(CE)** | 20 µL | 05N32-020 | 00884999014855 |

MULTIPLE MYELOMA

# Vysis LSI TP53 (17p13.1) SpectrumOrange Probe



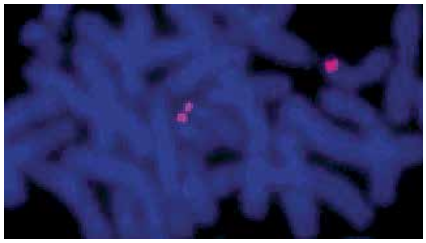


## PRODUCT DESCRIPTION

The LSI TP53 (previously designated as p53) Probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene. The ability to use FISH probes such as the LSI p53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the p53 locus.The LSI p53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.

## RESULTS OF HYBRIDIZATION

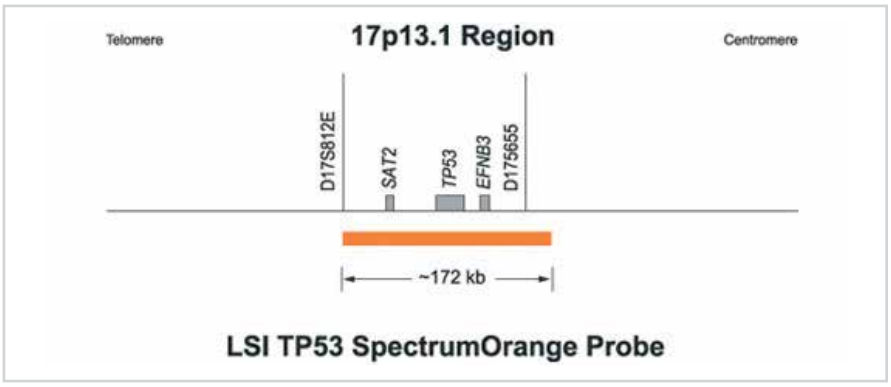
In a cell containing a deletion of the LSI p53 locus, one orange LSI p53 signal will be observed (1O signal pattern). In a cell harboring amplification of the p53 locus multiple copies of the orange signal will be observed. In a normal cell the two orange (2O) signal pattern is observed.



**Normal hybridization:** LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 |

# Vysis TP53 / CEP 17 FISH Probe Kit

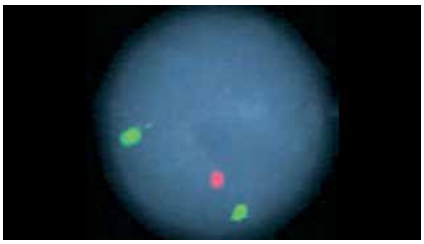




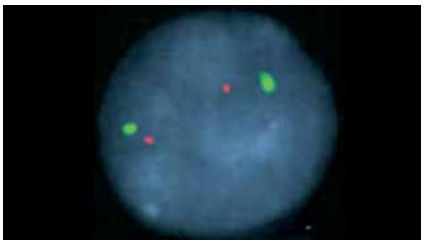
## PRODUCT DESCRIPTION

The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma. The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.



**Abnormal hybridization:** Nucleus showing the two green and one orange signal.



**Normal hybridization:** Nucleus showing the two green and two orange signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 |

MYELODYSPLASTIC SYNDROME

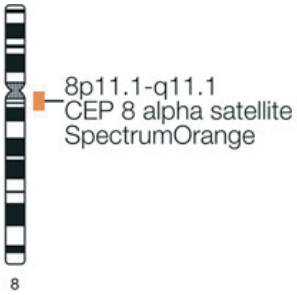
# Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit

## PRODUCT DESCRIPTION

CEP 8 is a SpectrumOrange labeled probe specific for the alpha satellite (centromeric) region, 8p11.1-q11.1.

The CEP 8 DNA Probe Kit which is available for in vitro diagnostic use and may be used as an adjunct to standard karotyping to identify and enumerate chromosome 8 in cells obtained from bone marrow. In multi-site clinical trials, the CEP 8 DNA Probe Kit for interphase analysis was 96% sensitive and 98% specific as compared to traditional cytogenetic analysis. A close association has been made between trisomy 8 and both myeloid blast crisis and basophilia. Trisomy 8 is a prevalent genetic aberration in several specific diseases:

- Chronic Myelogenous Leukemia (CML)
- Acute Myeloid Leukemia (AML)
- Myeloproliferative disorders (MPD)
- Myelodysplastic Syndrome (MDS)
- Other hematologic disorders not specified (HDNOS)



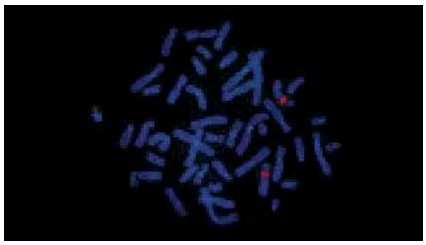

## CEP 8 SPECTRUMORANGE DNA PROBE KIT CONTENT

Components of the CEP 8 SpectrumOrange DNA Probe Kit include:

- CEP 8 SpectrumOrange alpha satellite DNA for centromere region 8p11.1-q11.1 predenatured in hybridization buffer (220 µL)
- NP-40 (detergent for wash solution: 1000 µL)
- DAPI II counterstain (300 µL)
- 20X SSC (66 g)
- Control slides for the CEP 8 kit are also sold separately. See Order No. 30-805000 and Order No. 30-805002.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the CEP 8 probe is a two orange (2O) signal pattern. In an abnormal cell containing trisomy 8, the expected pattern will be a three orange (3O) signal pattern.



**Normal hybridization:** CEP 8 SpectrumOrange hybridized to a normal cell showing two orange signals indicating two copies of chromosome 8.

## INTENDED USE

The CEP 8 SpectrumOrange DNA Probe Kit is intended to detect AT rich alpha satellite sequences in the centromere region of chromosome 8 in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosome 8 via fluorescence in situ hybridization (FISH) in interphase nuclei and in metaphase spreads of cells obtained from bone marrow in patients with myeloid disorders [Chronic myelogenous leukemia (CML), Acute myeloid leukemia (AML), Myeloproliferative disorder (MPD), Myelodysplastic syndrome (MDS), and Hematological disorders not otherwise specified (HDNOS)]. It is not intended to be used as a stand alone assay for test reporting. It is not intended for use in long term cell cultured materials such as amniocytes, fibroblasts and tumor cells.

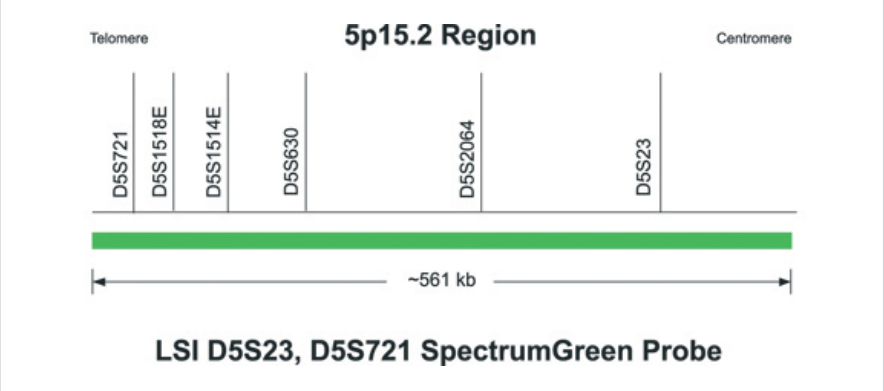
## LIMITATIONS

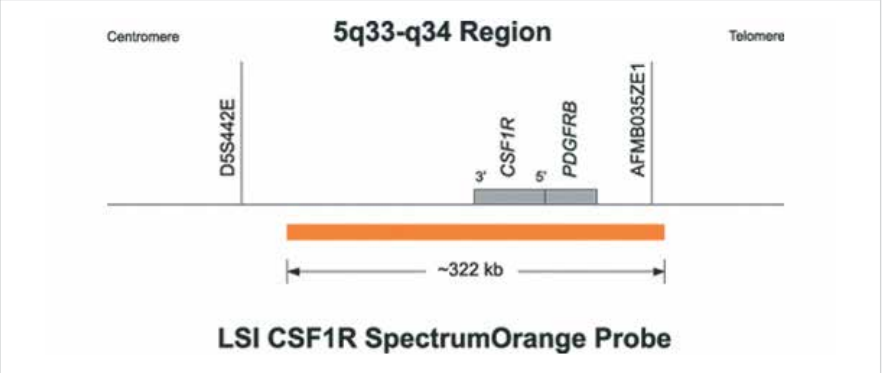
- The CEP 8 SpectrumOrange DNA Probe Kit has been characterized only for identifying chromosomes in nuclear preparations or metaphase spreads from bone marrow specimens.
- The clinical interpretation of any test results should be done in conjunction with standard cytogenetic analysis and should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
- Clinical specimens with >2.2% tri-signaled nuclei are considered to have an abnormal trisomy 8 clone. Those with ≤ 2.2% tri-signaled nuclei should be considered normal, although the presence of trisomy 8 is not completely excluded.
- The CEP 8 SpectrumOrange DNA Probe Kit is not intended for long term cell cultured materials such as amniocytes, fibroblasts and tumor cells.
- FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
- If significant peripheral blood contamination is present in the bone marrow specimen, the blood may dilute the specimen; it is important to recognize the potential effects this dilution effect may have on the FISH assay results.
- It is possible that patients may have chromosome polymorphism which may hybridize with CEP 8 probe. FISH metaphase analysis should be done in addition to FISH interphase analysis. Polymorphism was not investigated in the clinical trials.
- This assay will not detect the presence of other chromosome abnormalities frequently associated with hematological disorders.
- The efficacy of this assay for monitoring of trisomy 8 or disease progression has not been demonstrated.

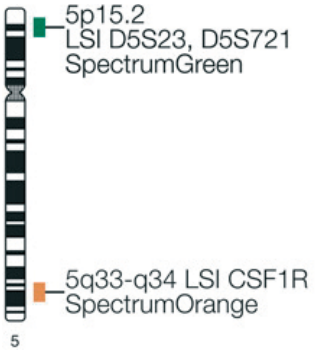
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 |

MYELODYSPLASTIC SYNDROME

# Vysis CSF1R/D5S23, D5S721 FISH Probe Kit




## PRODUCT DESCRIPTION

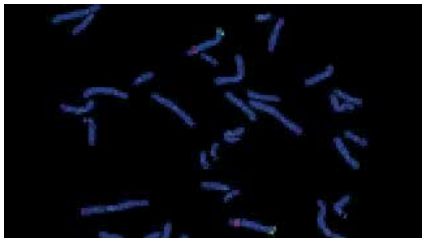
The LSI CSF1R and LSI D5S23, D5S721 fluorescence in situ hybridization (FISH) probes are intended to detect loss of the LSI CSF1R probe target in the chromosome 5q33-q34 region.

Commonly deleted regions (CDRs) have been defined on chromosome 5q for myeloid malignancies by FISH and other techniques. A 1.5 Mb CDR containing the CSF1R gene has been established for the 5q- syndrome, a specific type of myelodysplastic syndrome. The loss of the hybridization signal from one copy of the LSI CSF1R probe target may be used to establish a deletion within the 5q- syndrome CDR. The Vysis LSI CSF1R/D5S23, D5S721 Dual Color Probe has been used in several studies to determine deletion of the LSI CSF1R probe target.

The Vysis LSI CSF1R/D5S23, D5S721 Dual Color probe is a mixture of the approximately 322 kb SpectrumOrange labeled CSF1R probe and the approximately 561 kb SpectrumGreen labeled D5S23, D5S721 probe.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for the LSI CSF1R/D5S23, D5S721 probe is the two orange, two green (2O2G) signal pattern. In a hybridized abnormal cell containing the 5q33-q34 deletion, the one orange, two green (1O2G) signal pattern will be observed.

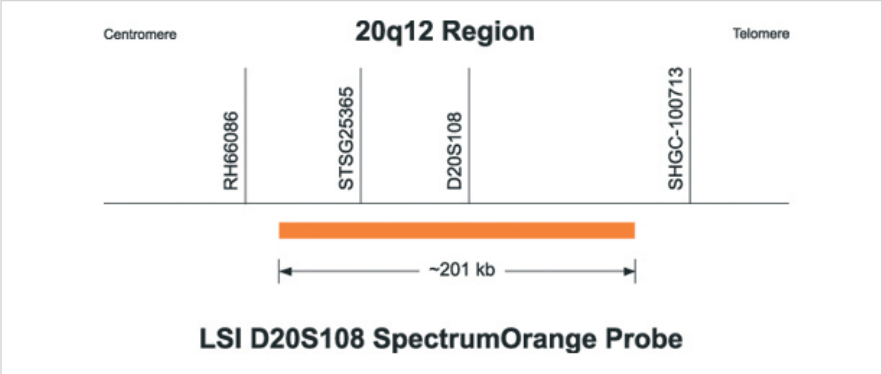


**Normal hybridization:** LSI CSF1R/D5S23, D5S721 Dual Color Probe hybridized to a normal metaphase cell showing the two orange, two green (2O2G) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CSF1R/D5S23, D5S721 FISH Probe Kit **(CE)** | 20 µL | 05N03-020 | 00884999014336 |

MYELODYSPLASTIC SYNDROME

# Vysis D20S108 FISH Probe Kit





## PRODUCT DESCRIPTION

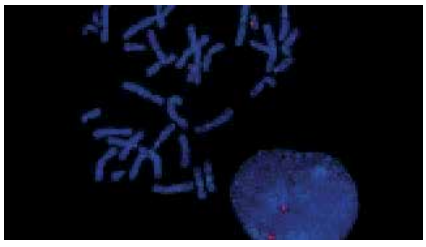
The Vysis LSI D20S108 fluorescence in situ hybridization (FISH) probe is intended to detect deletions of Vysis LSI D20S108 probe target locus on 20q12.

Acquired deletions of the long arm of chromosome 20 are found in ~4% of patients with a myelodysplastic syndrome (MDS) and in 1 to 2% of patients with acute myeloid leukemia (AML) and myeloproliferative disorders (MPD). Cytogenetic analysis of del(20q) revealed that the deletion is variable in size, with a commonly deleted region (CDR) spanning 20q11.2 to q12. Within the commonly deleted segment lies the SRC oncogene and possibly other tumor suppressor genes. The CDR is defined as a 2.7 Mb segment in MPD and a 2.6 Mb segment in AML/MDS, with an overlapping region of 1.7 Mb. In a study of 36 MPD, MDS, and AML patients with del(20q), statistical analyses showed that patients with del(20q) as a sole cytogenetic aberration (favorable subgroup) live longer than patients with del(20q) and other chromosomal changes (poor prognosis subgroup). Among patients from MDS, MPD and MDS/MPD groups, Douet-Guilbert et al identified one commonly deleted region in all 38 investigated samples using FISH, including the Vysis LSI D20S108 FISH Probe.

The Vysis LSI D20S108 Probe is an approximately 201 kb SpectrumOrange labeled probe and contains the D20S108 locus located on chromosome 20q12.

## RESULTS OF HYBRIDIZATION

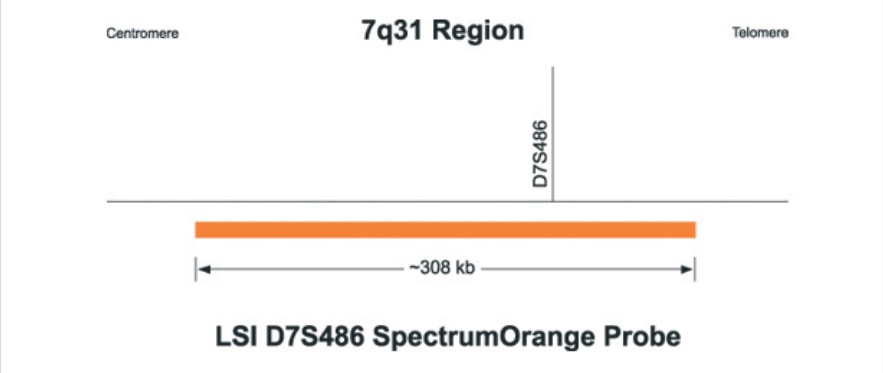
In a normal cell hybridized with the LSI D20S108 probe, the expected pattern is the two orange (2O) signal pattern. In an abnormal cell containing the deletion, the one orange (1O) signal pattern will be observed.

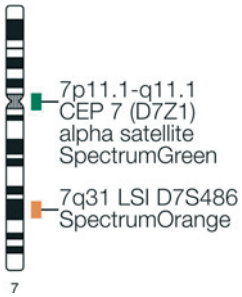


**Normal hybridization:** LSI D20S108 Single Color Probe hybridized to normal cells showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D20S108 FISH Probe Kit **(CE)** | 20 µL | 05N02-020 | 00884999014329 |

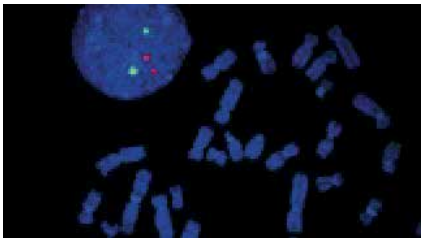
# Vysis D7S486/ Vysis CEP 7 FISH Probe Kit




## PRODUCT DESCRIPTION

The Vysis D7S486/ CEP 7 FISH Probe Kit is a device intended for specimen characterization and detects the LSI D7S486 probe target on chromosome 7q31 and the CEP 7 probe target on chromosome 7p11.1-q11.1 in bone marrow and peripheral blood specimens from patients with acute myeloid leukemia or myelodysplastic syndrome. The assay results are intended to be interpreted by a qualified pathologist or cytogeneticist. This device is not intended for high-risk uses such as selecting therapy, predicting therapeutic response or disease screening. The use of this device for diagnosis, prognosis, monitoring, or risk assessment has not been established.

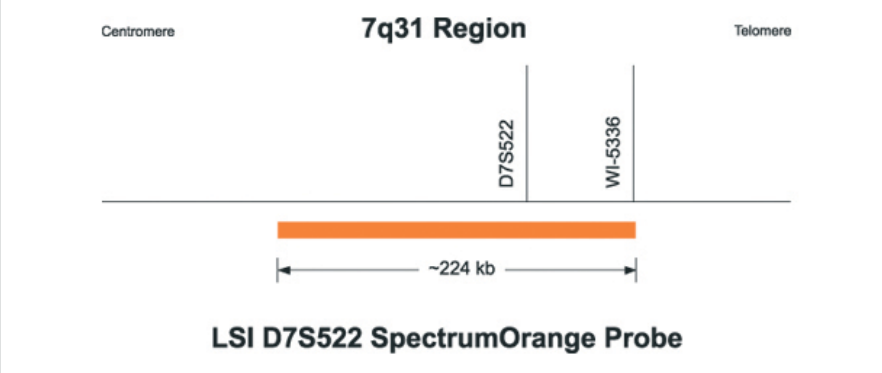


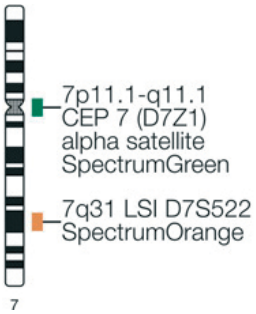
**Normal hybridization:** LSI D7S486/CEP 7 Dual Color Probe hybridized to a nucleus showing the two orange, two green (2O2G) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D7S486/ Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N07-020 | 00884999014367 |

MYELODYSPLASTIC SYNDROME

# Vysis D7S522/ Vysis CEP 7 FISH Probe Kit




## PRODUCT DESCRIPTION

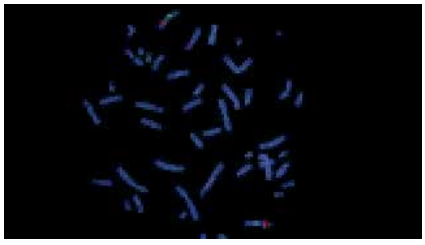
The Vysis D7S522/CEP7 FISH Probe Kit is intended to detect the copy number of the LSI D7S522 and CEP 7 probe targets located at chromosome 7q31 and 7p11.1-q11.1, respectively.

Monosomy 7 and loss of chromosome 7q are observed in a variety of myeloid malignancies such as myelodysplastic syndromes (MDS) and acute myeloid leukemia (AML). In some instances, these abnormalities are associated with patient outcome. The Vysis LSI D7S522 SpectrumOrange/CEP 7 SpectrumGreen Probes have been used to detect copy number abnormalities of the LSI D7522 and CEP7 probe targets in both AML and MDS.

The Vysis LSI D7S522 SpectrumOrange/CEP 7 SpectrumGreen Probes are a mixture of a SpectrumOrange D7S522 probe (7q31) and a SpectrumGreen CEP 7 probe (7p11.1-q11.1). The LSI D7S522 probe target is approximately 224 Kb in length. The CEP 7 probe targets the D7Z1 alpha satellite sequence at the centromere of chromosome 7.

## RESULTS OF HYBRIDIZATION

In a normal cell hybridized with the LSI D7S522/CEP 7 Probe, the expected pattern is the two orange, two green signal pattern. In an abnormal cell containing the deletion, the one orange, two green signal pattern will be observed.

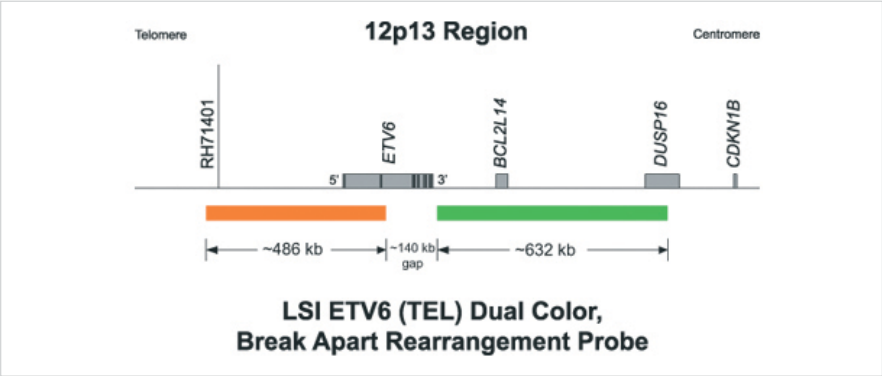


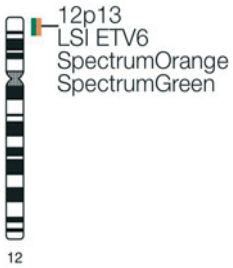
**Normal hybridization:** LSI D7S522/CEP 7 Dual Color Probe hybridized to a normal metaphase cell showing the two orange, two green signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D7S522/Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N08-020 | 00884999014374 |

MYELODYSPLASTIC SYNDROME

# Vysis ETV6 Break Apart FISH Probe Kit




## PRODUCT DESCRIPTION

The LSI ETV6 fluorescence in situ hybridization (FISH) probe set is intended to detect rearrangements of the ETV6 gene locus in the chromosome 12p13 region.

Rearrangements of the short arm of chromosome 12 are frequently recurring abnormalities found in a variety of hematologic malignancies of both myelocytic and lymphoid origin. They include balanced and unbalanced translocations which prevalently involve band 12p13. The ETV6 (TEL) gene is the most common target found to be rearranged with more than 40 chromosome bands. ETV6-RUNX1 (AML1) gene fusion resulting from a t(12;21) has been characterized as the most common genetic lesion in pediatric acute lymphoblastic leukemia (ALL) and is associated with a favorable outcome.

The Vysis LSI ETV6 Dual Color Break Apart Rearrangement Probe has successfully been used in disease and therapy monitoring of different poor prognosis AML cases.

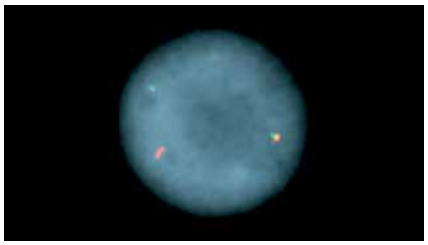
The Vysis LSI ETV6 (TEL) (12p13) Dual Color Break Apart Rearrangement Probe is a mixture of two probes. The 632 kb SpectrumGreen probe begins about 6 kb proximal to the ETV6 (TEL) gene and extends to toward the centromere. The SpectrumOrange probe begins within ETV6 intron 2 and extends toward the 12p telomere for approximately 490 kb. There is a gap between the two probes of about 140 kb.

## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals.

The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 12 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

**Normal hybridization:** Normal cell hybridization using the LSI ETV6 (TEL) (12p13) Dual Color, Break Apart Rearrangement Probe.

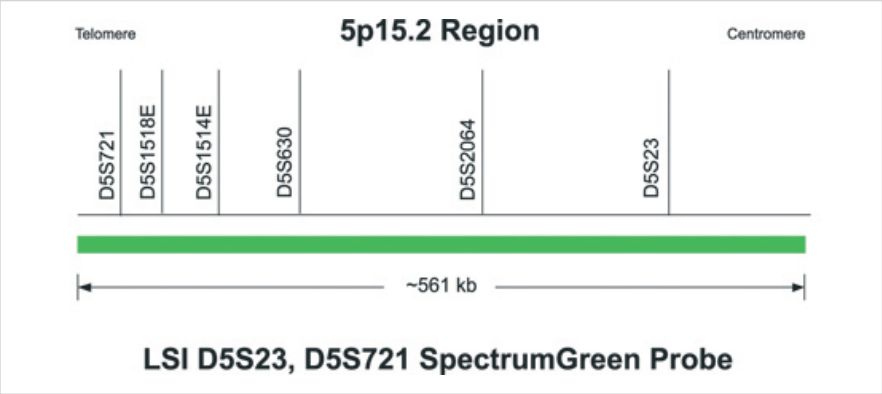


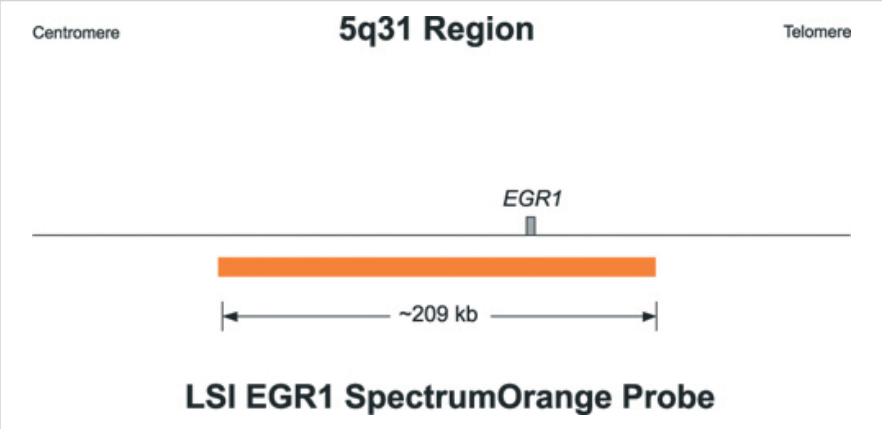
**Abnormal hybridization:** Abnormal cell hybridization using the LSI ETV6 (TEL) (12p13) Dual Color, Break Apart Rearrangement Probe.

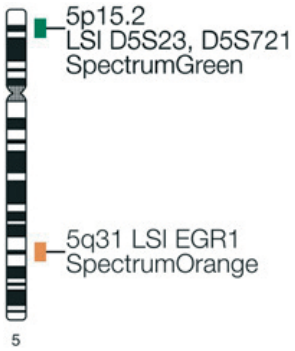
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ETV6 Break Apart FISH Probe Kit **(CE)** | 20 µL | 04N09-020 | 00884999007932 |

MYELODYSPLASTIC SYNDROME

# Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit



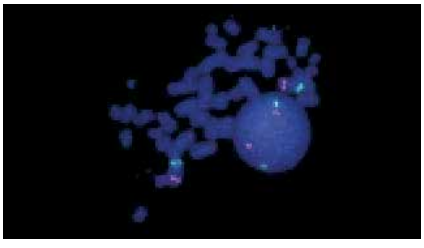




## PRODUCT DESCRIPTION

The LSI EGR1/D5S23, D5S721 Dual Color Probe may be used to detect deletions of 5q31 containing the EGR1 locus. The LSI D5S23, D5S721 probe aids in determining if the deletion is of the whole chromosome 5 (-5) versus 5q-.The LSI EGR1/D5S23, D5S721 Probe is a mixture of the approximately 200 kb SpectrumOrange labeled LSI EGR1 probe and the approximately 450 kb SpectrumGreen labeled LSI D5S23, D5S721 probe.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the LSI EGR1/D5S23, D5S721 probe is the two orange, two green (2O2G) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange, two green (1O2G) signal pattern will be observed.

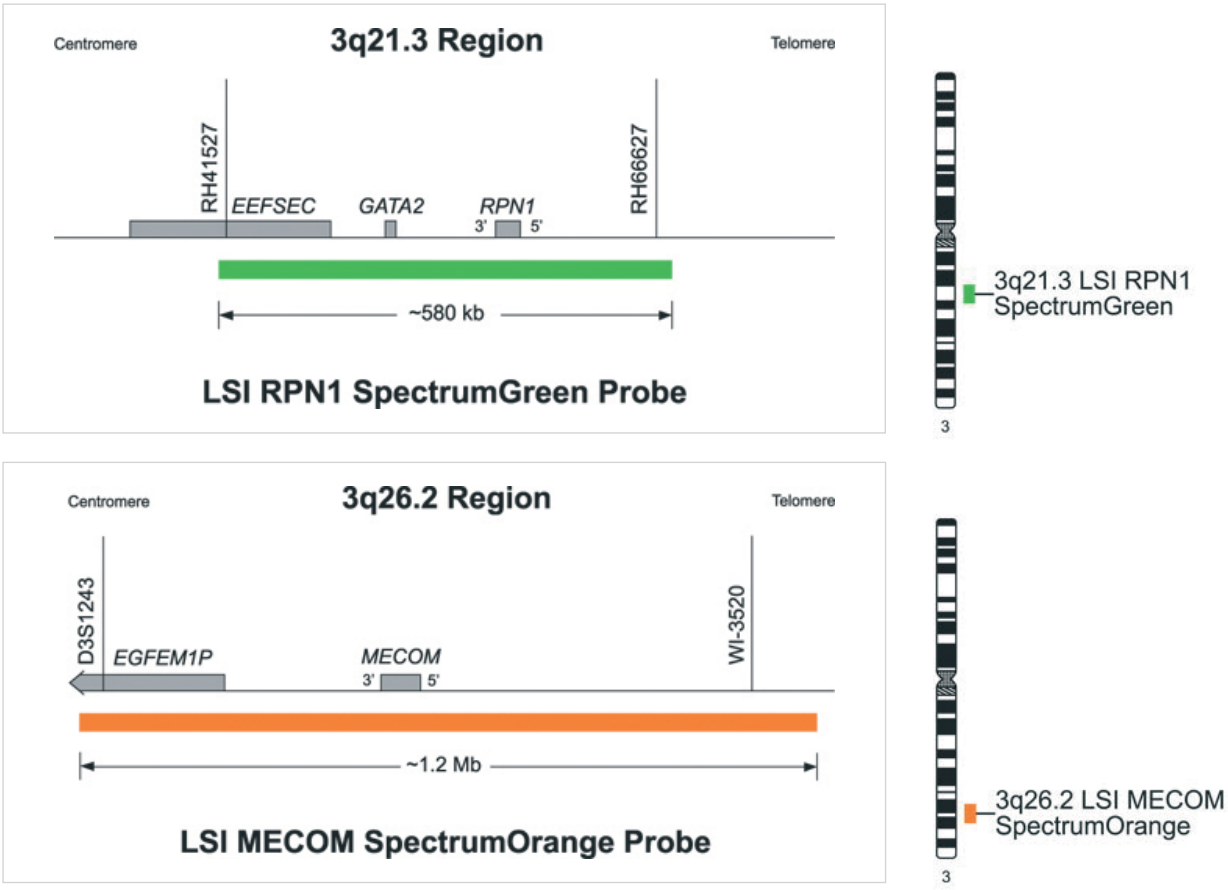


**Normal hybridization:** LSI EGR1/D5S721, D5S23 Dual Color Probe hybridized to normal cells showing the two orange, two green (2O2G) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit **(CE)** | 20 µL | 08L68-020 | 00884999031586 |

MYELODYSPLASTIC SYNDROME

# Vysis RPN1/MECOM DF FISH Probe Kit




## PRODUCT DESCRIPTION

The Vysis RPN1/MECOM DF FISH Probe Kit is intended to detect a fusion between the ribophorin I gene (RPN1) and the MDS1 and EVI1 complex locus gene (MECOM) using the fluorescence in situ hybridization (FISH) technique.

Acute myeloid leukemia (AML) with inv(3)(q21;q26.2) or t(3;3) (q21;q26.2) represents 1 to 2% of all AML. It has an aggressive disease course with short survival and poor response to chemotherapy. AML with inv(3)(q21;q26.2) or t(3;3) (q21;q26.2) is associated with an unfavorable prognosis. These abnormalities may also be found in a similar percentage of myelodysplastic syndromes (MDS). Due to the subtle appearance of this rearrangement, particularly inv(3), conventional cytogenetic chromosome analysis may miss these abnormalities.

The Vysis RPN1/MECOM DF FISH Probe Kit identifies rearrangements between the RPN1 gene and the MECOM locus by detecting the fusion of the Locus Specific Identifier (LSI) RPN1 SpectrumGreen and LSI MECOM SpectrumOrange probe signals resulting from chromosomal rearrangement between the hybridization targets of the 2 probes.

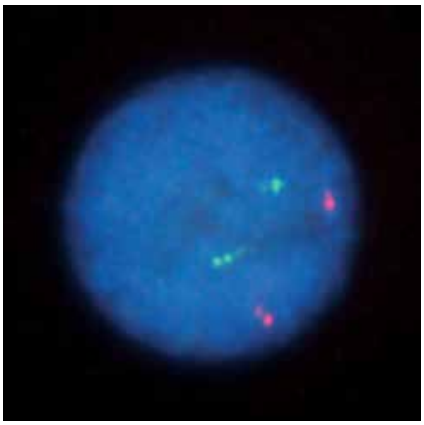
 

## RESULTS OF HYBRIDIZATION

The most frequently expected signal pattern of the Vysis LSI RPN1/MECOM Dual Color Dual Fusion Probes in abnormal specimens is 1 orange, 1 green, and 2 orange/green fusion signals. Other signal patterns may occur in abnormal specimens, and metaphase analysis may be helpful in characterization of such patterns.

The most commonly expected signal pattern of the Vysis LSI RPN1/ MECOM Dual Color Dual Fusion Probes in normal specimens is 2 orange and 2 green signals. Due to the proximity of the 2 probes on the q arm of chromosome 3, however, the orange and green signals may sometimes appear as a fusion in a normal nucleus. This effect can produce a pattern of 1 orange, 1 green, and 1 orange/green fusion signal or, more rarely, 2 orange/green fusion signals.

**Abnormal hybridization:** Vysis LSI RPN1/ MECOM Dual Color Dual Fusion Probes hybridized to a nucleus containing a simple balanced t(3;3)(q21.3;q26.2). One orange, one green and two orange/green fusion signals are observed.

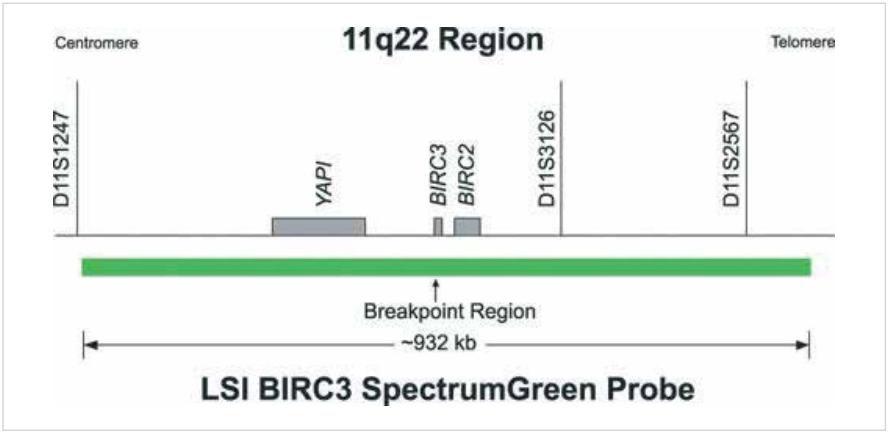


**Normal hybridization:** Vysis LSI RPN1/ MECOM Dual Color Dual Fusion Probes hybridized to a nucleus containing non-rearranged RPN1 and MECOM regions. Two orange and two green signals are observed.

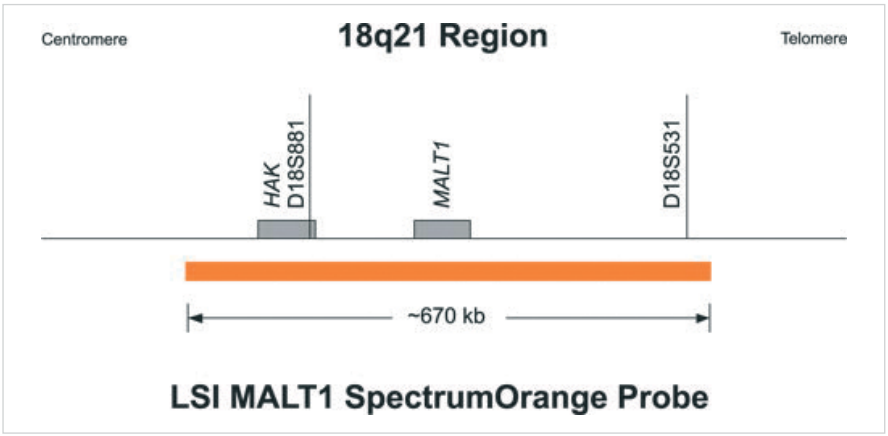
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis RPN1/MECOM DF FISH Probe Kit **(CE)** | 10 µL | 06N60-010 | 00884999034914 |

NON-HODGKINS LYMPHOMA

# Vysis LSI BIRC3/MALT1 DF Fish Probe Kit









## PRODUCT DESCRIPTION

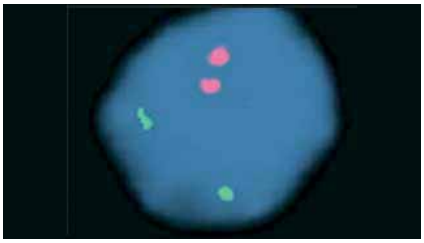
The Vysis BIRC3/MALT1 DF FISH Probe Kit is intended to detect the t(11;18)(q21;q21) reciprocal translocation involving the BIRC3 (also know as API2) and MALT1 gene regions using the fluorescence in situ hybridization (FISH) technique.

The t(11;18)(q21;q21) translocation is the most common chromosomal translocation found in mucosa-associated lymphoid tissue (MALT) lymphoma and is the most common in gastric MALT lymphoma. Thet(11;18)(q21;q21) translocation is associated with failure to respond toHelicobacter pylori5 eradication and an aggressive disease. The VysisLSI BIRC3/MALT1 Dual Color Dual Fusion probe has been used to identify the t(11;18)(q21;q21) translocation in published reports.

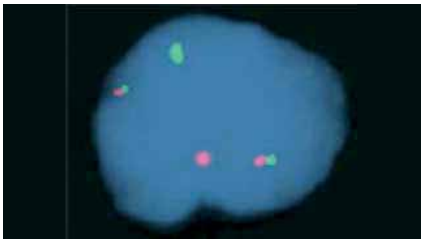
## RESULTS OF HYBRIDIZATION

In a normal cell that lacks the t(11;18)(q21;q21) translocation, a two orange, two green signal pattern will be observed reflecting the two intact copies of MALT1 and BIRC3, respectively.

In an abnormal cell containing the t(11;18)(q21;q21) translocation, a one orange (MALT1), one green (BIRC3), and two fusion (BIRC3/MALT1 and MALT1/BIRC3) signal pattern will be observed. Some samples containing the t(11;18) may display signal patterns differently than the one orange, one green, and two fusions.



**Normal hybridization:** Result fo the hybridization of the LSI BIRC3/MALT1 Dual Color Dual Fusion Probes as observed in normal interphase cells.

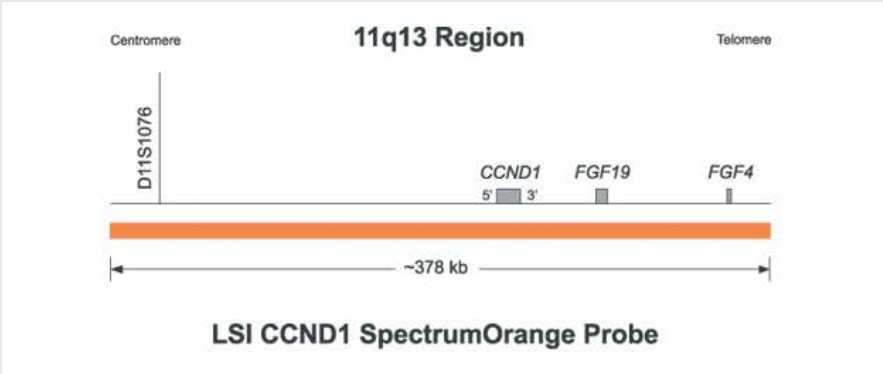


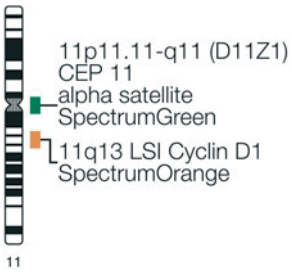
**Abnormal hybridization:** An abnormal cell hybridized with the LSI BIRC3/MALT1 Dual Color Dual Fusion Probes. The cell in this image shows the one orange, one green and two fusion signal pattern indicative of the t(11;18)(q21;q21) translocation.

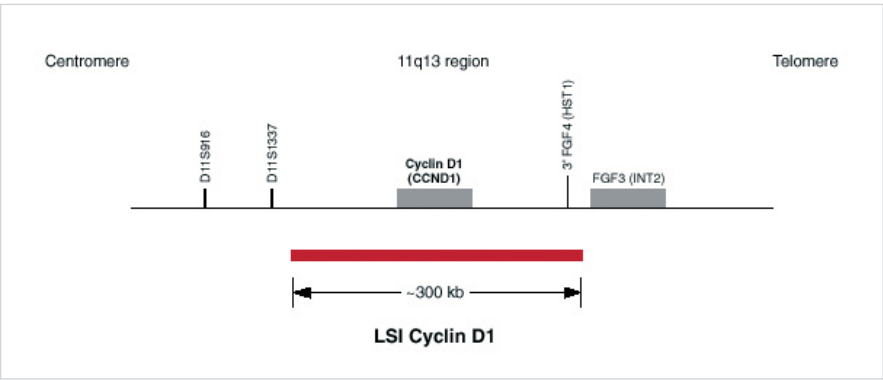
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BIRC3/MALT1 DF Fish Probe Kit **(CE)** | 20 µL | 05N50-020 | 00884999014985 |

NON-HODGKINS LYMPHOMA

# Vysis CCND1/CEP 11 FISH Probe Kit




## PRODUCT DESCRIPTION

Amplification of the chromosome 11q13 region, which harbors the Cyclin D1 (CCND1, PRAD1) oncogene, has been reported to occur in up to 15% of breast cancers. CCND1 amplification has been reported to be a prognostic marker.

Several studies used the Vysis CCND1/CEP 11 FISH Probe Kit to detect CCND1 amplification in breast cancer samples. Al-Karaya et al. analyzed a tissue microarray of 2197 breast cancer samples using the probe kit and found CCND1 amplification in 20.1% of cases. CCND1 amplification was associated with high tumor grade and a tendency toward shortened survival. Jirstrom et al. analyzed a tissue microarray of 500 breast cancer specimens from patients treated and not treated with adjuvant tamoxifen. The study found CCND1 amplification to be agonistic to tamoxifen with amplified patients having a significantly higher risk of recurrence.

The Vysis LSI CCND1 SpectrumOrange/CEP11 SpectrumGreen Probes have been applied to cancers other than breast cancer. For example, Katz et al. found elevated CCND1 copy number to be sensitive indicator of mantle cell lymphoma, and could distinguish mantle cell lymphoma from most other B-cell non Hodgkins lymphoma specimens.

The Vysis LSI Cyclin D1 (11q13) SpectrumOrange/ CEP 11 SpectrumGreen Probe is a mixture of two probes, The CCND1 probe is approximately 300 kb , contains the CCND1 gene, and is labeled in SpectrumOrange. The second probe is specific to the D11Z1 alpha satellite centromeric repeat of chromosome 11 and is labeled in SpectrumGreen.

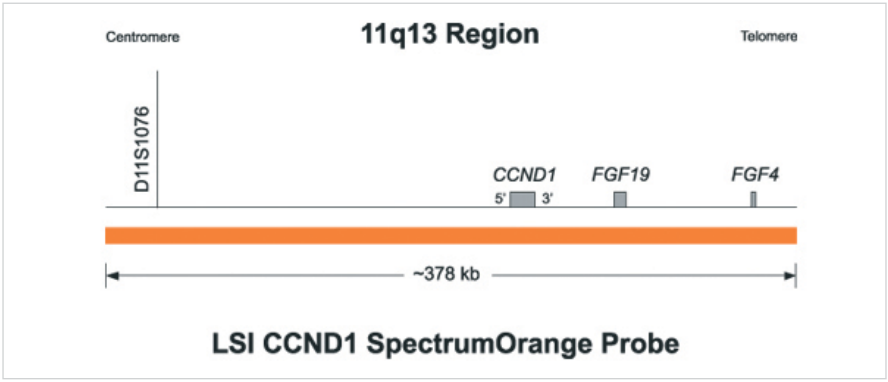
## RESULTS OF HYBRIDIZATION

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two orange and two green signals. The anticipated signal pattern in abnormal cells having a gain of copy number of the CCND1 target without a gain of the CEP 11 target is two green and multiple orange orange signals. Other patterns may be observed if additional genetic alterations are present.

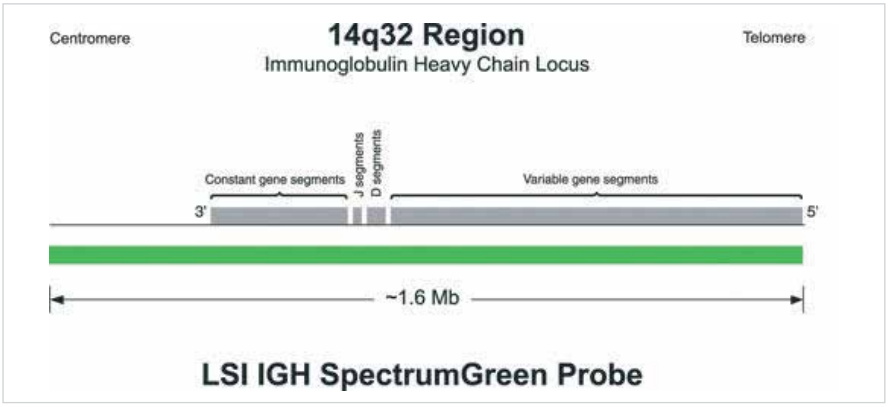
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 |

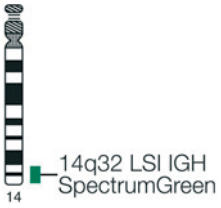
NON-HODGKINS LYMPHOMA

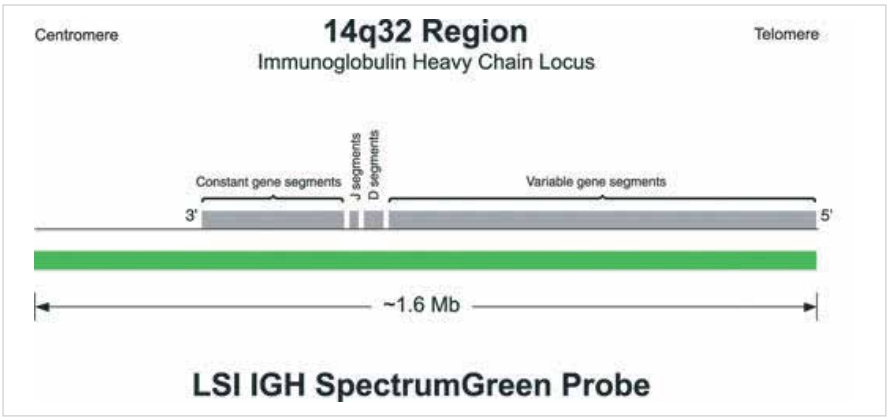
# Vysis IGH/CCND1 DF FISH Probe Kit








 Please note some products may not be for sale in all markets. Contact your local representative for availability.

## PRODUCT DESCRIPTION

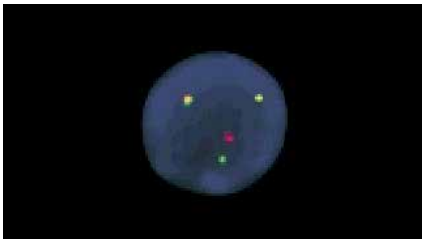
These fluorescence in situ hybridization (FISH) probes are intended to detect the t(11;14)(q13;q32) reciprocal translocation involving the IGH and CCND1 gene regions.

Mantle cell lymphoma is commonly associated with the balanced translocation t(11;14)(q13;q32). Mantle cell lymphoma has the most aggressive clinical course among the small cell lymphomas. FISH has emerged as an important aid in the diagnosis of mantle cell lymphoma. The Vysis LSI IGH/CCND1 Dual Color Dual Fusion Probes have been used in publications to detect t(11;14) in Mantle Cell Lymphoma.

## RESULTS OF HYBRIDIZATION

LSI IGH/CCND1 hybridized to a cell containing t(11;14) with breakpoints at the MTC on 11q13 and at the IGH J region on 14q32 is expected to result in a signal pattern of two orange/green (yellow) fusions, one on each of the abnormal chromosomes 11 and 14 and single orange and green signals from the normal chromosomes.

Due to the gap between the two probes in the IGH probe set, the normal IGH loci may sometimes appear as two slightly separated green signals. This gap may also cause a slight separation of the orange and green signals on the der(11) chromosome, in some instances. Analysis of t(11;14) samples suggests that due to variation in breakpoint location on 11q13 loss of V segments within the LSI IGH probe target, some samples containing t(11;14) might display signal patterns different than 1O1G2F.

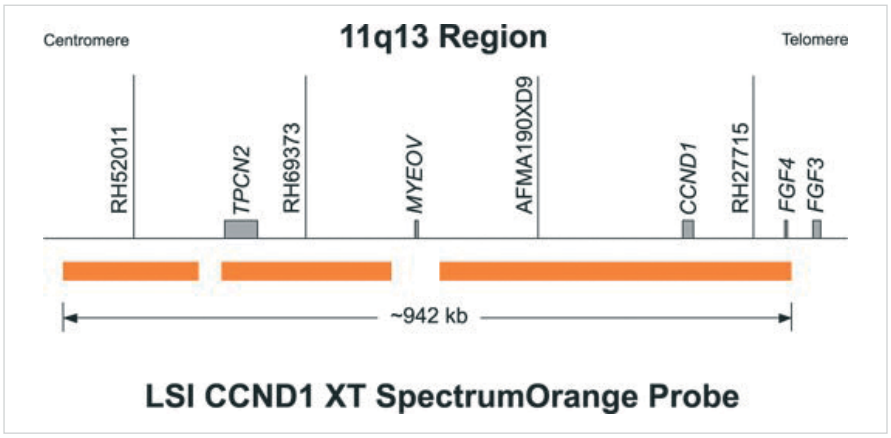


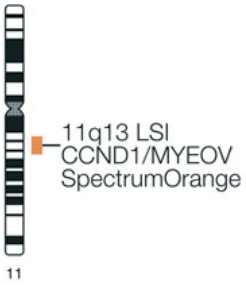
**Normal hybridization:** LSI IGH/CCND1 Dual Color, Dual Fusion Translocation Probe hybridized to an abnormal nucleus showing the common 1O1G2F signal pattern.

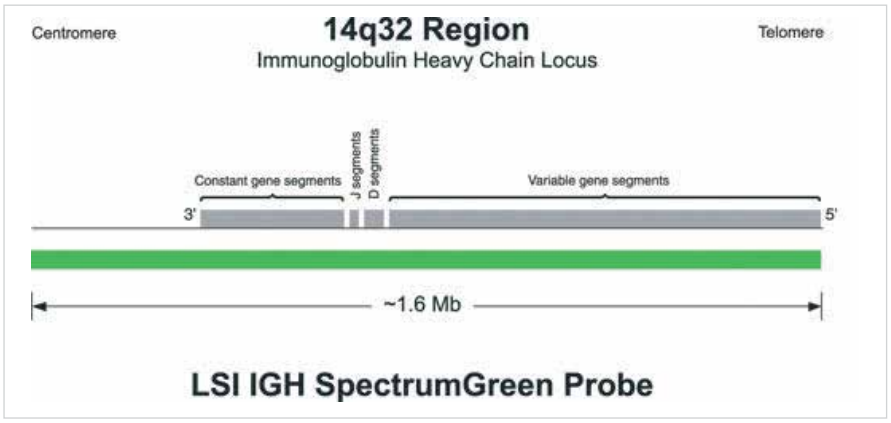
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis IGH/CCND1 DF FISH Probe Kit **(CE)** | 20 µL | 08L58-020 | 00884999031487 |

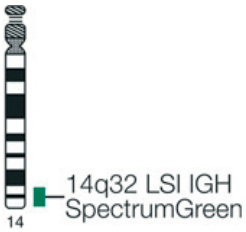
NON-HODGKINS LYMPHOMA

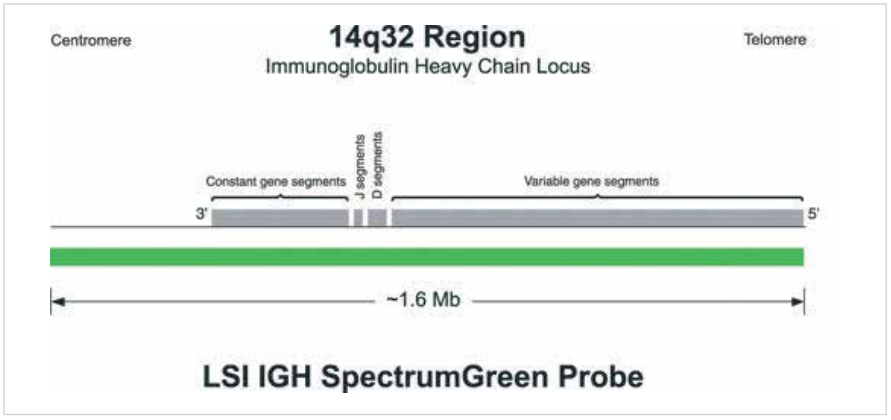
# Vysis IGH/CCND1 XT DF FISH Probe Kit




 Please note some products may not be for sale in all markets. Contact your local representative for availability.

## PRODUCT DESCRIPTION

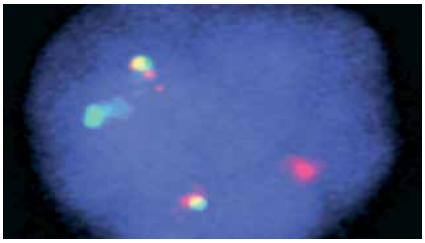
These fluorescence in situ hybridization (FISH) probes are intended to detect t(11;14)(q13;q32) reciprocal translocation involving the IGH and CCND1 gene regions.

The t(11;14)(q13;q32) is the most common translocation detected in myeloma. Patients with t(11;14) have been reported to have a bettersurvival and response to treatment particularly high dose therapy and stem cell support. The Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes have been used in publications to detect t(11;14).

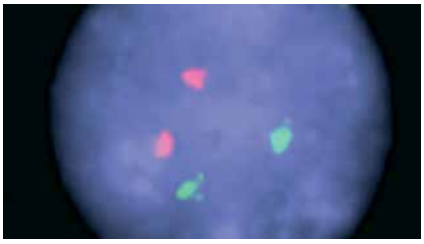
## RESULTS OF HYBRIDIZATION

In an abnormal cell containing the t(11;14), one orange (CCND1/MYEOV), one green (IGH), and two fusion signal pattern (der (11) and der (14)) may be observed. Some samples containing the t(11;14) may display signal patterns different than one orange, one green, and two fusions.

In a normal cell that lacks the t(11;14), a two orange and two green signal pattern will be observed reflecting the two intact copies of CCND1/MYEOV and IGH respectively.



**Abnormal hybridization:** An abnormal interphase cell hybridized with the Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes. The cell in this image shows the one orange (CCND1/MYEOV), one green (IGH), two fusion (der (11) and der (14)) signal pattern indicative of a t(11;14).

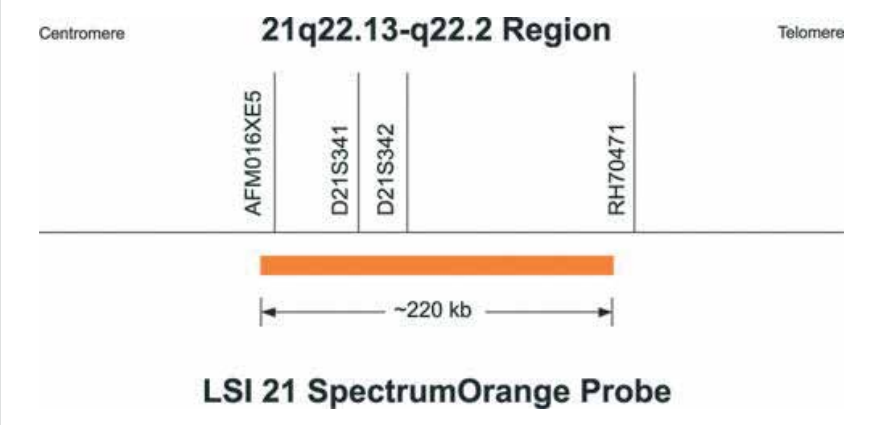


**Normal hybridization:** A normal interphase cell hybridized with the Vysis LSI IGH/CCND1 XT Dual Color Dual Fusion Probes. The cell shows the expected two orange (CCND1/MYEOV), two green (IGH) signal pattern.

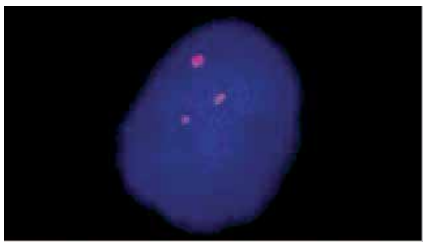
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis IGH/CCND1 XT DF FISH Probe Kit **(CE)** | 20 µL | 05N33-020 | 00884999014862 |

NON-HODGKINS LYMPHOMA

# Vysis LSI 21 SpectrumOrange



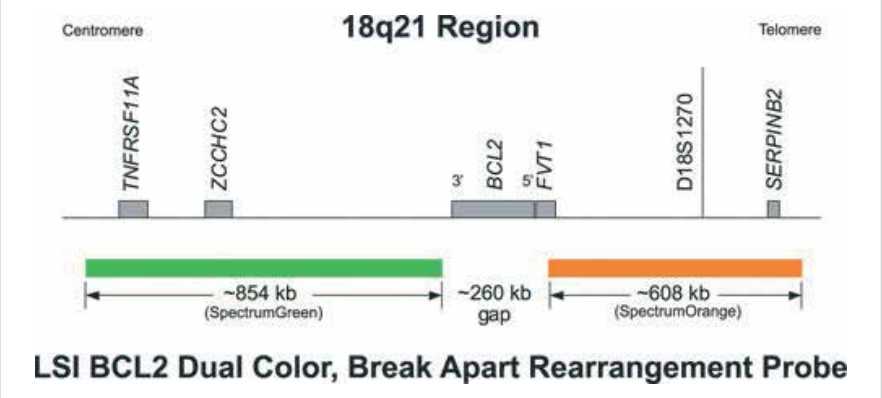




**Abnormal hybridization:** LSI 21 SpectrumOrange hybridized to a cultured amniocyte.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 21 SpectrumOrange **(ASR)** | 20 µL | 05J13-002 | 00884999011168 |

# Vysis LSI BCL2 Break Apart FISH Probe Kit





## PRODUCT DESCRIPTION

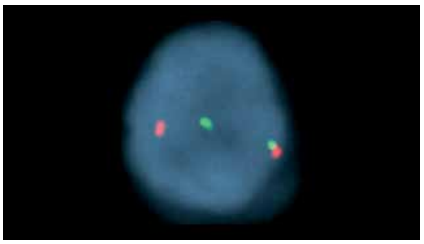
The Vysis BCL2 Break Apart FISH Probe Kit is intended to detect chromosomal rearrangements at the BCL2 locus on chromosome 18q21 using the fluorescence in situ hybridization (FISH) technique.

The t(14;18)(q32;q21) translocation involving the IGH and BCL2 loci is observed in approximately 80% of follicular lymphoma and about 20% of diffuse large B-cell lymphoma (DLBCL). BCL2 gene rearrangementshave been shown to correlate with a significantly worse prognosis in DLBCL of non-germinal center phenotype (2). The Vysis LSI BCL2 Dual Color Break Apart Rearrangement Probe has been used to detect BCL2 gene rearrangements on tissue micro arrays of DLBCL specimens. Primary mediastinal B-cell lymphoma (PMBCL) is a DLBCL with a clinically favorable outcome. In one study, 25 cases of PMBCL were analyzed by PCR and FISH for BCL2 gene rearrangements. Three cases with BCL2 gene rearrangements were detected by the Vysis LSI BCL2 Dual Color Break Apart Rearrangement Probe.

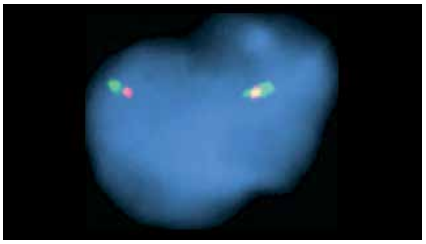
## RESULTS OF HYBRIDIZATION

The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 18 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals.



**Abnormal hybridization:** Abnormal cell hybridization using the LSI BCL2 Dual Color Break Apart Rearrangement Probe.

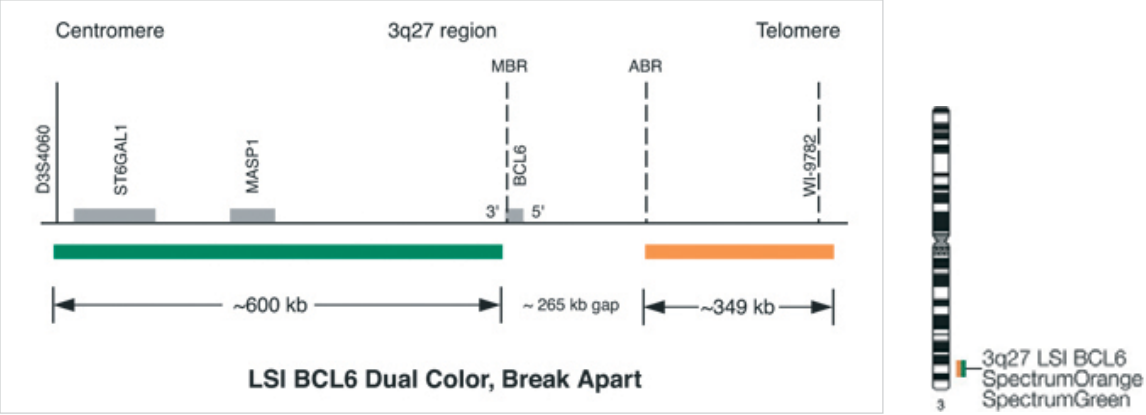


**Normal hybridization:** Normal cell hybridization using the LSI BCL2 Dual Color Break Apart Rearrangement Probe.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCL2 Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N51-020 | 00884999014992 |

NON-HODGKINS LYMPHOMA

# Vysis LSI BCL6 (ABR) Dual Color Break Apart Rearrangement Probe




## PRODUCT DESCRIPTION

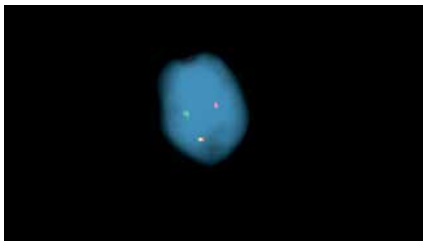
The LSI BCL6 (ABR)* Dual Color, Break Apart Rearrangement Probe targets chromosome breaks associated with a number of different translocations that involve the BCL6 gene located on chromosome 3.

The LSI BCL6 (ABR)* Dual Color, Break Apart Rearrangement Probe consists of a 5' BCL6 probe and 3' BCL6 probe. The 5' BCL6 SpectrumOrange probe is ~349 kb in size and flanks the ABR of BCL6. The 3' BCL6 SpectrumGreen probe is approximately 600kb in size and flanks the 3' end of BCL6. There is an approximate 265 kb gap between the two probes.

**ABR**- *Alternate Breakpoint Region*

## RESULTS OF HYBRIDIZATION

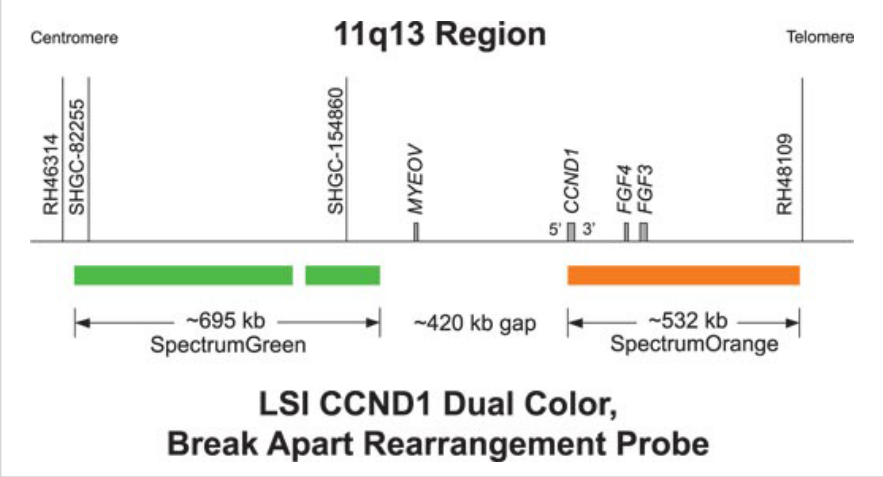
In a normal cell hybridized with the BCL6 probe, the expected signal pattern is two orange/green (2F) fusion signals.

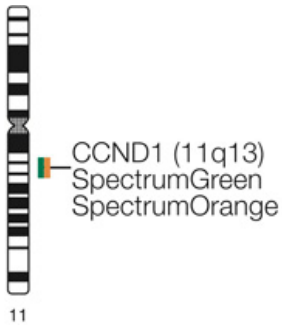


**Abnormal hybridization:** LSI BCL6 (ABR) Dual Color, Break Apart Rearrangement Probe hybridized to a nucleus with a translocation breakpoint involving the BCL6 gene showing a one orange, one green, one fusion (1O1G1F) pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCL6 (ABR) Dual Color Break Apart Rearrangement Probe **(ASR)** | 20 µL | 01N23-020 | 00884999000582 |

# Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit




## PRODUCT DESCRIPTION

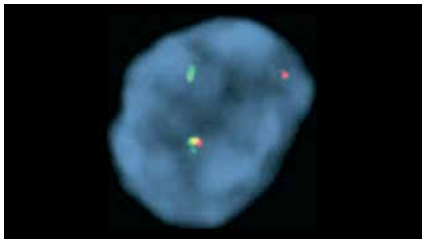
The CCND1 Dual Color Break Apart Rearrangement FISH probe is intended to detect chromosomal rearrangements involving the Cyclin D1 (CCND1) gene region at chromosome 11q13.

Mantle cell lymphoma (MCL) is an aggressive B-cell lymphoma and is commonly characterized by over-expression of CCND1 resulting from the t(11;14)(q13;q32) translocation. Over-expression of CCND1, which can result from chromosomal anomalies such as translocations or gain of the involved area, have been found to occur in multiple myeloma (MM) and MCL. The CCND1 Dual Color Break Apart Rearrangement Probe has been used to help identify rearrangement in the CCND1 breakpoint region in MCL.

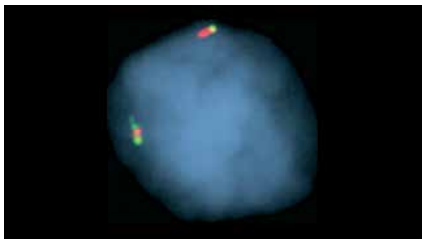
## RESULTS OF HYBRIDIZATION

The anticipated signal pattern in abnormal cells having a chromosomal breakpoint within the gap between the two probe targets on one chromosome 11 is one orange, one green, and one fusion signal. Other patterns may be observed if additional genetic alterations are present.

Hybridization of this probe to interphase nuclei of normal cells is expected to produce two pair of overlapping, or nearly overlapping, orange and green (yellow fusion) signals.



**Abnormal hybridization:** Abnormal cell hybridization using the LSI CCND1 (11q13) Dual Color Break Apart Rearrangement Probe.

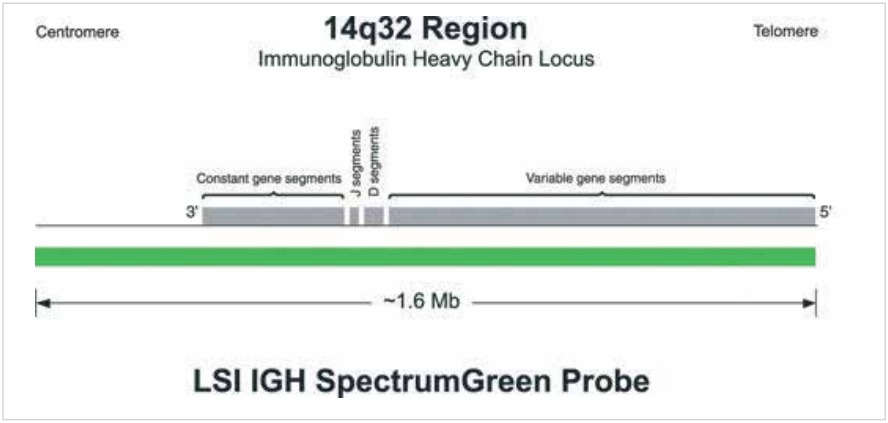


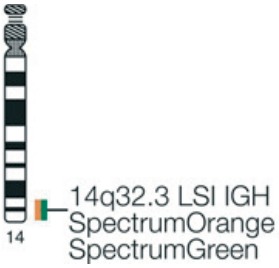
**Normal hybridization:** Normal cell hybridization using the LSI CCND1 (11q13) Dual Color Break Apart Rearrangement Probe.

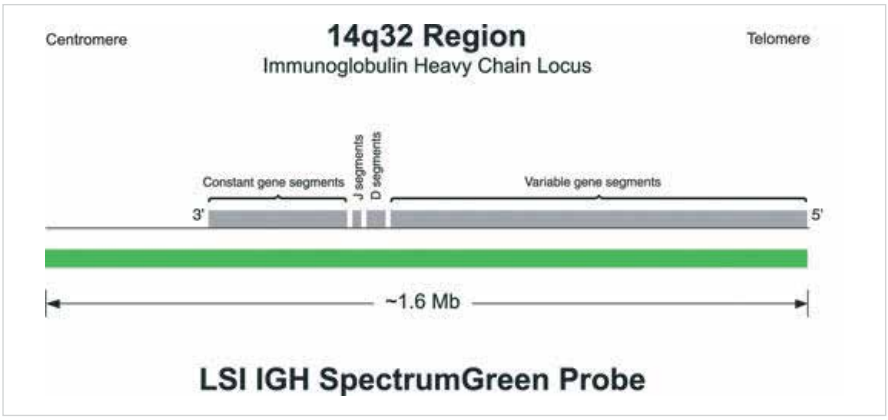
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 05N38-020 | 00884999014909 |

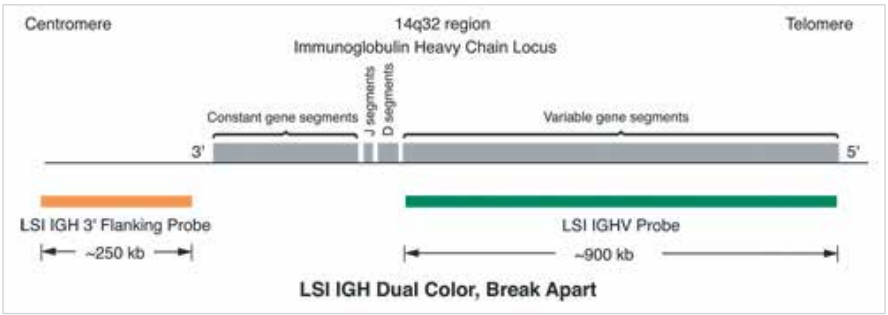
NON-HODGKINS LYMPHOMA

# Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe



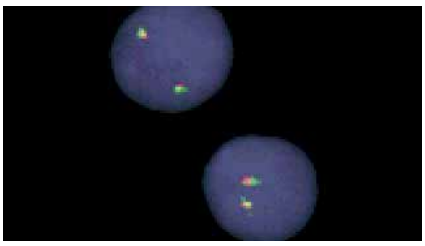
## PRODUCT DESCRIPTION

The LSI IGH Dual Color, Break Apart Rearrangement Probe is designed to detect chromosomal breakage of the immunoglobulin heavy chain (IGH) locus that is associated with 14q32 translocations involving a variety of other loci. Breakpoints within the IGH locus may occur at either the J segments [e.g., breakpoints commonly observed with t(14;18)] or within switch sequences located within the constant gene segments.

The LSI IGH Dual Color, Break Apart Rearrangement Probe is a mixture of two probes that hybridize to opposite sides of the J through constant regions of the IGH locus. The approximately 900 kb SpectrumGreen labeled LSI IGHV probe covers essentially the entire IGH variable region. The hybridization target of the approximately 250 kb SpectrumOrange labeled LSI IGH 3' flanking probe lies completely 3' to the IGH locus. As a result of this probe design, any translocation with a breakpoint at the J segments or within switch sequences should produce separate orange and green signals.

## RESULTS OF HYBRIDIZATION

When hybridized to a normal nucleus, the LSI IGH Dual Color, Break Apart Rearrangement Probe produces a two orange/green (yellow) fusion (2F) signal pattern. As there is no probe targeted to the J or constant regions, a slight gap between the two differently colored probe signals may sometimes be observed in nuclei from normal cells. When the IGH Dual Color, Break Apart Translocation Probe is hybridized to a nucleus containing an IGH translocation, one orange, one green, and one orange/green fusion signal pattern is observed (1O1G1F). This signal pattern indicates that the genomic targets for the LSI IGHV and LSI IGH 3' flanking probes have been physically separated as a result of the translocation. As V(D)J rearrangements may occur on either, or both, of the translocated and non-translocated IGH alleles, the green LSI IGHV probe signal intensity on either, or both, of the alleles may be diminished as a result of probe target deletion in some samples.

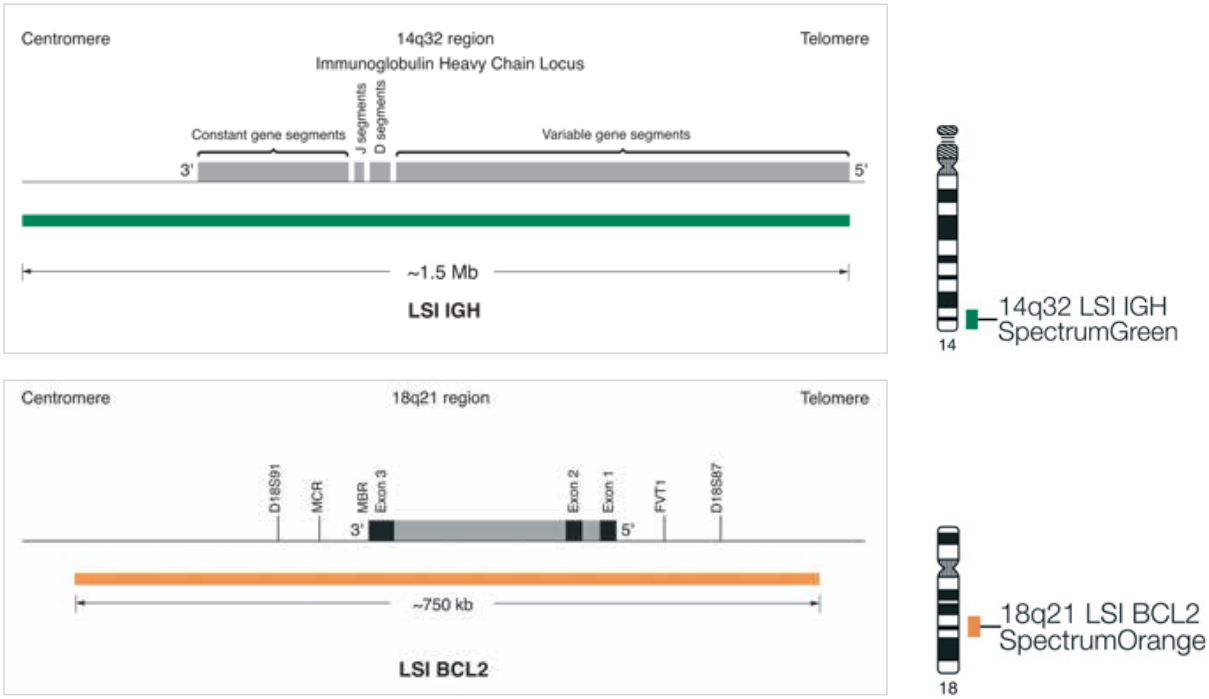


**Normal hybridization:** LSI IGH Dual Color, Break Apart Rearrangement Probe hybridized to nuclei exhibiting the expected two fusion (2F) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L63-020 | 00884999031531 |

NON-HODGKINS LYMPHOMA

# LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe










## PRODUCT DESCRIPTION

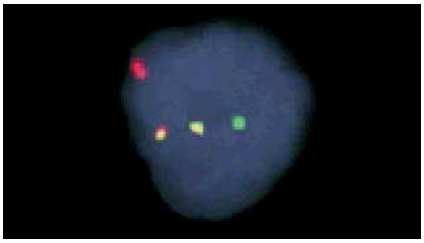
The LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe is designed to detect the juxtaposition of immunoglobulin heavy chain (IGH) locus and BCL gene sequences. The translocation involving IGH at 14q32 and BCL2 at 18q21, t(14;18)(q32;q21) is common. Relocation of an IGH transcriptional enhancer next to the BCL2 gene as a result of the t(14;18) translocation is thought to cause constitutive over-expression of the anti-apoptotic BCL2 protein. The breakpoints at 14q32 occur at the IGH J segments and about 75% of the breaks at 18q21 occur in either the 2.8 kb major breakpoint region (MBR) 3' of BCL2 exon 3 or in the minor cluster region (MCR) located about 30 kb 3' to the MBR. The remaining BCL2 breakpoints are thought to lie between the MBR and MCR regions, or 5' of the BCL2 gene.

The LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe is a mixture of the LSI IGH probe labeled with SpectrumGreen spanning approximately 1.5 Mb and containing sequences homologous to essentially the entire IGH locus, as well as sequences extending about 300 kb beyond the 3' end of the IGH locus. The LSI BCL2 probe labeled with SpectrumOrange covers an approximate 750 kb region, including the entire BCL2 gene with additional sequences extending approximately 250 kb both distal and proximal to the gene.

## RESULTS OF HYBRIDIZATION

The expected pattern in a normal nucleus hybridized with the LSI IGH/BCL2 probe is the two orange, two green signal pattern (2O2G). In a nucleus harboring a t(14;18), the most common pattern is one orange signal, one green signal (representing the normal homolog) and two orange/green (yellow) fusion signals representing the two derivative chromosomes resulting from the reciprocal translocation (1O1G2F pattern). Patterns other than 1O1G2F may be observed in some abnormal cells including instances of nuclei containing more than two fusion signals.

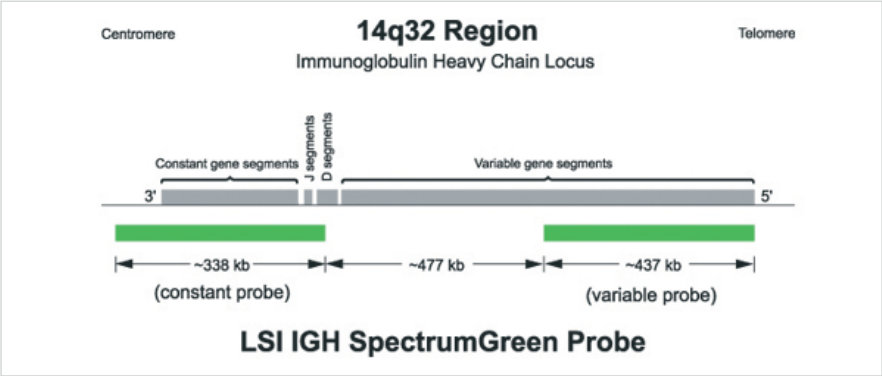


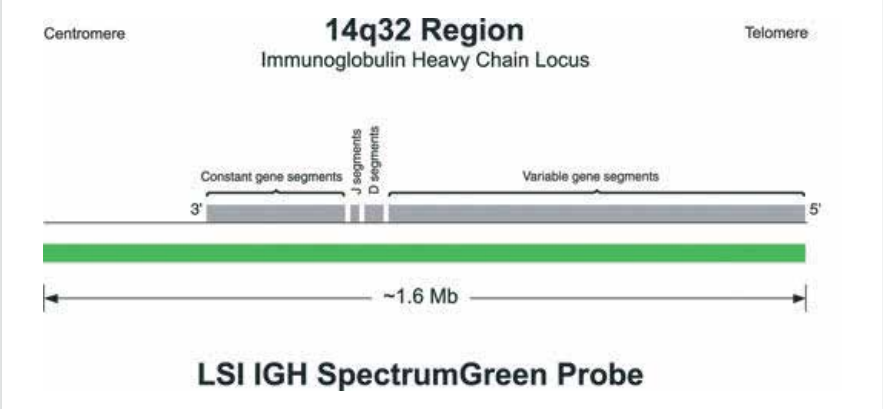
**Abnormal hybridization:** LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe hybridized to a nucleus containing the t(14;18) (q32;q21) showing the 1O1G2F signal pattern.

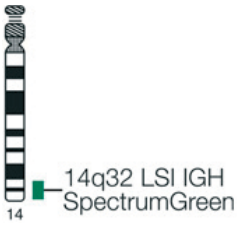
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe **(CE)** | 20 µL | 08L60-020 | 00884999031500 |

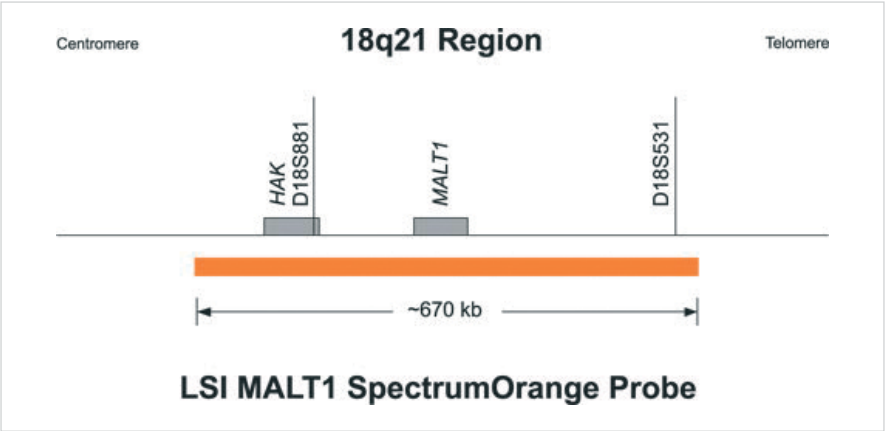
NON-HODGKINS LYMPHOMA

# Vysis LSI IGH/MALT1 DF FISH Probe Kit



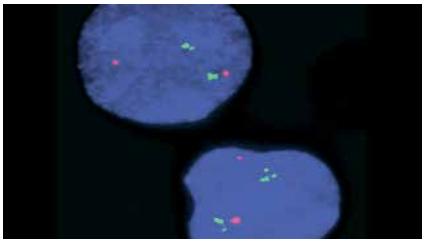


 Please note some products may not be for sale in all markets. Contact your local representative for availability.

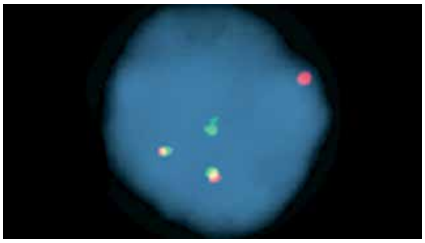
## PRODUCT DESCRIPTION

The Vysis IGH/MALT1 DF FISH Probe Kit is intended to detect the t(14;18)(q32;q21) reciprocal translocation involving the IGH and MALT1 gene regions using the fluorescence in situ hybridization (FISH) technique.

The t(14;18)(q32;q21) translocation is the second most common chromosomal translocation found in mucosa-associated lymphoid tissue (MALT) lymphoma1 and is the most common in non-gastric MALTlymphoma. The t(14;18)(q32;q21) translocation has been used toaid in the diagnosis of MALT lymphomas. The Vysis LSI IGH/MALT1Dual Color Dual Fusion Probes have been used to identify the t(14;18) (q32;q21) translocation in published reports.



**Normal hybridization:** Result of the hybridization of the LSI IGH/MALT1 t(14;18)(q32;q21) Dual Color, Dual Fusion Translocation Probe as observed in interphase cells.

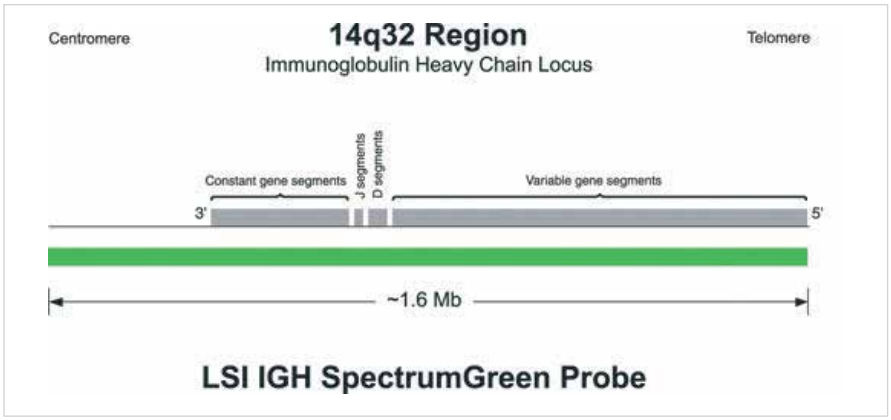


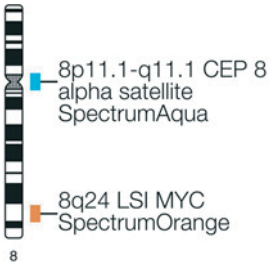
**Abnormal hybridization:** Cell hybridized with the LSI IGH/MALT1 t(14;18)(q32;q21) Dual Color, Dual Fusion Translocation Probe. The cell in this image shows the one orange, one green and two fusion signal pattern.

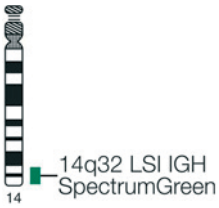
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH/MALT1 DF FISH Probe Kit **(CE)** | 20 µL | 05N47-020 | 00884999014961 |

NON-HODGKINS LYMPHOMA

# Vysis LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probe Kit


 Please note some products may not be for sale in all markets. Contact your local representative for availability.

## PRODUCT DESCRIPTION

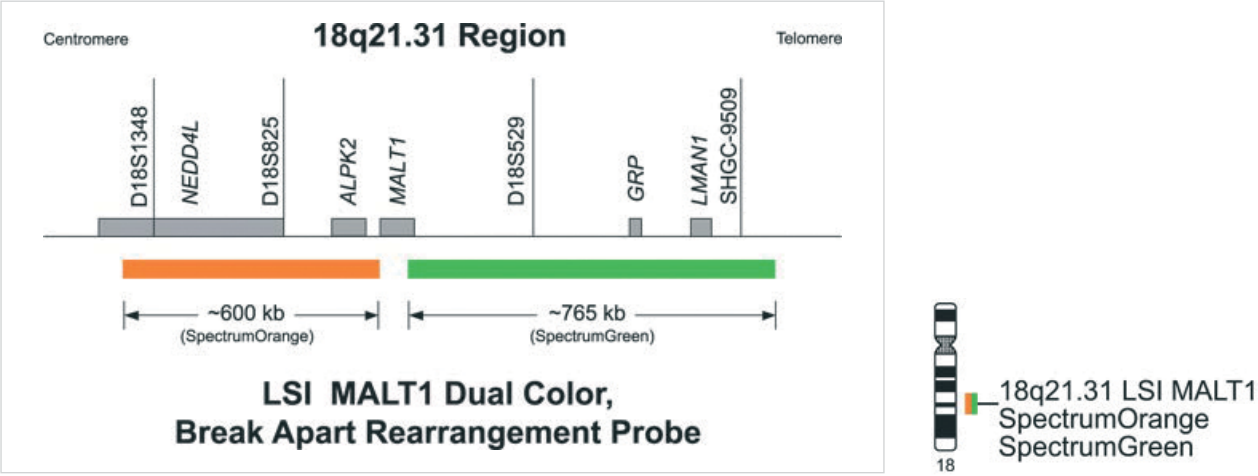
The Vysis IGH/MYC/CEP 8 Tri-Color Dual Fusion FISH probes are intended to detect the t(8;14)(q24;q32)reciprocal translocation involving the IGH and MYC gene regions.

The t(8;14)(q24;q32) translocation is a hallmark of Burkitt's Lymphoma (BL) and occurs in about 80% of BL cases. As such, testing for t(8;14)(q24;q32) or variants is indicated as an essential test for BL. TheVysis LSI IGH/MYC/CEP 8 Tri-color Dual Fusion probe has been used to identify the t(8;14)(q24;q32) translocation in published reports. The aqua CEP 8 probe serves as a control for the copy number of chromosome 8.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probe Kit **(CE)** | 20 µL | 04N10-020 | 00884999007949 |

NON-HODGKINS LYMPHOMA

# Vysis LSI MALT1 Break Apart FISH Probe Kit







## PRODUCT DESCRIPTION

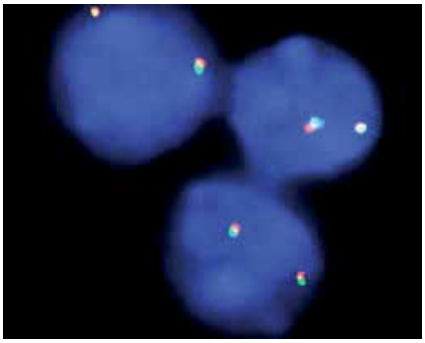
This fluorescence in situ hybridization (FISH) probe is intended to detect chromosomal rearrangements at the MALT1 locus on chromosome 18q21.

In gastric MALT lymphoma 1/3 or less of cases have been reported to carry the t(11;18) API2-MALT1 translocation. This translocation is usually indicative of unresponsiveness to H.Pylori eradication and is present inadvanced disease state. The Vysis LSI MALT1 Dual Color Break Apart Rearrangement probe has been used to detect MALT1 gene region rearrangements in a study of 90 diagnostic specimens from gastric MALT lymphoma patients. This same study also found some patients to have extra copies of the intact MALT1 gene indicated by greater than two copies of the fusion signal and this to be an indicator of poor prognosis. Another study performedto determine the clinical activity of Rituximab in 27 patients resistant to, or not eligible for, anti-H. pylori therapy also utilized the Vysis LSI MALT1 Dual Color Break Apart Rearrangement probe to detect rearrangements in the MALT1 gene region.

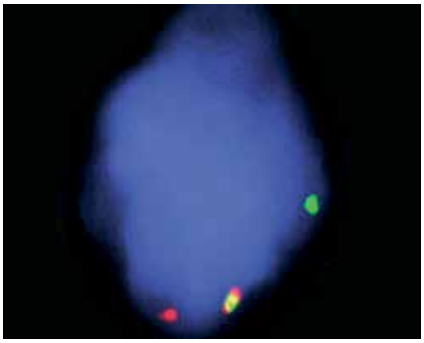
## RESULTS OF HYBRIDIZATION

In a normal cell that lacks a t(18q21) in the MALT1 gene region, a two fusion signal pattern will be observed reflecting the two intact copies of MALT1.

In an abnormal cell with a t(18q21), a one fusion, one green, one orange signal pattern will be observed.



**Normal hybridization:** Result of the hybridization of the Vysis LSI MALT1 Dual Color Break Apart Rearrangement Probe as observed in three normal interphase cells.

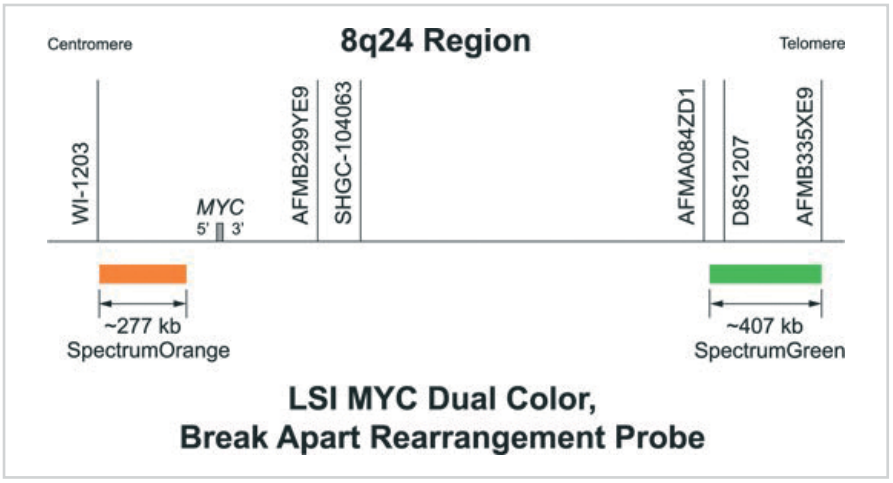


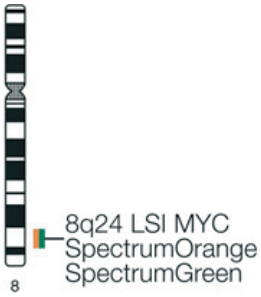
**Abnormal hybridization:** An abnormal cell hybridized with the Vysis LSI MALT1 Dual Color Break Apart Rearrangement Probe. The cell in this image shows the one fusion, one orange, and one green signal pattern indicative of a rearrangement of one copy of the MALT1 gene region.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MALT1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N48-020 | 00884999014978 |

NON-HODGKINS LYMPHOMA

# Vysis LSI MYC Break Apart Rearrangement Probe Kit



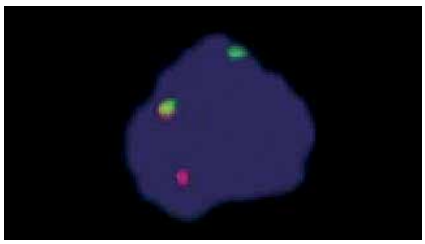

## PRODUCT DESCRIPTION

The Vysis LSI MYC Break Apart Rearrangement probe is intended to detect chromosomal rearrangements involving the MYC gene region on chromosome 8q24. It is particularly useful for detection of aberrations with breakpoints located far telomeric to MYC such as those that can occur in the variant t(8;22)(q24.1;q11.2)IGL-MYC and t(2;8)(p11.2;q24.1)IGK-MYC rearrangements.

Translocations involving the MYC region have diagnostic and prognostic importance in B-cell malignancies. In Burkitt's lymphoma approximately 75% to 80% of cases carry t(8;14)IGH-MYC and the remainder are associated with t(8;22)IGL-MYC or t(2;8)IGK-MYC. In approximately 5 to 10% of diffuse large B-cell lymphoma (DLBCL) patients also have MYC region rearrangements, and detection of these rearrangements with the MYC Dual Color Break Apart Rearrangement Probe has been associated with a poor prognosis. It has been suggested that FISHanalysis for MYC rearrangements should be performed on all DLBCL patients.

## RESULTS OF HYBRIDIZATION

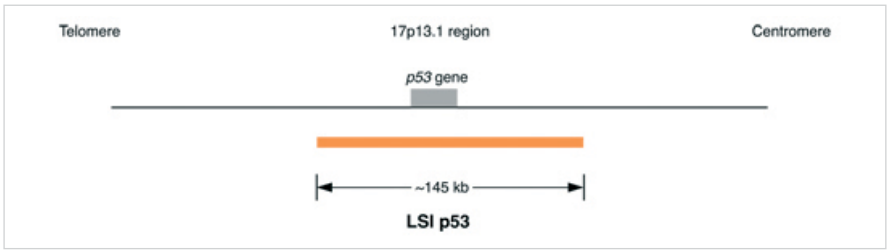
An abnormal nucleus hybridized with the LSI MYC Dual Color Break Apart Rearrangement Probe produces a two orange/green (yellow) fusion (2F) pattern. A one orange, one green, and one fusion pattern (1O1G1F) is expected from a sample with a t(2;8), t(8;22) or t(8;14) having a breakpoint within the gap between the hybridization targets of the LSI MYC probes.



**Abnormal hybridization:** LSI MYC Dual Color Break Apart Rearrangement Probe hybridized to an abnormal nucleus showing a one orange, one green and one orange/green fusion (1O1G1F) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYC Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 01N63-020 | 00884999000827 |

# Vysis LSI TP53 (17p13.1) SpectrumOrange Probe



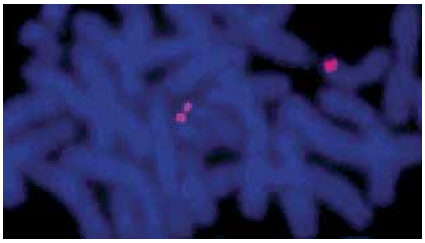


## PRODUCT DESCRIPTION

The LSI TP53 (previously designated as p53) Probe maps to the 17p13.1 region on chromosome 17 containing the p53 gene. The ability to use FISH probes such as the LSI p53 (17p13.1) for interphase cytogenetics has provided new insights into chromosomal aberrations. This probe may be used to detect the deletion (not mutation) or amplification of the p53 locus.The LSI p53 (17p13.1) SpectrumOrange Probe is an approximately 145 kb probe.

## RESULTS OF HYBRIDIZATION

In a cell containing a deletion of the LSI p53 locus, one orange LSI p53 signal will be observed (1O signal pattern). In a cell harboring amplification of the p53 locus multiple copies of the orange signal will be observed. In a normal cell the two orange (2O) signal pattern is observed.

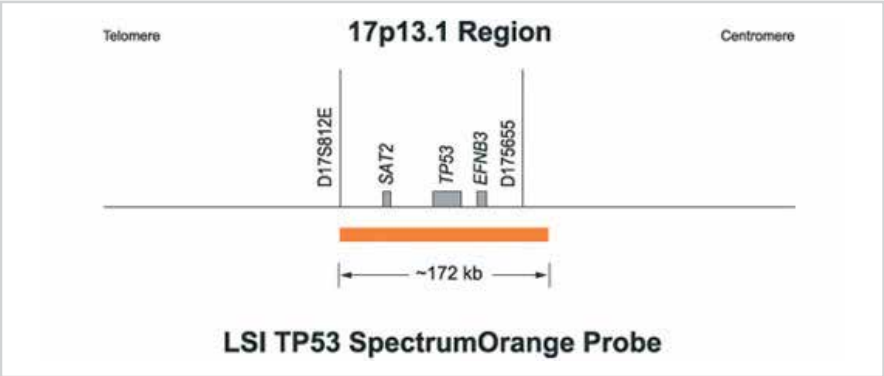


**Normal hybridization:** LSI p53 Probe hybridized to a normal cell showing the two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TP53 (17p13.1) SpectrumOrange Probe **(CE)** | 20 µL | 08L64-020 | 00884999031548 |

CHRONIC LYMPHOCYTIC LEUKEMIA

# Vysis TP53 / CEP 17 FISH Probe Kit

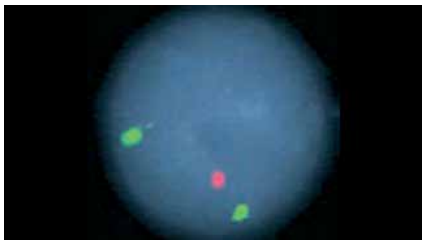




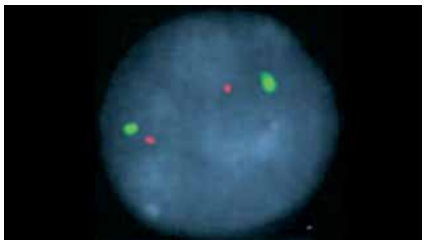
## PRODUCT DESCRIPTION

The Vysis TP53/CEP 17 FISH Probe Kit is intended to detect the copy number of the LSI TP53 probe target located at chromosome 17p13.1 and of the CEP 17 probe target located at the centromere of chromosome 17.

A recurring deletion that occurs in various leukemias, such as CLL and multiple myeloma, is the loss of the 17p13 region, which has been associated with poor patient outcome, both in CLL and in myeloma. The LSI TP53/CEP 17 probe combination has been used to detect the loss of the TP53 region in CLL and myeloma studies.



**Abnormal hybridization:** Nucleus showing the two green and one orange signal.



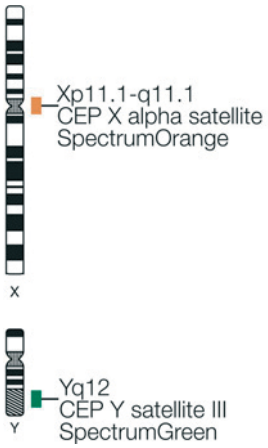
**Normal hybridization:** Nucleus showing the two green and two orange signals.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 |

# Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit

## PRODUCT DESCRIPTION

The CEP X/Y DNA Probe Kit, which is available for in vitro diagnostic use and may be used as an adjunct to standard karotyping to evaluate engraftment success in recipients of sex mismatched bone-marrow transplantation by determining the proportion of XX and XY donor cells. Following transplantation, an assessment of the proportion of cells belonging to the donor and to the recipient can be used to evaluate engraftment, detect the presence of clonal neoplasms and determine disease recurrence. This probe kit offers a limit of detection of 1% through a combination of CEP X and CEP Y fluorescently labeled DNA probes for specific regions of chromosome X and chromosome Y, respectively. This probe provides rapid (results in 3 hours or less) and accurate identification of the genetic sex of the bone marrow cells. Bone-marrow transplantation is a critical therapeutic strategy in the management of hematologic malignancies, such as:




- Chronic Myelogenous Leukemia (CML)
- Acute Myeloid Leukemia (AML)
- Acute Lymphocytic Leukemia (ALL)
- Myeloproliferative Disorder (MPD)
- Chronic Lymphocytic Leukemia (CLL)
- Myelodysplastic Syndrome (MDS)
- Other hematologic disorders not otherwise specified (HDNOS)

The CEP X/Y probe is a mixture of a SpectrumOrange labeled CEP X DNA probe and a SpectrumGreen labeled CEP Y DNA probe specific for the alpha satellite centromeric region of chromosome X and the satellite III (Yq12) region of chromosome Y.

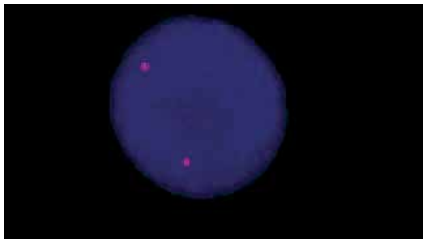
- Materials Provided With the CEP X/Y DNA Probe Kit:
- CEP X/Y DNA probe pre-denatured in hybridization buffer (220 µL)
- NP-40 (detergent for wash solution 1000 µL)
- DAPI II counterstain (300 µL)
- 20X SSC (66 g)

Control slides for the CEP X/Y kit are also sold separately. See Order No. 30-805011, Order No. 30-805012.

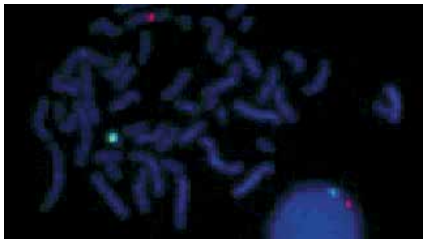
## RESULTS OF HYBRIDIZATION

In a normal female cell the two orange (2O) single pattern for female donor cells will be observed.

In a normal male cell, the expected pattern for a nucleus hybridized with the CEP X/Y DNA Probe is the one orange, one green (1O1G) signal pattern.



**Female**



**Male**

## INTENDED USE

The CEP X SpectrumOrange / Y SpectrumGreen DNA probe kit is intended to detect alpha satellite sequences in the centromere region of chromosome X and satellite III DNA at the Yq12 region of chromosome Y in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosomes X and Y via fluorescence in situ hybridization (FISH) in interphase nuclei and metaphase spreads obtained from bone marrow specimens in subjects who received opposite-sex bone marrow transplantation for chronic myelogenous leukemia (CML), acute myeloid leukemia (AML), myeloproliferative disorder (MPD), myelodysplastic syndrome (MDS), acute and lymphoid leukemia (ALL), or hematological disorder not otherwise specified (HDNOS). It is not intended to be used as a stand alone assay for test reporting; FISH results are intended to be reported and interpreted only in conjunction with results from standard cytogenetic analysis, performed concurrently, using the same patient specimen. This device is not intended for use in subjects with like-sex bone marrow transplants; with matrices other than unstimulated, cultured bone marrow specimens; or in screening for constitutional X and Y chromosome aneuploidies.

## LIMITATIONS

1. The CEP X/Y DNA Probe Kit has been optimized only for identifying chromosomes in interphase nuclei or metaphase spreads from bone marrow specimens.

2. This assay identifies only the proportion of donor and recipient cells in bone marrow specimens from recipients of opposite-sex bone marrow transplantation. It does not distinguish between malignant and normal cells; it is not designed to detect structural or other chromosome abnormalities in malignant clones, which is possible with standard cytogenetics.

3. The Y chromosome is sometimes lost in bone marrow cells of elderly males regardless of whether the specimen is from a donor, a recipient, or collected from a patient in the post-bone marrow transplantation period [8].

4. It is important to have pretransplant cytogenetic results on both donor and recipient for the following reasons: (1) There are rare male patients who may have an unusual Y chromosome (lacking the Yq heterochromatic region) which cannot be identified with the CEP X/Y assay. (2) Some individuals may have target sequences at alternate chromosome locations that hybridize to the CEP X or Y probes. This has not been investigated for CEP X, however, chromosome polymorphisms which hybridize with the Y probe occur with a frequency of 1 in 2,000 [9]. Such cases may be detected by CEP X/Y metaphase analysis and sometimes by standard cytogenetic analysis. (3) Constitutional sex chromosome aneuploidy, including mosaicism, present in either donor or recipient can complicate signal enumeration and test interpretation.

5. In a male donor or recipient with a 46,XY,-Y,+X karyotype, a certain percentage of cells with XX signals will be detected by CEP X/Y.

6. If significant peripheral blood contamination is present in the bone marrow specimen, the blood may dilute the specimen. It is important to recognize the potential effects this dilution effect may have on the FISH assay results; dilution of the bone marrow with blood may alter the donor:recipient cell ratio.
7. The CEP X/Y assay has been validated only for use with unstimulated, cultured bone marrow specimens obtained from recipients of opposite-sex BMT. It is not intended for chromosome X and Y enumeration in other patient populations or with other test matrices such as amniocytes, chorionic villi, fibroblasts, tumor cells, long term cultures, among others.
8. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
9. This device is not intended for use in subjects with like-sex bone marrow transplants or for use in diagnostic testing or screening for constitutional X and Y chromosome aneuploidies.
10. Residual fetal cells may potentially exist in either donor or recipient cells, however the levels at which these cells exist is likely to be below the levels of detection of both standard cytogenetics and FISH.
11. The CEP X/Y assay has not been validated for monitoring engraftment status.
12. The clinical significance and interpretation of FISH results should be made in conjunction with proper controls, standard cytogenetic analysis, and within the context of the patient's medical history and other clinical findings.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-050 | 00884999027091 |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-050 | 00884999027022 |

# VYSIS FISH: GENETICS

Identification and characterization of chromosome anomalies in preimplantation, prenatal, and postnatal genetics is critical for managing quality of life. FISH is a powerful tool for determining many types of chromosome anomalies. In addition to AneuVysion, the only FDA-cleared product for rapid detection of aneusomy in amniotic fluid samples, Abbott Molecular offers an expansive line of DNA FISH probes for preimplantation, prenatal and postnatal genetic testing and research.

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

## ABBOTT MOLECULAR PRODUCTS, POWERED BY VYSIS FISH TECHNOLOGY, PROVIDE THE FOLLOWING ADVANTAGES:

- Rapid, sensitive, and specific detection and characterization of chromosome abnormalities.
- Ability to test metaphase chromosomes from cultured samples and interphase cells from specimens that cannot be cultured.
- Direct-labeled probes, as compared to indirect labeling methods, provide:
  - Less background signal, thereby simplifying interpretation.
  - Reduced costs associated with labeling reagents and technician time.
- Dual and Tri Colored probe mixes for many microdeletion detection tests.
  - Each mix includes a probe specific for the critical chromosome region implicated in the disease of interest and a control probe to another region on the same chromosome labeled with a different fluorophore.
  - Inclusion of a control probe in most products ensures proper hybridization and facilitates identification of the chromosome of interest.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **CHROMOSOME ENUMERATION PROBES** | | | | |
| Vysis CEP 1 (D1Z5) SpectrumOrange Probe | 20 µL | 06J39-026 | 00884999020153 | - |
| Vysis CEP 1 SpectrumOrange Probe | 20 µL | 06J36-001 | 00884999019690 | - |
| Vysis CEP 2 (D2Z1) SpectrumOrange Probe | 20 µL | 06J36-027 | 00884999019867 | - |
| Vysis CEP 3 (D3Z1) SpectrumOrange Probe | 20 µL | 06J36-003 | 00884999019706 | - |
| Vysis CEP 4 SpectrumAqua Probe | 20 µL | 06J54-004 | 00884999021709 | - |
| Vysis CEP 4 SpectrumGreen Probe | 20 µL | 06J37-004 | 00884999019935 | - |
| Vysis CEP 4 SpectrumOrange Probe | 20 µL | 06J36-004 | 00884999019713 | - |
| Vysis CEP 6 (D6Z1) SpectrumAqua Probe | 20 µL | 06J54-006 | 00884999021716 | - |
| Vysis CEP 6 (D6Z1) SpectrumGreen Probe | 20 µL | 06J37-006 | 00884999019942 | - |
| Vysis CEP 6 (D6Z1) SpectrumOrange Probe | 20 µL | 06J36-006 | 00884999019720 | - |
| Vysis CEP 7 (D7Z1) SpectrumAqua Probe | 20 µL | 06J54-007 | 00884999021723 | - |
| Vysis CEP 7 (D7Z1) SpectrumGreen Probe | 20 µL | 06J37-007 | 00884999019959 | - |
| Vysis CEP 7 (D7Z1) SpectrumOrange Probe | 20 µL | 06J36-007 | 00884999019737 | - |
| Vysis CEP 8 (D8Z2) SpectrumGreen Probe | 20 µL | 06J37-008 | 00884999019966 | - |
| Vysis CEP 8 SpectrumAqua Probe | 20 µL | 06J54-008 | 00884999021730 | - |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 | 282 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 | 282 |
| Vysis CEP 9 SpectrumAqua Probe | 20 µL | 06J54-009 | 00884999021747 | - |
| Vysis CEP 9 SpectrumGreen Probe | 20 µL | 06J37-009 | 00884999019973 | - |
| Vysis CEP 9 SpectrumOrange Probe | 20 µL | 06J36-009 | 00884999019744 | - |
| Vysis CEP 10 SpectrumAqua Probe | 20 µL | 06J54-010 | 00884999021754 | - |
| Vysis CEP 10 SpectrumGreen Probe | 20 µL | 06J37-010 | 00884999019980 | - |
| Vysis CEP 10 SpectrumOrange Probe | 20 µL | 06J36-010 | 00884999019751 | - |
| Vysis CEP 11 (D11Z1) SpectrumAqua Probe | 20 µL | 06J54-011 | 00884999021761 | - |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Vysis CEP 11 (D11Z1) SpectrumGreen Probe | 20 µL | 06J37-011 | 00884999019997 | - |
| Vysis CEP 11 (D11Z1) SpectrumOrange Probe | 20 µL | 06J36-011 | 00884999019768 | - |
| Vysis CEP 12 (D12Z3) SpectrumGreen Probe | 20 µL | 06J37-012 | 00884999020009 | - |
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-012 | 00884999027084 | 284 |
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-012 | 00884999027015 | 284 |
| Vysis CEP 15 (D15Z1) SpectrumAqua Probe | 20 µL | 06J54-015 | 00884999021785 | - |
| Vysis CEP 15 (D15Z1) SpectrumGreen Probe | 20 µL | 06J37-015 | 00884999020023 | - |
| Vysis CEP 15 (D15Z4) SpectrumOrange Probe | 20 µL | 06J36-015 | 00884999019799 | - |
| Vysis CEP 16 (D16Z3) SpectrumAqua Probe | 20 µL | 05J09-016 | 00884999010970 | - |
| Vysis CEP 16 (D16Z3) SpectrumGreen Probe | 20 µL | 05J10-016 | 00884999011052 | - |
| Vysis CEP 16 (D16Z3) SpectrumOrange Probe | 20 µL | 05J08-016 | 00884999010871 | - |
| Vysis CEP 17 (D17Z1) SpectrumAqua Probe | 20 µL | 06J38-017 | 00884999020139 | - |
| Vysis CEP 17 (D17Z1) SpectrumGreen Probe | 20 µL | 06J37-017 | 00884999020047 | - |
| Vysis CEP 17 (D17Z1) SpectrumOrange Probe | 20 µL | 06J36-017 | 00884999019812 | - |
| Vysis CEP 18 (D18Z1) SpectrumAqua Probe | 20 µL | 05J09-018 | 00884999010987 | - |
| Vysis CEP 18 (D18Z1) SpectrumGreen Probe | 20 µL | 05J10-018 | 00884999011069 | - |
| Vysis CEP 18 (D18Z1) SpectrumOrange Probe | 20 µL | 05J08-018 | 00884999010888 | - |
| Vysis CEP 20 (D20Z1) SpectrumOrange Probe | 20 µL | 06J36-020 | 00884999019836 | - |
| Vysis CEP X (DXZ1) SpectrumAqua Probe | 20 µL | 05J09-023 | 00884999010994 | - |
| Vysis CEP X (DXZ1) SpectrumGreen / Vysis CEP Y (DYZ3) SpectrumOrange Probe | 20 µL | 05J10-051 | 00884999011137 | - |
| Vysis CEP X (DXZ1) SpectrumGreen Probe | 20 µL | 05J10-023 | 00884999011076 | - |
| Vysis CEP X (DXZ1) SpectrumOrange Probe | 20 µL | 05J08-023 | 00884999010895 | - |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-050 | 00884999027091 | 286 |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-050 | 00884999027022 | 286 |

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Vysis CEP Y (DYZ1) SpectrumAqua Probe | 20 µL | 05J09-024 | 00884999011007 | - |
| Vysis CEP Y (DYZ1) SpectrumGreen Probe | 20 µL | 05J10-024 | 00884999011083 | - |
| Vysis CEP Y (DYZ1) SpectrumOrange Probe | 20 µL | 05J08-024 | 00884999010901 | - |
| Vysis CEP Y (DYZ3) SpectrumOrange Probe | 20 µL | 05J08-025 | 00884999010918 | - |
| Vysis LSI 13 (13q14) SpectrumGreen Probe **(CE)** | 20 µL | 08L67-020 | 00884999031579 | 289 |
| Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe **(CE)** | 20 µL | 08L65-020 | 00884999031555 | 290 |
| Vysis LSI 21 SpectrumOrange Probe Kit **(CE)** | 20 µL | 08L54-020 | 00884999031449 | 291 |
| Vysis LSI 22 (BCR) SpectrumGreen Probe **(ASR)** | 20 µL | 05J17-024 | 00884999011236 | 292 |
| **POSTNATAL GENETICS: MICRODELETION SYNDROMES** | | | | |
| LSI SNRPN / CEP 15 (D15Z1) / LSI PML TriColor Probe **(ASR)** | 10 µL | 01N12-010 | 00884999000476 | 302 |
| Vysis 1p36 Microdeletion Region Probe - LSI p58 (1p36) (SpectrumOrange)/TelVysion 1p (SpectrumGreen)/LSI 1q25 (SpectrumAqua) **(ASR)** | 20 µL | 05J21-020 | 00884999011328 | 293 |
| Vysis Cri-du-Chat Region Probe - LSI D5S23, D5S721 **(ASR)** | 20 µL | 05J20-025 | 00884999011298 | 294 |
| Vysis DiGeorge Region Probe - LSI TUPLE 1 SpectrumOrange/ LSI ARSA SpectrumGreen **(ASR)** | 20 µL | 05J21-028 | 00884999011342 | 295 |
| Vysis DiGeorge Region Probe - LSI TUPLE 1 SpectrumOrange/ LSI ARSA SpectrumGreen Probe Kit **(CE)** | 20 µL | 08L59-020 | 00884999031494 | 295 |
| Vysis DiGeorge Region Probe - LSI TUPLE1 (HIRA) SpectrumOrange/TelVysion 22q SpectrumGreen Probe **(ASR)** | 10µL | 01N14-010 | 00884999000490 | 296 |
| Vysis Kallman Region Probe - LSI KAL SpectrumOrange/Vysis CEP X SpectrumGreen **(ASR)** | 20 µL | 05J23-070 | 00884999011380 | 298 |
| Vysis LSI D22S75 (N25 region) SpectrumOrange/ LSI ARSA SpectrumGreen Probe **(ASR)** | 10 µL | 05N24-010 | 00884999014770 | 299 |
| Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit **(CE)** | 20 µL | 08L68-020 | 00884999031586 | 300 |
| Vysis LSI MAPT **(ASR)** | 10 µL | 02N19-010 | 00884999002708 | 301 |
| Vysis LSI SNRPN / CEP 15 (D15Z1) / LSI PML TriColor Probe Kit **(CE)** | 10µL | 06N27-010 | 00884999025608 | 302 |
| Vysis LSI Xq13.2 (XIST) **(ASR)** | 10 µL | 01N61-001 | 00884999000810 | 303 |
| Vysis Miller-Dieker Region/Isolated LissenVysis CEPhaly Probe LSI LIS1 SpectrumOrange/LSI RARA SpectrumGreen **(ASR)** | 20 µL | 05J88-001 | 00884999012790 | 304 |
| Vysis Prader-Willi/Angelman Region Probe - LSI D15S10 (SO)/ Vysis CEP 15 (D15Z1) (SA)/PML (SG) **(ASR)** | 10µl | 01N13-010 | 00884999000483 | 305 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Vysis Prader-Willi/Angelman Region Probe - LSI D15S10 (SO)/ Vysis CEP 15 (D15Z1) (SA)/PML (SG) Kit **(CE)** | 10 µL | 05N58-010 | 00884999015067 | 305 |
| Vysis Prader-Willi/Angelman Region Probe - LSI D15S11/Vysis CEP 15(D15Z1) **(ASR)** | 20 µL | 05J19-014 | 00884999011274 | 306 |
| Vysis Prader-Willi/Angelman Region Probe - LSI GABRB3 SpectrumOrange/Vysis CEP 15 (D15Z1) SpectrumGreen **(ASR)** | 20 µL | 05J22-015 | 00884999011366 | 307 |
| Vysis Smith-Magenis Region Probe - LSI SMS Region SpectrumOrange/LSI RARA SpectrumGreen **(ASR)** | 20 µL | 05J25-003 | 00884999011427 | 308 |
| Vysis Sotos Region Probe - LSI NSD1 (5q35) SpectrumOrange Probe **(ASR)** | 20 µL | 05J48-007 | 00884999011915 | 309 |
| Vysis SRY Probe - LSI SRY SpectrumOrange **(ASR)** | 20 µL | 05J27-079 | 00884999011496 | 310 |
| Vysis SRY Probe LSI SRY Spectrum Orange/Vysis CEP X Spectrum Green **(ASR)** | 20 µL | 05J27-007 | 00884999011472 | 311 |
| Vysis SRY Probe LSI SRY Spectrum Orange/Vysis CEP X Spectrum Green Probe Kit **(CE)** | 20 µL | 06N29-020 | 00884999025622 | 311 |
| Vysis Steroid Sulfatase Deficiency Probe - LSI STS SpectrumOrange/LSI Vysis CEPX Spectrum Green **(ASR)** | 20 µL | 05J28-004 | 00884999011519 | 312 |
| Vysis Williams Region Probe - LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen Probe Kit **(CE)** | 20 µL | 06N28-020 | 00884999025615 | 313 |
| Vysis Williams Region Probe - LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen Probes **(ASR)** | 20 µL | 05J30-045 | 00884999011564 | 313 |
| Vysis Wolf-Hirschhorn Region Probe - LSI WHS SpectrumOrange/CEP 4 SpectrumGreen | 20 µL | 05J29-074 | 00884999011533 | 315 |
| **POSTNATAL GENETICS : TELOMERIC REGIONS: REARRANGEMENTS, DELETIONS AND ADDITIONS** | | | | |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 | 316 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 | 316 |
| TelVysion 1p SpectrumGreen | 5 µL | 05J03-001 | 00884999009882 | - |
| TelVysion 1q SpectrumOrange | 5 µL | 05J04-001 | 00884999010246 | - |
| TelVysion 2p SpectrumGreen | 5 µL | 05J03-002 | 00884999009899 | - |
| TelVysion 2q SpectrumOrange | 5 µL | 05J04-002 | 00884999010253 | - |
| TelVysion 3p SpectrumGreen | 5 µL | 05J03-003 | 00884999009905 | - |
| TelVysion 3q SpectrumOrange | 5 µL | 05J04-003 | 00884999010260 | - |
| TelVysion 4p SpectrumGreen | 5 µL | 05J03-004 | 00884999009912 | - |

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| TelVysion 4q SpectrumOrange | 5 µL | 05J04-004 | 00884999010277 | - |
| TelVysion 5p SpectrumGreen | 5 µL | 05J03-005 | 00884999009929 | - |
| TelVysion 5q SpectrumOrange | 5 µL | 05J04-005 | 00884999010284 | - |
| TelVysion 6p SpectrumGreen | 5 µL | 05J03-006 | 00884999009936 | - |
| TelVysion 6q SpectrumOrange | 5µl | 05J04-006 | 00884999010291 | - |
| TelVysion 7p SpectrumGreen | 5 µL | 05J03-007 | 00884999009943 | - |
| TelVysion 7q SpectrumOrange | 5 µL | 05J04-007 | 00884999010307 | - |
| TelVysion 8p SpectrumGreen | 5 µL | 05J03-008 | 00884999009950 | - |
| TelVysion 8q SpectrumOrange | 5 µL | 05J04-008 | 00884999010314 | - |
| TelVysion 9p SpectrumGreen | 5 µL | 05J03-009 | 00884999009967 | - |
| TelVysion 9q SpectrumOrange | 5 µL | 05J04-009 | 00884999010321 | - |
| TelVysion 10p SpectrumGreen | 5 µL | 05J03-010 | 00884999009974 | - |
| TelVysion 10q SpectrumOrange | 5 µL | 05J04-010 | 00884999010338 | - |
| TelVysion 11p SpectrumGreen | 5 µL | 05J03-011 | 00884999009981 | - |
| TelVysion 11q SpectrumOrange | 5 µL | 05J04-011 | 00884999010345 | - |
| TelVysion 12p SpectrumGreen | 5 µL | 05J03-012 | 00884999009998 | - |
| TelVysion 12q SpectrumOrange | 5 µL | 05J04-012 | 00884999010352 | - |
| TelVysion 13q SpectrumOrange | 5 µL | 05J04-013 | 00884999010369 | - |
| TelVysion 14q SpectrumOrange | 5 µL | 05J04-014 | 00884999010376 | - |
| TelVysion 15q SpectrumOrange | 5 µL | 05J04-015 | 00884999010383 | - |
| TelVysion 16p SpectrumGreen | 5 µL | 05J03-016 | 00884999010031 | - |
| TelVysion 16q SpectrumOrange | 5 µL | 05J04-016 | 00884999010390 | - |
| TelVysion 17p SpectrumGreen | 5 µL | 05J03-017 | 00884999010048 | - |
| TelVysion 17q SpectrumOrange | 5 µL | 05J04-017 | 00884999010406 | - |
| TelVysion 18p SpectrumGreen | 5 µL | 05J03-018 | 00884999010055 | - |
| TelVysion 18q SpectrumOrange | 5 µL | 05J04-018 | 00884999010413 | - |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

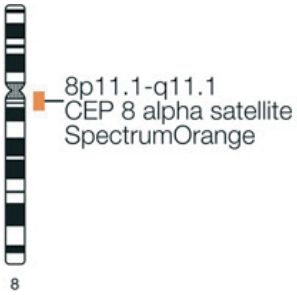
| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| TelVysion 19p SpectrumGreen | 5 µL | 05J03-019 | 00884999010062 | - |
| TelVysion 19q SpectrumOrange | 5 µL | 05J04-019 | 00884999010420 | - |
| TelVysion 20p SpectrumGreen | 5 µL | 05J03-020 | 00884999010079 | - |
| TelVysion 20q SpectrumOrange | 5 µL | 05J04-020 | 00884999010437 | - |
| TelVysion 21q SpectrumOrange | 5 µL | 05J04-021 | 00884999010444 | - |
| TelVysion 22q SpectrumOrange | 5 µL | 05J04-022 | 00884999010451 | - |
| Vysis TelVysion Xp/Yp SpectrumGreen Probe | 5 µL | 05J03-023 | 00884999010109 | - |
| Vysis TelVysion Xq/Yq SpectrumOrange Probe | 5 µL | 05J04-023 | 00884999010468 | - |
| **PRENATAL GENETICS** | | | | |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE & FDA IVD)** | 10 Assays | 05J38-010 | 00884999011694 | 318 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE & FDA IVD)** | 30 Assays | 05J38-030 | 00884999011700 | 318 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE & FDA IVD)** | 50 Assays | 05J38-050 | 00884999011717 | 318 |
| ProbeChek Control Slides for CEP X/Y Assay; Control low-level female: 95% XY, 5% XX; 5 slides **(CE)** | 5 Slides | 07J21-011 | 00884999027053 | - |
| ProbeChek Control Slides for CEP X/Y Assay; Control low-level male: 95% XX, 5% XY; 5 slides **(CE)** | 5 Slides | 07J21-012 | 00884999027060 | - |
| ProbeChek MultiVysion Control Slides 5 slides **(CE)** | 5 Slides | 05J07-001 | 00884999010864 | - |
| ProbeChek Prenatal Control Slides for Amniocyte; Male Amniocyte Control Slides; 5 slides **(CE)** | 5 Slides | 05J39-005 | 00884999011731 | - |
| ProbeChek Prenatal Control Slides for Positive Control; 5 slides **(CE)** | 5 Slides | 05J36-005 | 00884999011663 | - |
| Vysis LSI 13 (13q14) SpectrumGreen Probe **(CE)** | 20 µL | 08L67-020 | 00884999031579 | 321 |
| Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe **(CE)** | 20 µL | 08L65-020 | 00884999031555 | 322 |
| Vysis LSI 21 SpectrumOrange Probe Kit **(CE)** | 20 µL | 08L54-020 | 00884999031449 | 323 |
| Vysis LSI 22 (BCR) SpectrumGreen Probe **(ASR)** | 20 µL | 05J17-024 | 00884999011236 | 324 |
| Vysis MultiVysion PB Multi-color Probe **(CE)** | 60 µL | 08L62-020 | 00884999031524 | 325 |
| Vysis MultiVysion PGT Multi-color Probe **(CE)** | 30 µL | 08L69-010 | 00884999031593 | 327 |

CHROMOSOME ENUMERATION PROBES

# Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit

## PRODUCT DESCRIPTION

CEP 8 is a SpectrumOrange labeled probe specific for the alpha satellite (centromeric) region, 8p11.1-q11.1.




The CEP 8 DNA Probe Kit which is available for in vitro diagnostic use and may be used as an adjunct to standard karotyping to identify and enumerate chromosome 8 in cells obtained from bone marrow. In multi-site clinical trials, the CEP 8 DNA Probe Kit for interphase analysis was 96% sensitive and 98% specific as compared to traditional cytogenetic analysis. A close association has been made between trisomy 8 and both myeloid blast crisis and basophilia. Trisomy 8 is a prevalent genetic aberration in several specific diseases:

- Chronic Myelogenous Leukemia (CML)
- Acute Myeloid Leukemia (AML)
- Myeloproliferative disorders (MPD)
- Myelodysplastic Syndrome (MDS)
- Other hematologic disorders not specified (HDNOS)

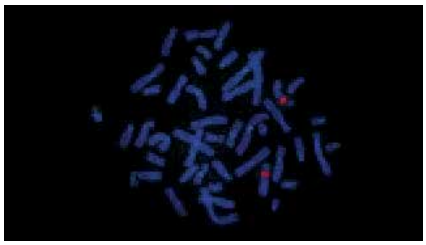
## CEP 8 SPECTRUMORANGE DNA PROBE KIT CONTENT

Components of the CEP 8 SpectrumOrange DNA Probe Kit include:

- CEP 8 SpectrumOrange alpha satellite DNA for centromere region 8p11.1-q11.1 predenatured in hybridization buffer (220 µL)
- NP-40 (detergent for wash solution: 1000 µL)
- DAPI II counterstain (300 µL)
- 20X SSC (66 g)
- Control slides for the CEP 8 kit are also sold separately. See Order No. 30-805000 and Order No. 30-805002.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for a nucleus hybridized with the CEP 8 probe is a two orange (2O) signal pattern. In an abnormal cell containing trisomy 8, the expected pattern will be a three orange (3O) signal pattern.



**Normal hybridization:** CEP 8 SpectrumOrange hybridized to a normal cell showing two orange signals indicating two copies of chromosome 8.

## INTENDED USE

The CEP 8 SpectrumOrange DNA Probe Kit is intended to detect AT rich alpha satellite sequences in the centromere region of chromosome 8 in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosome 8 via fluorescence in situ hybridization (FISH) in interphase nuclei and in metaphase spreads of cells obtained from bone marrow in patients with myeloid disorders [Chronic myelogenous leukemia (CML), Acute myeloid leukemia (AML), Myeloproliferative disorder (MPD), Myelodysplastic syndrome (MDS), and Hematological disorders not otherwise specified (HDNOS)]. It is not intended to be used as a stand alone assay for test reporting. It is not intended for use in long term cell cultured materials such as amniocytes, fibroblasts and tumor cells.

## LIMITATIONS

- The CEP 8 SpectrumOrange DNA Probe Kit has been characterized only for identifying chromosomes in nuclear preparations or metaphase spreads from bone marrow specimens.
- The clinical interpretation of any test results should be done in conjunction with standard cytogenetic analysis and should be evaluated within the context of the patient's medical history and other diagnostic laboratory test results.
- Clinical specimens with >2.2% tri-signaled nuclei are considered to have an abnormal trisomy 8 clone. Those with ≤ 2.2% tri-signaled nuclei should be considered normal, although the presence of trisomy 8 is not completely excluded.
- The CEP 8 SpectrumOrange DNA Probe Kit is not intended for long term cell cultured materials such as amniocytes, fibroblasts and tumor cells.
- FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
- If significant peripheral blood contamination is present in the bone marrow specimen, the blood may dilute the specimen; it is important to recognize the potential effects this dilution effect may have on the FISH assay results.
- It is possible that patients may have chromosome polymorphism which may hybridize with CEP 8 probe. FISH metaphase analysis should be done in addition to FISH interphase analysis. Polymorphism was not investigated in the clinical trials.
- This assay will not detect the presence of other chromosome abnormalities frequently associated with hematological disorders.
- The efficacy of this assay for monitoring of trisomy 8 or disease progression has not been demonstrated.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 |

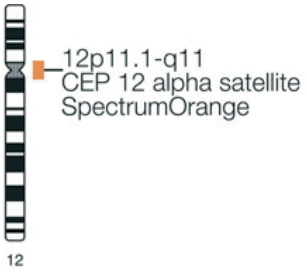
CHROMOSOME ENUMERATION PROBES

# Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit

## PRODUCT DESCRIPTION

CEP 12 DNA Probe is a SpectrumOrange labeled probe specific for the alpha satellite (centromeric) region, 12p11.1-q11.

The CEP 12 DNA Probe Kit which is available for in vitro diagnostic use and may be used as an adjunct to standard karotyping to identify and enumerate chromosome 12 in nuclei of cells obtained from peripheral blood lymphocytes in patients with B-cell chronic lymphocytic leukemia (B-CLL). In multi-site clinical trials, the CEP 12 analysis of interphase nuclei was 100% sensitive and 91% specific as compared to traditional cytogenetic analysis when adequate metaphase preparations could be produced. Results are available within 3 hours or less. Trisomy 12 is the most commonly reported chromosome aberration in CLL. Chromosomal aberrations, determined by cytogenetic analysis are present in up to 55% of all B-CLL cases.




## MATERIALS PROVIDED

Materials provided with the CEP 12 DNA Probe Kit:

- CEP 12 DNA probe pre-denatured in hybridization buffer (220 µL)
- NP-40 (detergent for wash solution: 1000 µL)
- DAPI II counterstain (300 µL)
- 20X SSC (66 g)

Control slides for the CEP 12 kit are also sold separately. See Order No. 30-805000, Order No. 30-805002.

## RESULTS OF HYBRIDIZATION

In a normal cell, the expected pattern for CEP 12 is the two orange (2O) signal pattern. In an abnormal cell containing trisomy 12, the expected pattern will be the three orange (3O) signal pattern.

**Normal hybridization:** CEP 12 SpectrumOrange hybridized to a normal cell showing two orange signals indicating two copies of chromosome 12.

## INTENDED USE

The CEP 12 SpectrumOrange DNA Probe Kit is intended to detect AT rich alpha satellite sequences in the centromere region of chromosome 12 in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosome 12 via fluorescence in situ hybridization (FISH) in interphase nuclei of cells obtained from peripheral blood lymphocytes in patients with B-cell chronic lymphocytic leukemia (CLL). It is not intended to be used as a stand alone assay for test reporting; FISH results are intended to be reported and interpreted only in conjunction with results of standard cytogenetic analysis, performed concurrently, utilizing the same patient specimen. The CEP 12 assay has not been validated for purposes other than those described above. It is not intended for use with test matrices other than peripheral blood lymphocytes from subjects with CLL, to screen for chromosome 12 aneuploidy, e.g., in asymptomatic individuals, or to monitor patients for residual disease.

## LIMITATIONS

1. The CEP 12 DNA Probe Kit has been optimized only for identifying chromosome 12 in interphase nuclei from peripheral blood specimens from patients with B-cell chronic lymphocytic leukemia.
2. The clinical interpretation of any abnormality or its absence by FISH should be done in conjunction with standard cytogenetic analysis and proper controls, and should be evaluated within the context of the patient's medical history and past diagnostic laboratory test results.
3. Clinical specimens with >2.0% tri-signaled nuclei are considered to have an abnormal trisomy 12 clone. Those with ≤ 2.0% tri-signaled nuclei should be considered normal, although the presence of trisomy 12 is not completely excluded. When the percentage of tri-signaled interphase nuclei are near the cutoff point (1.5-2.5%), the results should be interpreted with caution.
4. The CEP 12 assay has been validated only for use with peripheral blood lymphocytes obtained from patients with B-cell CLL leukemia. It is not intended to be used for chromosome 12 enumeration in other patient populations or with other test matrices such as amniocytes, chorionic villi, fibroblasts, tumor cells, long term cultures, among others.
5. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate; the CEP 12 DNA Probe Kit has been optimized for archived peripheral blood specimens stored only at -20°C or -80°C, as recommended.
6. The CEP 12 DNA Probe Kit has not been validated for monitoring disease status.
7. It is possible that some individuals may have target sequences at an alternate chromosomal location that may hybridize with CEP 12. This has not been investigated for this device; the user should assess this in metaphase spreads from each subject tested.
8. The CEP 12 assay is intended only to aid in the enumeration of chromosome 12 centromeres; it is not designed to detect chromosome 12 structural abnormalities.

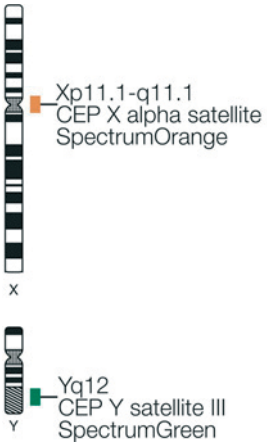
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-012 | 00884999027084 |
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-012 | 00884999027015 |

CHROMOSOME ENUMERATION PROBES

# Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit

## PRODUCT DESCRIPTION

The CEP X/Y DNA Probe Kit, which is available for in vitro diagnostic use and may be used as an adjunct to standard karotyping to evaluate engraftment success in recipients of sex mismatched bone-marrow transplantation by determining the proportion of XX and XY donor cells. Following transplantation, an assessment of the proportion of cells belonging to the donor and to the recipient can be used to evaluate engraftment, detect the presence of clonal neoplasms and determine disease recurrence. This probe kit offers a limit of detection of 1% through a combination of CEP X and CEP Y fluorescently labeled DNA probes for specific regions of chromosome X and chromosome Y, respectively. This probe provides rapid (results in 3 hours or less) and accurate identification of the genetic sex of the bone marrow cells. Bone-marrow transplantation is a critical therapeutic strategy in the management of hematologic malignancies, such as:




- Chronic Myelogenous Leukemia (CML)
- Acute Myeloid Leukemia (AML)
- Acute Lymphocytic Leukemia (ALL)
- Myeloproliferative Disorder (MPD)
- Chronic Lymphocytic Leukemia (CLL)
- Myelodysplastic Syndrome (MDS)
- Other hematologic disorders not otherwise specified (HDNOS)

The CEP X/Y probe is a mixture of a SpectrumOrange labeled CEP X DNA probe and a SpectrumGreen labeled CEP Y DNA probe specific for the alpha satellite centromeric region of chromosome X and the satellite III (Yq12) region of chromosome Y.

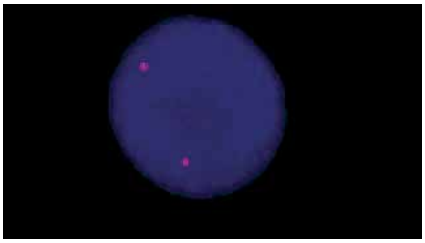
- Materials Provided With the CEP X/Y DNA Probe Kit:
- CEP X/Y DNA probe pre-denatured in hybridization buffer (220 µL)
- NP-40 (detergent for wash solution 1000 µL)
- DAPI II counterstain (300 µL)
- 20X SSC (66 g)

Control slides for the CEP X/Y kit are also sold separately. See Order No. 30-805011, Order No. 30-805012.

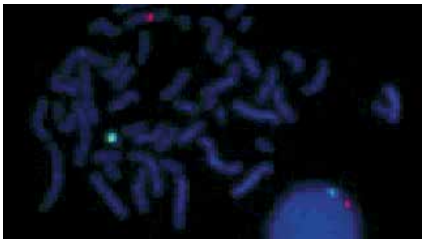
## RESULTS OF HYBRIDIZATION

In a normal female cell the two orange (2O) single pattern for female donor cells will be observed.

In a normal male cell, the expected pattern for a nucleus hybridized with the CEP X/Y DNA Probe is the one orange, one green (1O1G) signal pattern.



**Female**



**Male**

## INTENDED USE

The CEP X SpectrumOrange / Y SpectrumGreen DNA probe kit is intended to detect alpha satellite sequences in the centromere region of chromosome X and satellite III DNA at the Yq12 region of chromosome Y in conjunction with routine diagnostic cytogenetic testing. It is indicated for use as an adjunct to standard cytogenetic analysis for identifying and enumerating chromosomes X and Y via fluorescence in situ hybridization (FISH) in interphase nuclei and metaphase spreads obtained from bone marrow specimens in subjects who received opposite-sex bone marrow transplantation for chronic myelogenous leukemia (CML), acute myeloid leukemia (AML), myeloproliferative disorder (MPD), myelodysplastic syndrome (MDS), acute and lymphoid leukemia (ALL), or hematological disorder not otherwise specified (HDNOS). It is not intended to be used as a stand alone assay for test reporting; FISH results are intended to be reported and interpreted only in conjunction with results from standard cytogenetic analysis, performed concurrently, using the same patient specimen. This device is not intended for use in subjects with like-sex bone marrow transplants; with matrices other than unstimulated, cultured bone marrow specimens; or in screening for constitutional X and Y chromosome aneuploidies.

## LIMITATIONS

1. The CEP X/Y DNA Probe Kit has been optimized only for identifying chromosomes in interphase nuclei or metaphase spreads from bone marrow specimens.

2. This assay identifies only the proportion of donor and recipient cells in bone marrow specimens from recipients of opposite-sex bone marrow transplantation. It does not distinguish between malignant and normal cells; it is not designed to detect structural or other chromosome abnormalities in malignant clones, which is possible with standard cytogenetics.

3. The Y chromosome is sometimes lost in bone marrow cells of elderly males regardless of whether the specimen is from a donor, a recipient, or collected from a patient in the post-bone marrow transplantation period [8].

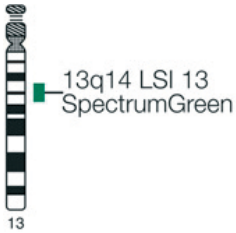
4. It is important to have pretransplant cytogenetic results on both donor and recipient for the following reasons: (1) There are rare male patients who may have an unusual Y chromosome (lacking the Yq heterochromatic region) which cannot be identified with the CEP X/Y assay. (2) Some individuals may have target sequences at alternate chromosome locations that hybridize to the CEP X or Y probes. This has not been investigated for CEP X, however, chromosome polymorphisms which hybridize with the Y probe occur with a frequency of 1 in 2,000 [9]. Such cases may be detected by CEP X/Y metaphase analysis and sometimes by standard cytogenetic analysis. (3) Constitutional sex chromosome aneuploidy, including mosaicism, present in either donor or recipient can complicate signal enumeration and test interpretation.

5. In a male donor or recipient with a 46,XY,-Y,+X karyotype, a certain percentage of cells with XX signals will be detected by CEP X/Y.

6. If significant peripheral blood contamination is present in the bone marrow specimen, the blood may dilute the specimen. It is important to recognize the potential effects this dilution effect may have on the FISH assay results; dilution of the bone marrow with blood may alter the donor:recipient cell ratio.
7. The CEP X/Y assay has been validated only for use with unstimulated, cultured bone marrow specimens obtained from recipients of opposite-sex BMT. It is not intended for chromosome X and Y enumeration in other patient populations or with other test matrices such as amniocytes, chorionic villi, fibroblasts, tumor cells, long term cultures, among others.
8. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
9. This device is not intended for use in subjects with like-sex bone marrow transplants or for use in diagnostic testing or screening for constitutional X and Y chromosome aneuploidies.
10. Residual fetal cells may potentially exist in either donor or recipient cells, however the levels at which these cells exist is likely to be below the levels of detection of both standard cytogenetics and FISH.
11. The CEP X/Y assay has not been validated for monitoring engraftment status.
12. The clinical significance and interpretation of FISH results should be made in conjunction with proper controls, standard cytogenetic analysis, and within the context of the patient's medical history and other clinical findings.

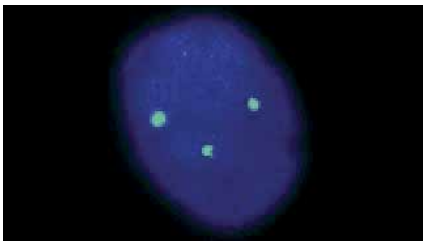
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-050 | 00884999027091 |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-050 | 00884999027022 |

# Vysis LSI 13 (13q14) SpectrumGreen Probe


## PRODUCT DESCRIPTION

LSI 13 (13q14) consists of a set of overlapping clones that contain the RB1 gene and flanking regions. The RB1 gene is 180 kb. The probe extends beyond the gene for 110-170 kb in the 5' direction and approximately 120 kb in the 3' direction. The entire probe is approximately 440 kb in size.

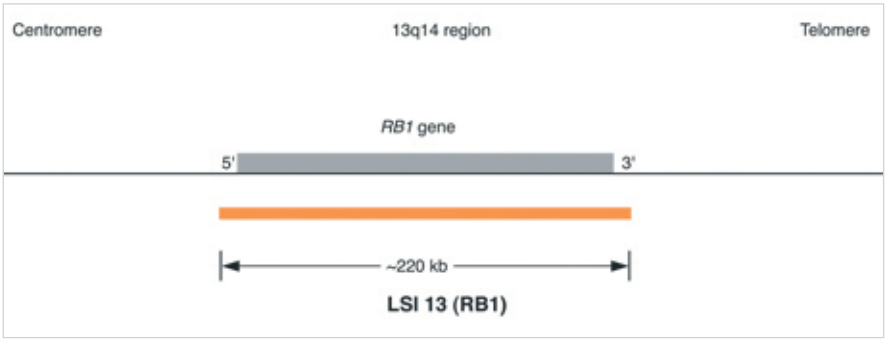


**Abnormal hybridization:** LSI 13 (13q14) SpectrumGreen hybridized to an amniocyte. Three green signals indicate three copies of chromosome 13

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 13 (13q14) SpectrumGreen Probe **(CE)** | 20 µL | 08L67-020 | 00884999031579 |

CHROMOSOME ENUMERATION PROBES

# Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe





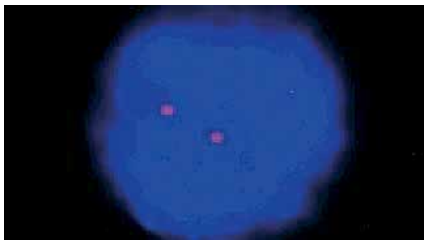
## PRODUCT DESCRIPTION

The LSI 13 (RB1) 13q14 SpectrumOrange Probe contains unique DNA sequences specific to the RB1 gene within the 13q14 region of chromosome 13. The presence or absence of the RB1 gene region may be detected using the LSI 13 (RB1) 13q14 Probe. This probe may be used to detect deletion (not mutation) of the RB1 gene locus.

The LSI 13 (RB1) 13q14 SpectrumOrange Probe is approximately 220 kb and contains sequences that target the entire RB1 gene.

## RESULTS OF HYBRIDIZATION

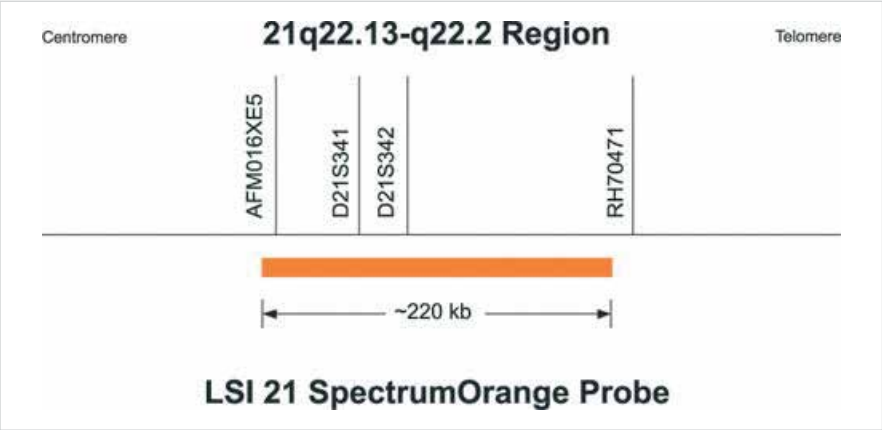
In a normal cell, the expected result for a nucleus hybridized with the LSI 13 (RB1) probe is a two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.



**Normal hybridization:** LSI 13 (RB1) 13q14 Probe hybridized to a normal nucleus showing a two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe **(CE)** | 20 µL | 08L65-020 | 00884999031555 |

# Vysis LSI 21 SpectrumOrange Probe Kit

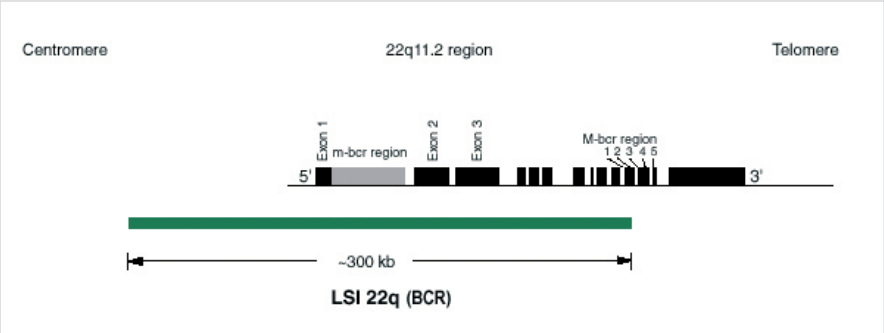




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 21 SpectrumOrange Probe Kit **(CE)** | 20 µL | 08L54-020 | 00884999031449 |

CHROMOSOME ENUMERATION PROBES

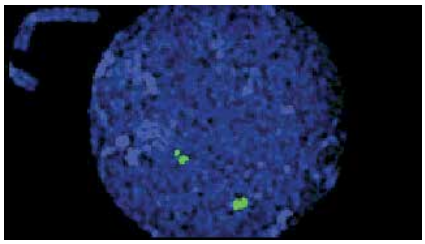
# Vysis LSI 22 (BCR) SpectrumGreen Probe





## PRODUCT DESCRIPTION

The LSI 22 (BCR) Probe is an approximately 300 kb SpectrumGreen probe corresponding to 22q11.2.

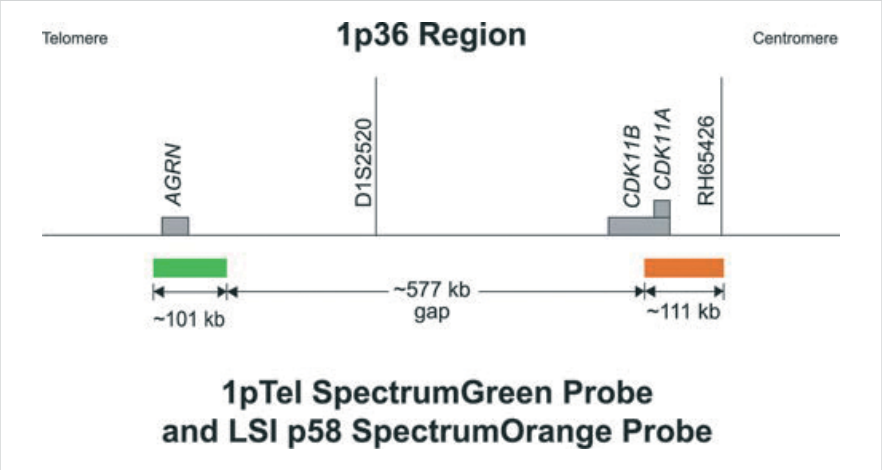


**Normal hybridization:** LSI 22 (BCR) SpectrumGreen hybridized to an interphase cell.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 22 (BCR) SpectrumGreen Probe **(ASR)** | 20 µL | 05J17-024 | 00884999011236 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis 1p36 Microdeletion Region Probe - LSI p58 (1p36) (SpectrumOrange)/TelVysion 1p (SpectrumGreen)/ LSI 1q25 (SpectrumAqua)

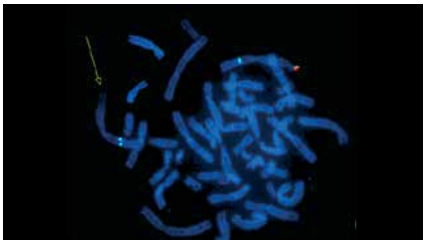




## PRODUCT DESCRIPTION

Terminal deletions involving the 1p subtelomere region and interstitial deletions of 1p36, as well as derivative chromosomes and complex rearrangements resulting in monosomy 1p36, are targeted with this probe set.

The 1p36 Microdeletion Probe Set includes FISH probes to the 1p subtelomere region labeled in SpectrumGreen, p58 (CDC2L1) within 1p36 labeled in SpectrumOrange, and a control probe on 1q25 labeled in SpectrumAqua.

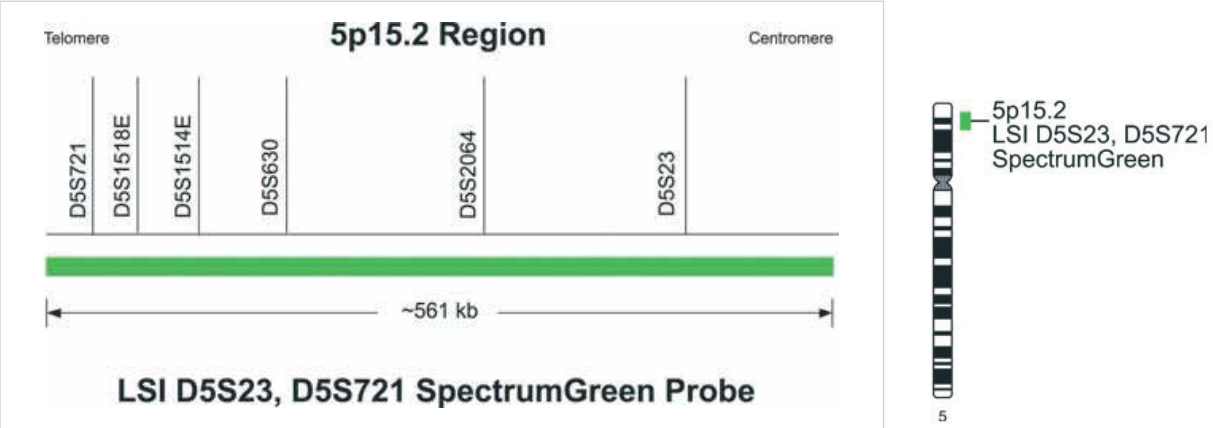


**Abnormal hybridization:** 1p36 Microdeletion Probe hybridized to a metaphase cell.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis 1p36 Microdeletion Region Probe - LSI p58 (1p36) (SpectrumOrange)/TelVysion 1p (SpectrumGreen)/LSI 1q25 (SpectrumAqua) **(ASR)** | 20 µL | 05J21-020 | 00884999011328 |

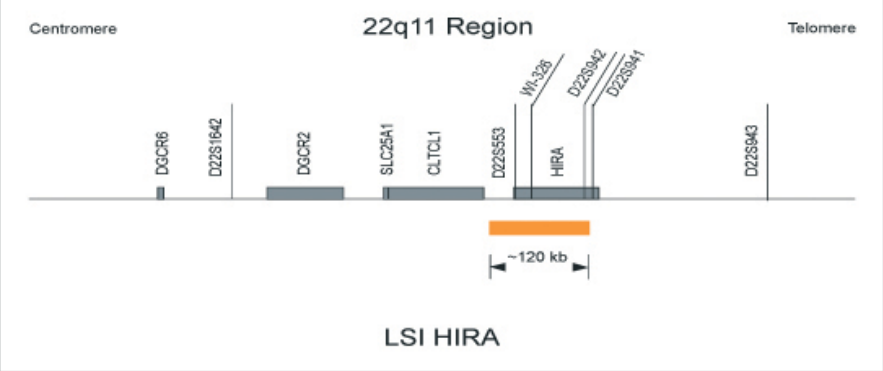
POSTNATAL GENETICS: MICRODELETION SYNDROMES

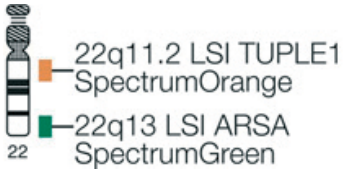
# Vysis Cri-du-Chat Region Probe - LSI D5S23, D5S721

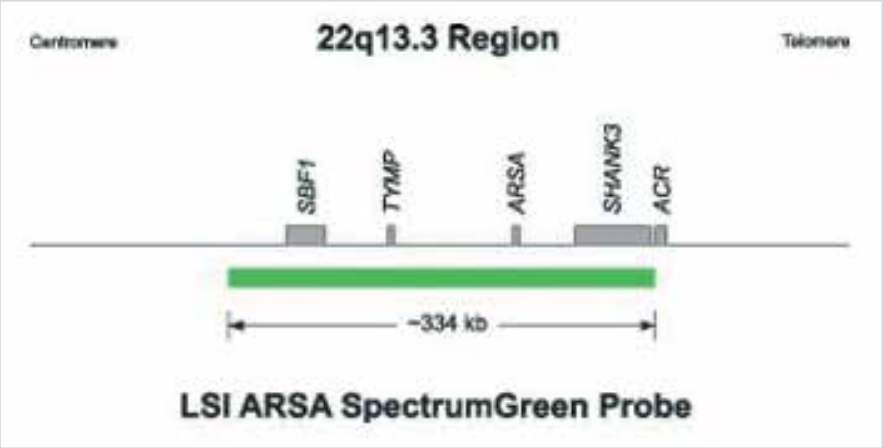



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Cri-du-Chat Region Probe - LSI D5S23, D5S721 **(ASR)** | 20 µL | 05J20-025 | 00884999011298 |

# Vysis DiGeorge Region Probe - LSI TUPLE 1 SpectrumOrange/LSI ARSA SpectrumGreen Probe Kit



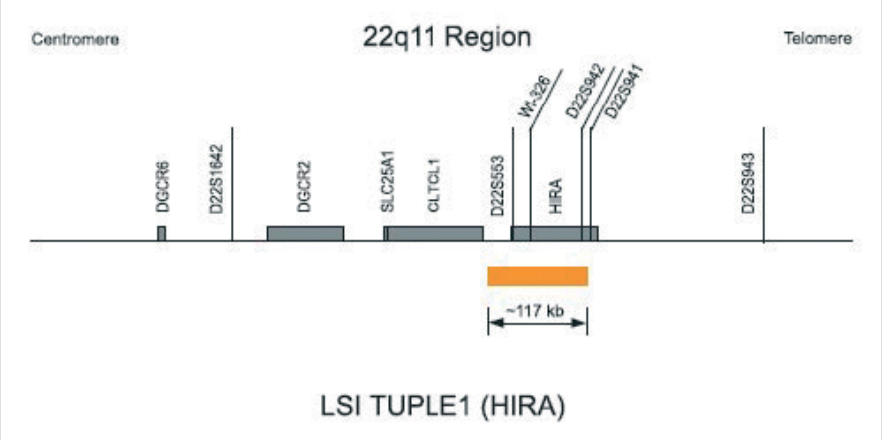



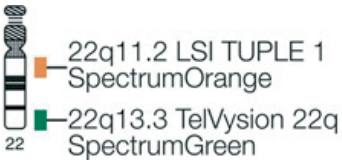



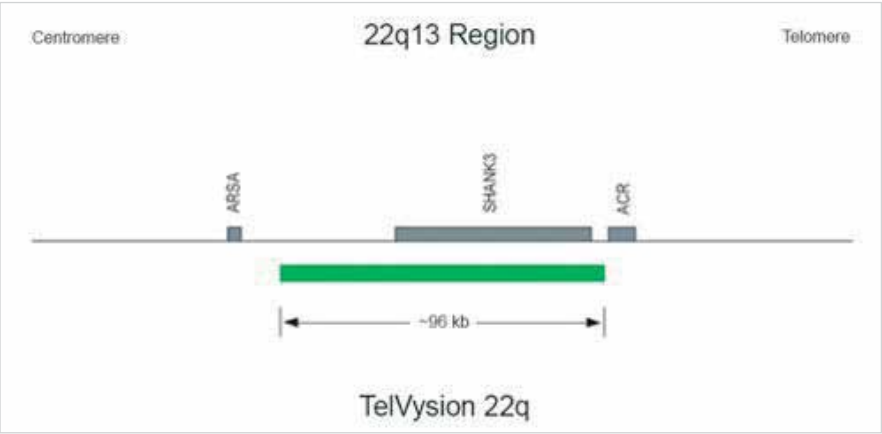

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis DiGeorge Region Probe - LSI TUPLE 1 SpectrumOrange/LSI ARSA SpectrumGreen Probe Kit **(CE)** | 20 µL | 08L59-020 | 00884999031494 |
| Vysis DiGeorge Region Probe - LSI TUPLE 1 SpectrumOrange/LSI ARSA SpectrumGreen **(ASR)** | 20 µL | 05J21-028 | 00884999011342 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

# Vysis DiGeorge Region Probe - LSI TUPLE1 (HIRA) SpectrumOrange/TelVysion 22q SpectrumGreen

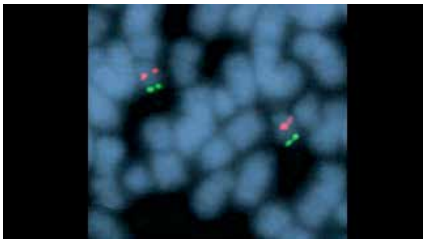



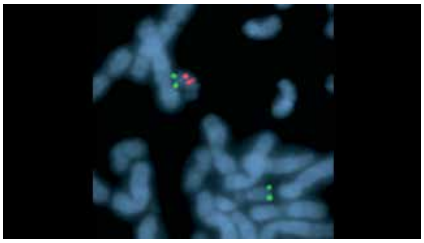

 

## PRODUCT DESCRIPTION

Vysis LSI TUPLE1 (HIRA) is a 117 kb SpectrumOrange probe that hybridizes to the 22q11 region of chromosome 22. The hybridization target spans from 87 kb centromeric to the HIRA gene to a point within the gene, 13 kb from from its telomeric end. TelVysion 22q is 96 kb in size, labeled in SpectrumGreen and hybridizes to the 22q13 subtelomeric region of chromosome 22.



**Normal hybridization:** Normal metaphase pattern showing two green 22q13.3 and two orange 22q11.2 signals.

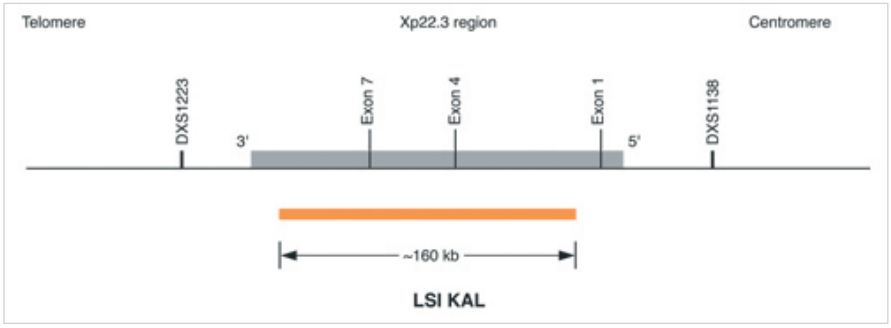


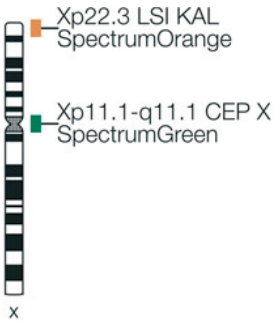
**Abnormal hybridization:** Abnormal metaphase pattern following hybridization to chromosome 22.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis DiGeorge Region Probe - LSI TUPLE1 (HIRA) SpectrumOrange/ TelVysion 22q SpectrumGreen Probe **(ASR)** | 10 µL | 01N14-010 | 00884999000490 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

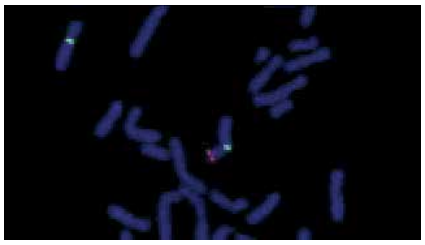
# Vysis Kallman Region Probe - LSI KAL SpectrumOrange/Vysis CEP X SpectrumGreen




## PRODUCT DESCRIPTION

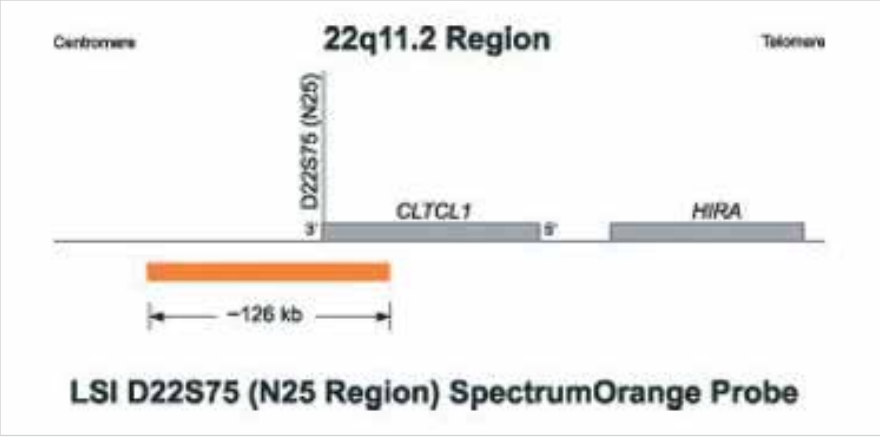
LSI KAL may be used to identify deletions of the KAL gene. This mixture contains the SpectrumOrange LSI KAL probe and the SpectrumGreen CEP X control probe. LSI KAL is known to contain KAL exons 4-7. The KAL probe does not extend past exon 1 or into the 3' region of the gene.

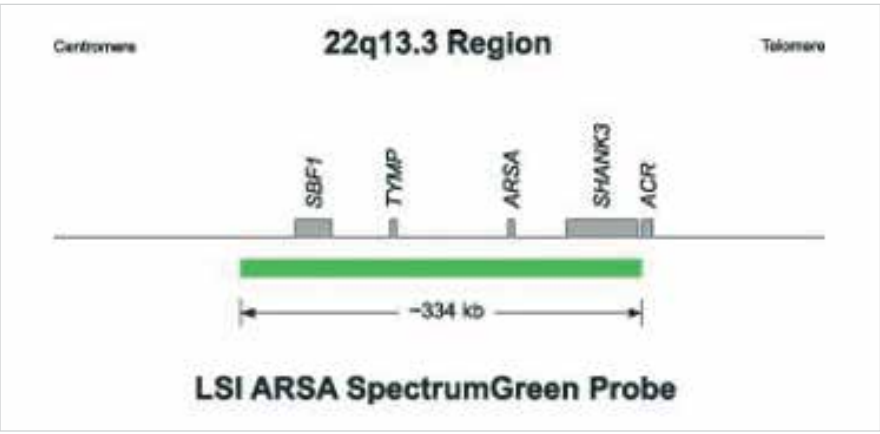


**Normal hybridization:** LSI KAL hybridized to a metaphase cell. Absence of the orange-pink signal on one chromosome X indicates deletion of the KAL locus.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Kallman Region Probe - LSI KAL SpectrumOrange/Vysis CEP X SpectrumGreen **(ASR)** | 20 µL | 05J23-070 | 00884999011380 |

# Vysis LSI D22S75 (N25 region) SpectrumOrange/ LSI ARSA SpectrumGreen Probe



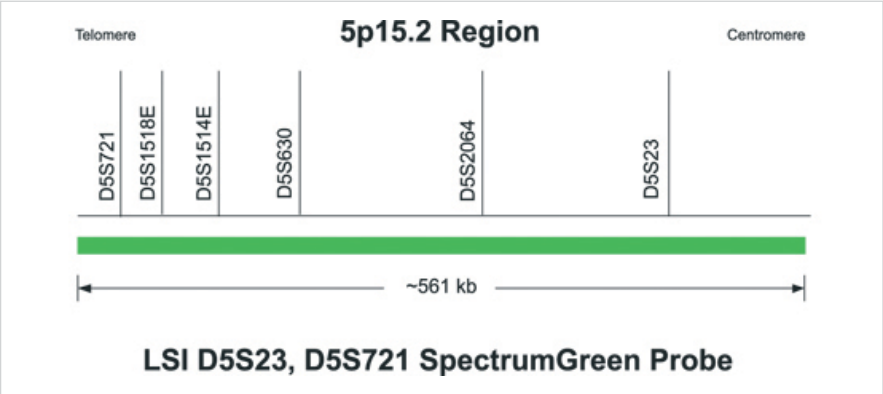



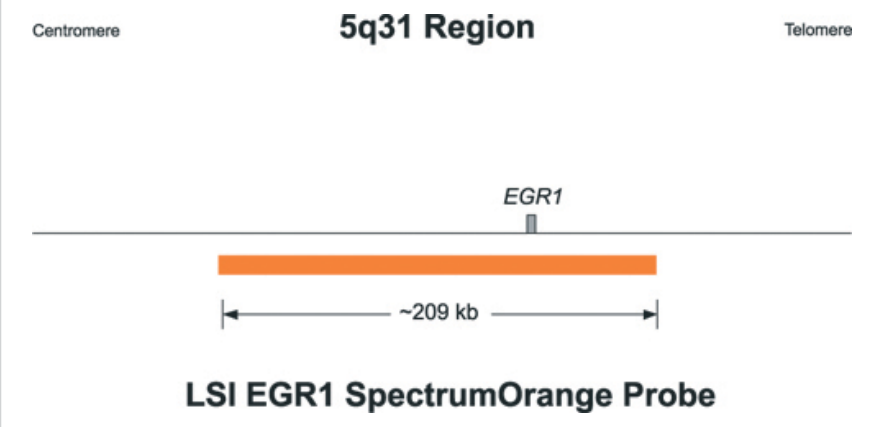


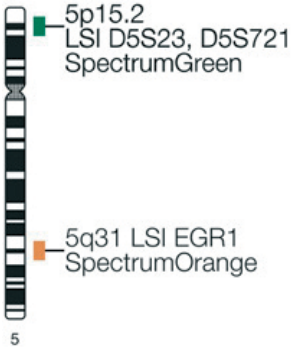
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI D22S75 (N25 region) SpectrumOrange/ LSI ARSA SpectrumGreen Probe **(ASR)** | 10 µL | 05N24-010 | 00884999014770 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

# Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit



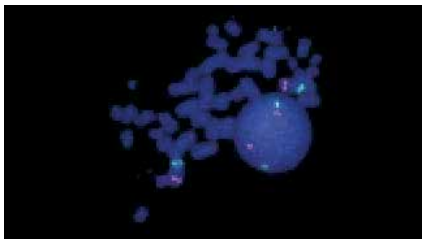




## PRODUCT DESCRIPTION

The LSI EGR1/D5S23, D5S721 Dual Color Probe may be used to detect deletions of 5q31 containing the EGR1 locus. The LSI D5S23, D5S721 probe aids in determining if the deletion is of the whole chromosome 5 (-5) versus 5q-.The LSI EGR1/D5S23, D5S721 Probe is a mixture of the approximately 200 kb SpectrumOrange labeled LSI EGR1 probe and the approximately 450 kb SpectrumGreen labeled LSI D5S23, D5S721 probe.

## RESULTS OF HYBRIDIZATION

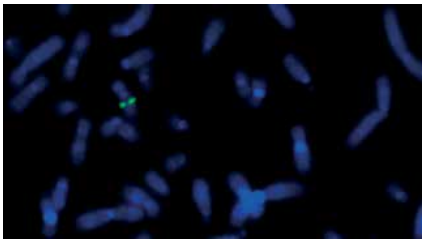
In a normal cell, the expected pattern for a nucleus hybridized with the LSI EGR1/D5S23, D5S721 probe is the two orange, two green (2O2G) signal pattern. In a hybridized abnormal cell containing the deletion, the one orange, two green (1O2G) signal pattern will be observed.



**Normal hybridization:** LSI EGR1/D5S721, D5S23 Dual Color Probe hybridized to normal cells showing the two orange, two green (2O2G) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit **(CE)** | 20 µL | 08L68-020 | 00884999031586 |

# Vysis LSI MAPT

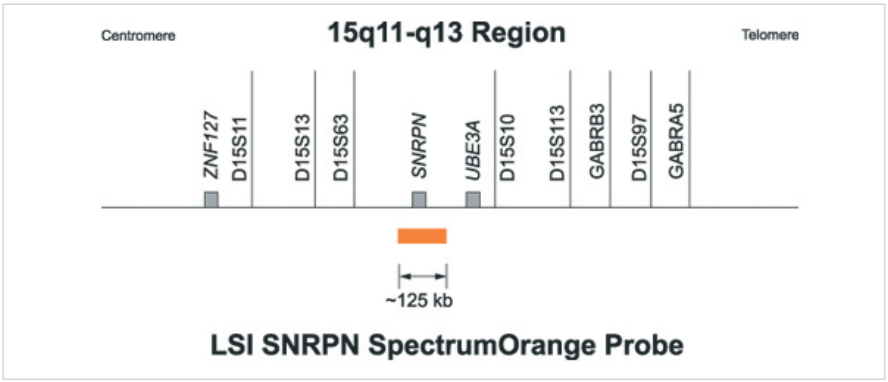


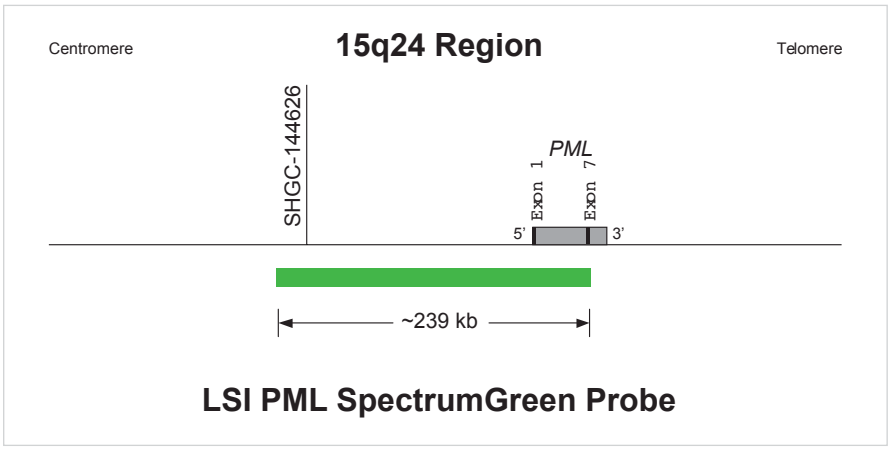
**Normal hybridization:** MAPT SpectrumGreen probe hybridized to a metaphase cell. Absence of the green signal on one chromosome 17 indicates deletion of the MAPT locus.

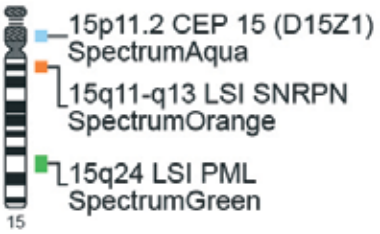
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MAPT **(ASR)** | 10 µL | 02N19-010 | 00884999002708 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

# LSI SNRPN (SO)/Vysis CEP 15 (D15Z1) (SA)/ LSI PML (SG) TriColor Probe Kit



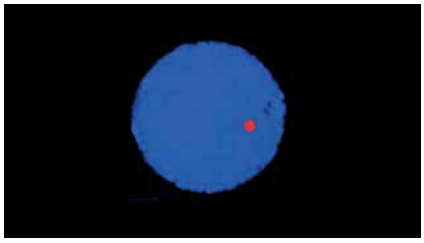




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| LSI SNRPN (SO)/Vysis CEP 15 (D15Z1) (SA)/LSI PML (SG) TriColor Probe Kit **(CE)** | 10 µL | 06N27-010 | 00884999025608 |
| LSI SNRPN (SO)/Vysis CEP 15 (D15Z1) (SA)/LSI PML (SG) TriColor Probe **(ASR)** | 10 µL | 01N12-010 | 00884999000476 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis LSI Xq13.2 (XIST)

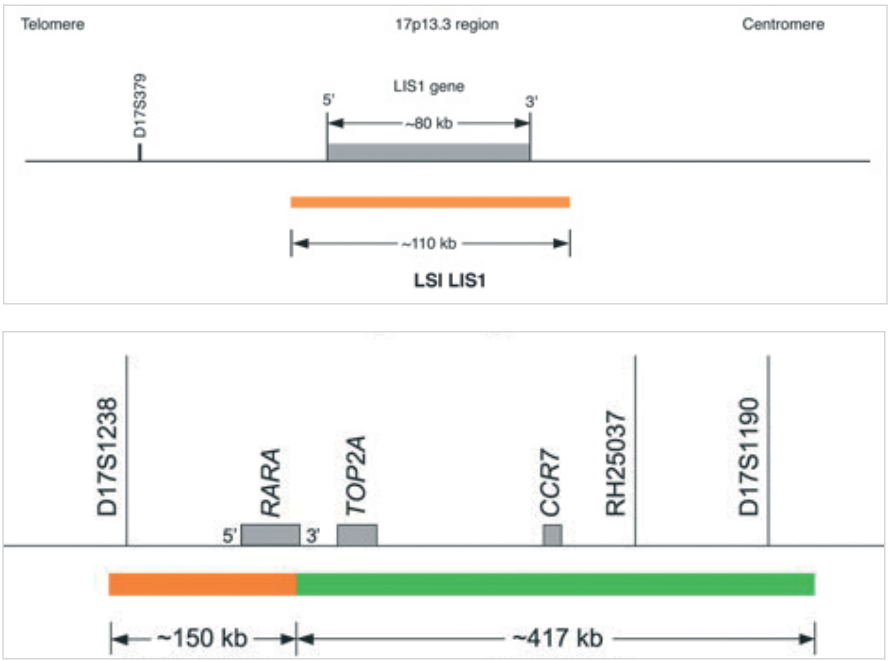


**Normal hybridization:** In a normal male cell hybridized with LSI Xq13.2 (XIST) SpectrumOrange probe, the expected signal pattern is one orange signal.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI Xq13.2 (XIST) **(ASR)** | 10 µL | 01N61-001 | 00884999000810 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

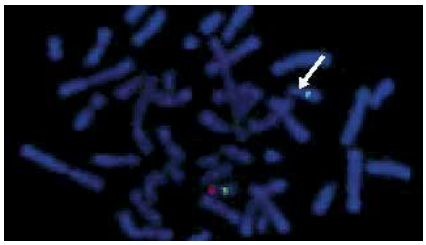
# Vysis Miller-Dieker Region/Isolated Lissencephaly Probe LSI LIS1 SpectrumOrange/LSI RARA





## PRODUCT DESCRIPTION

The Vysis LSI LIS1 FISH probe is approximately 110 kb in size and homologous to the LIS1 gene located at 17p13.3. The LSI LIS1 probe is directly labeled with SpectrumOrange and is mixed with a control probe, LSI RARA. LSI RARA is specific to the 17q21.1 region and is directly labeled with SpectrumGreen fluorophore.

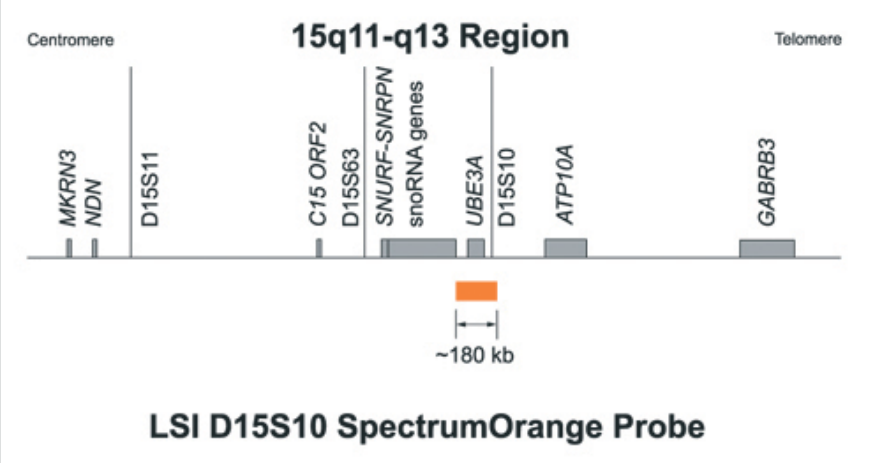


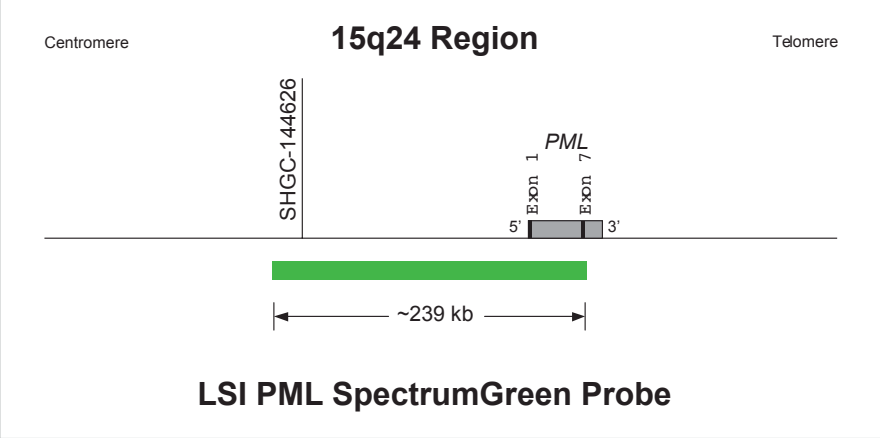
## RESULTS OF HYBRIDIZATION

Metaphase spread containing one chromosome 17 with SpectrumGreen LSI RARA and absence of the SpectrumOrange LSI LIS1 signal (arrow). The normal chromosome 17 shows the presence of SpectrumOrange LSI LIS1 and SpectrumGreen LSI RARA.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Miller-Dieker Region/Isolated Lissencephaly Probe LSI LIS1 SpectrumOrange/LSI RARA SpectrumGreen **(ASR)** | 20 µL | 05J88-001 | 00884999012790 |

# Vysis Prader-Willi/Angelman Region Probe - LSI D15S10 (SO)/Vysis CEP 15 (D15Z1) (SA)/PML (SG)



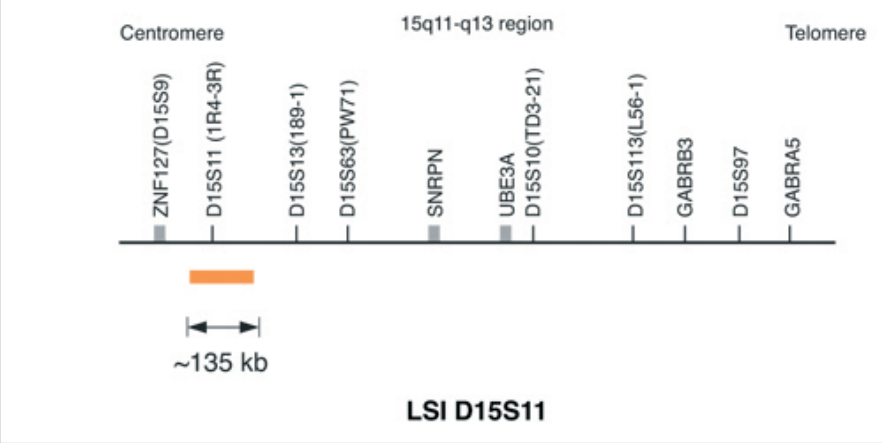





| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Prader-Willi/Angelman Region Probe - LSI D15S10 (SO)/Vysis CEP 15 (D15Z1) (SA)/PML (SG) **(CE)** | 10 µL | 05N58-010 | 00884999015067 |
| Vysis Prader-Willi/Angelman Region Probe - LSI D15S10 (SO)/Vysis CEP 15 (D15Z1) (SA)/PML (SG) **(ASR)** | 10 µL | 01N13-010 | 00884999000483 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

# Vysis Prader-Willi/Angelman Region Probe - LSI D15S11/Vysis CEP 15 (D15Z1)





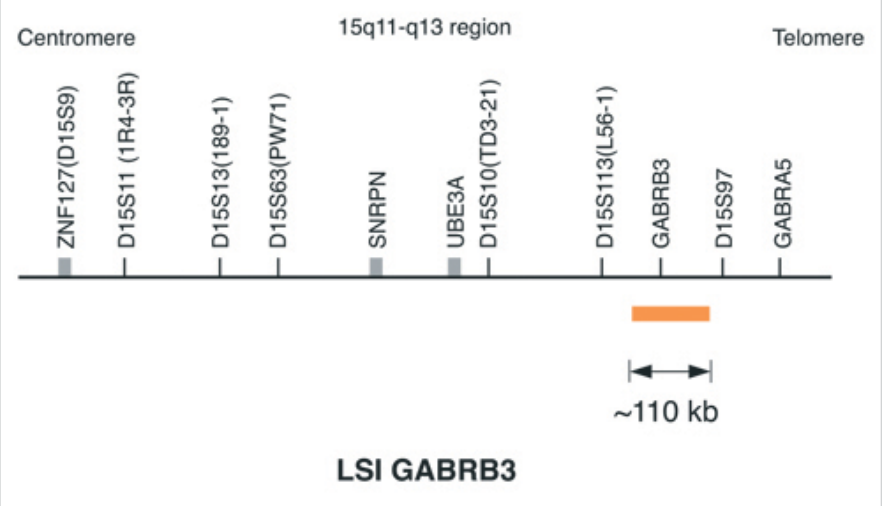
## PRODUCT DESCRIPTION

Four products are offered for the detection or characterization of abnormalities involving 15q11-q13. Vysis 15q11-q13 probes are premixed with a CEP 15 control probe. The SNRPN and D15S10 probe mixes also include LSI PML (15q22), a control probe useful for detecting rare translocations in AS and PWS.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Prader-Willi/Angelman Region Probe - LSI D15S11/Vysis CEP 15 (D15Z1) **(ASR)** | 20 µL | 05J19-014 | 00884999011274 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis Prader-Willi/Angelman Region Probe - LSI GABRB3 SpectrumOrange/Vysis CEP 15 (D15Z1) SpectrumGreen





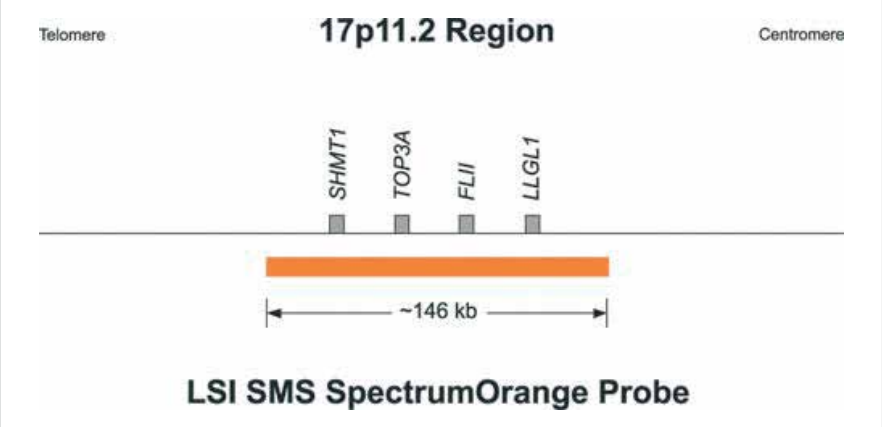
## PRODUCT DESCRIPTION

Four products are offered for the detection or characterization of abnormalities involving 15q11-q13. Vysis 15q11-q13 probes are premixed with a CEP 15 control probe. The SNRPN and D15S10 probe mixes also include LSI PML (15q22), a control probe useful for detecting rare translocations in AS and PWS.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Prader-Willi/Angelman Region Probe - LSI GABRB3 SpectrumOrange/Vysis CEP 15 (D15Z1) SpectrumGreen **(ASR)** | 20 µL | 05J22-015 | 00884999011366 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

# Vysis Smith-Magenis Region Probe - LSI SMS Region SpectrumOrange/LSI RARA SpectrumGreen



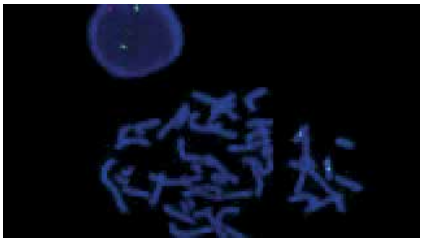


## PRODUCT DESCRIPTION

LSI SMS is approximately 140 kb in size and homologous to the Smith-Magenis region. The LSI SMS probe is directly labeled with SpectrumOrange and is mixed with the LSI RARA control probe. LSI RARA is specific to 17q21.1 and is directly labeled with SpectrumGreen.

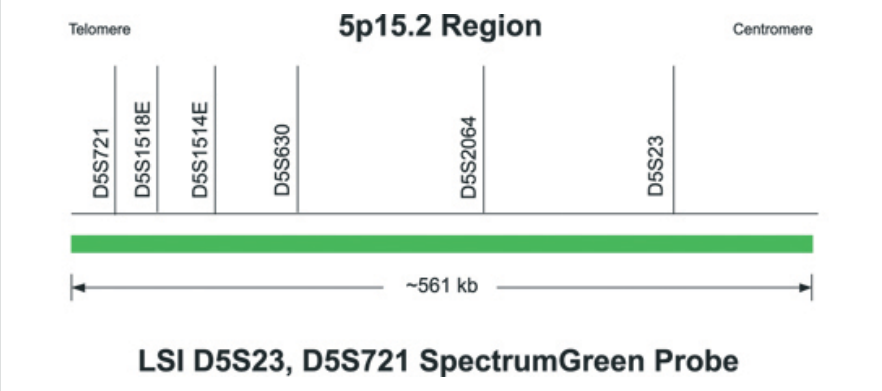
## RESULTS OF HYBRIDIZATION

Metaphase spread containing one chromosome 17 with the SpectrumGreen SpectrumGreen the SpectrumOrange LSI SMS Probe signal. The normal chromosome 17 shows the presence of the SpectrumOrange LSI SMS Probe and the SpectrumGreen LSI RARA Control Probe.

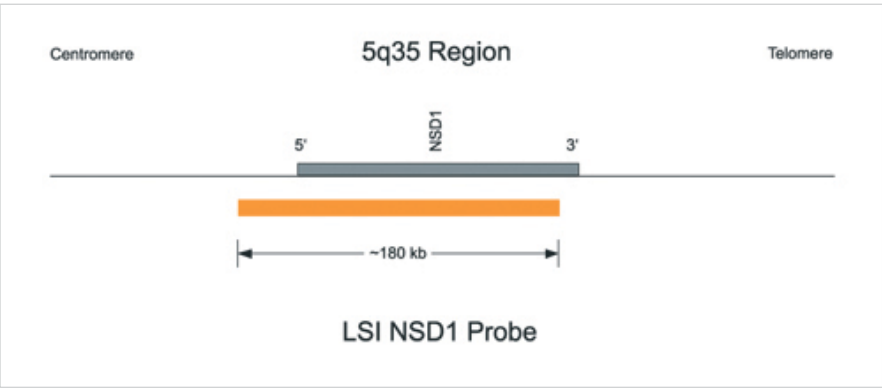


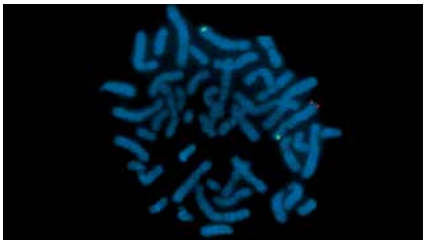
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Smith-Magenis Region Probe - LSI SMS Region SpectrumOrange/ LSI RARA SpectrumGreen **(ASR)** | 20 µL | 05J25-003 | 00884999011427 |

# Vysis Sotos Region Probe - LSI NSD1 (5q35) SpectrumOrange Probe







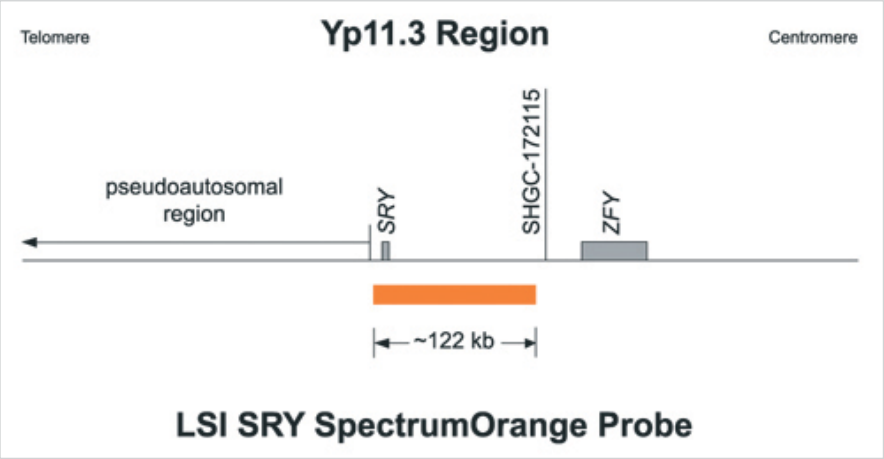



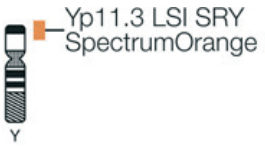
**Abnormal hybridization:** LSI NSD1 (5q35) SpectrumOrange Probe Set hybridized to a metaphase cell.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Sotos Region Probe - LSI NSD1 (5q35) SpectrumOrange Probe **(ASR)** | 20 µL | 05J48-007 | 00884999011915 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

# Vysis SRY Probe - LSI SRY SpectrumOrange

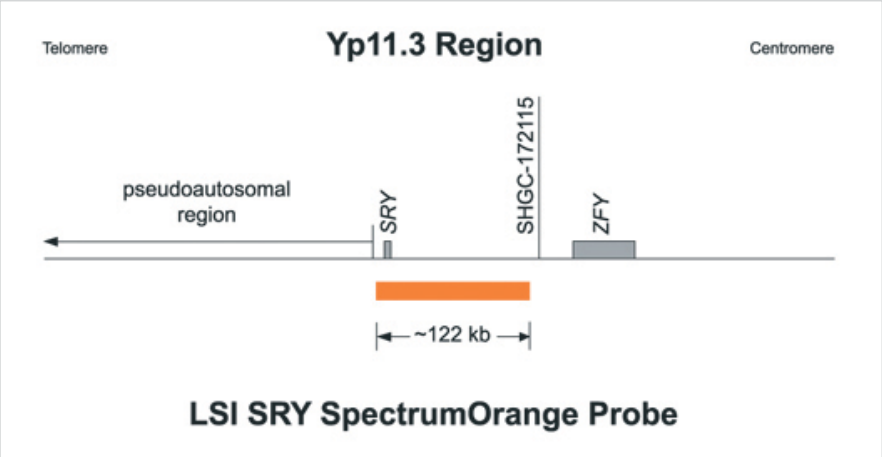


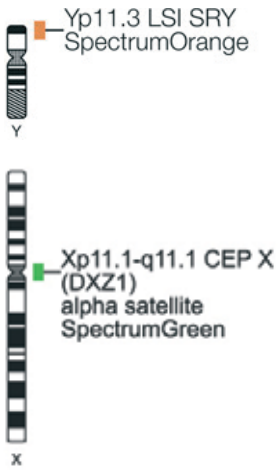




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis SRY Probe - LSI SRY SpectrumOrange **(ASR)** | 20 µL | 05J27-079 | 00884999011496 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis SRY Probe LSI SRY Spectrum Orange/ Vysis CEP X Spectrum Green Probe Kit

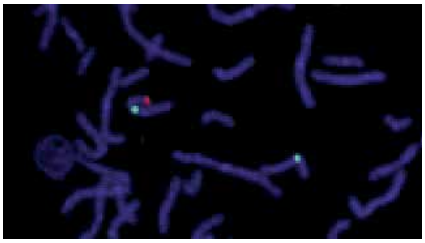



## PRODUCT DESCRIPTION

The SRY gene is located within 10 kb of the pseudoautosomal region of Yp. The LSI SRY probe is useful in detecting deletions of SRY or presence of the gene in rearrangements involving the X chromosome, autosomes and marker chromosomes.

The LSI SRY DNA FISH probe is an approximately 120 kb probe specific to the SRY gene and flanking sequences. This probe is direct labeled with SpectrumOrange and is available as a single probe or mixed with the CEP X SpectrumGreen probe.

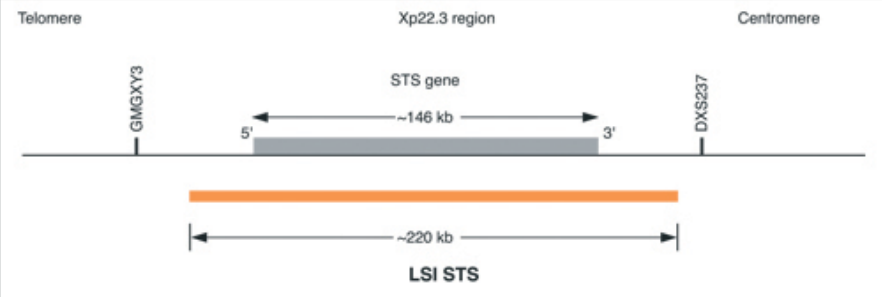


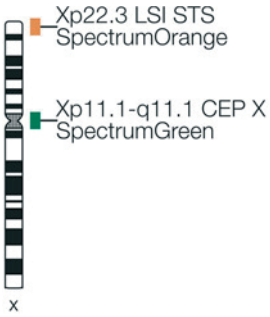
**Abnormal hybridization:** LSI SRY SpectrumOrange/CEP X SpectrumGreen metaphase hybridization.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis SRY Probe LSI SRY Spectrum Orange/Vysis CEP X Spectrum Green Probe Kit **(CE)** | 20 µL | 06N29-020 | 00884999025622 |
| Vysis SRY Probe LSI SRY Spectrum Orange/Vysis CEP X Spectrum Green **(ASR)** | 20 µL | 05J27-007 | 00884999011472 |

POSTNATAL GENETICS: MICRODELETION SYNDROMES

# Vysis Steroid Sulfatase Deficiency Probe - LSI STS SpectrumOrange/LSI Vysis CEP X Spectrum Green



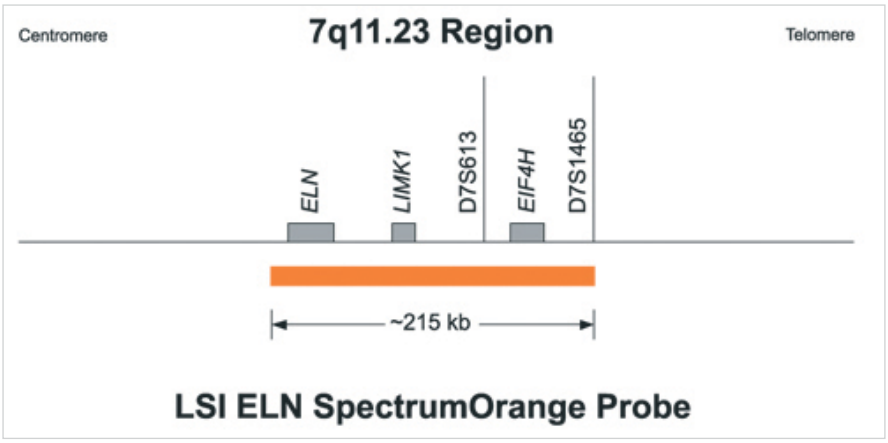

## PRODUCT DESCRIPTION

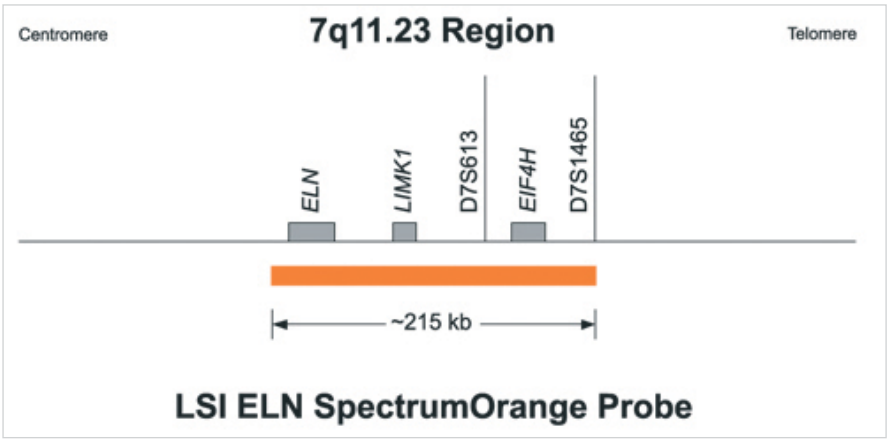
LSI STS may be used to identify deletions of the STS gene located in band Xp22.3. This mixture contains the SpectrumOrange LSI STS probe and the SpectrumGreen CEP X control probe. The LSI STS, approximately 220 kb in size, includes the entire STS gene. The STS probe does not contain the more telomeric locus GMGXY3 or the more centromeric locus DXS237.

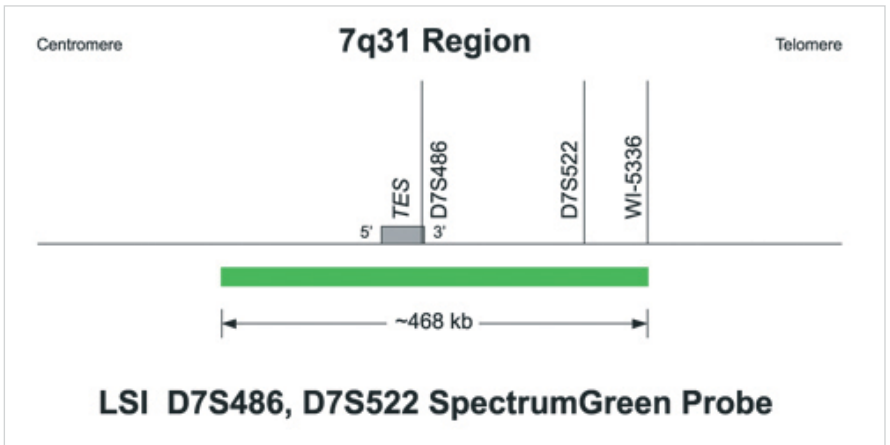
**Normal hybridization:** LSI STS probe hybridized to a metaphase cell demonstrating a normal 2O signal pattern.

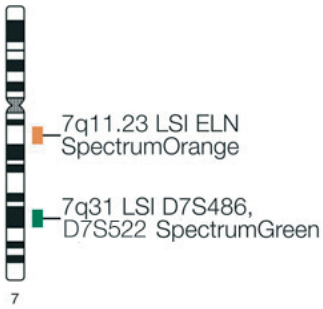
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Steroid Sulfatase Deficiency Probe - LSI STS SpectrumOrange/LSI Vysis CEPX Spectrum Green **(ASR)** | 20 µL | 05J28-004 | 00884999011519 |

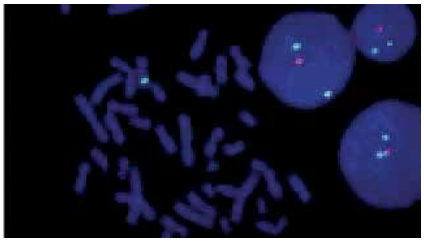
# Vysis Williams Region Probe - LSI ELN SpectrumOrange/ LSI D7S486, D7S522 SpectrumGreen Probe Kit



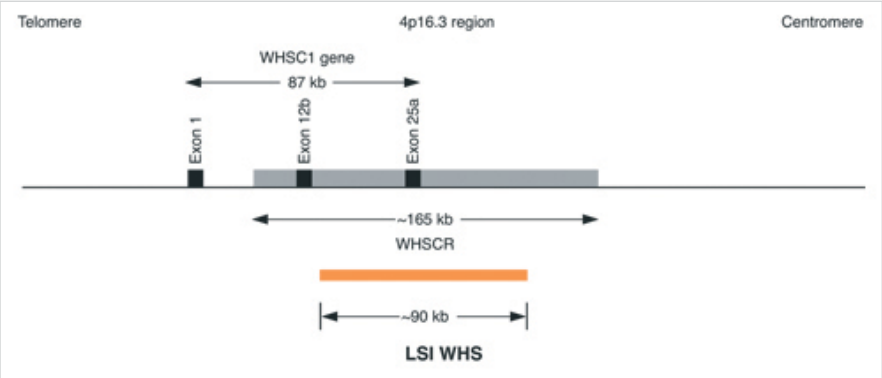



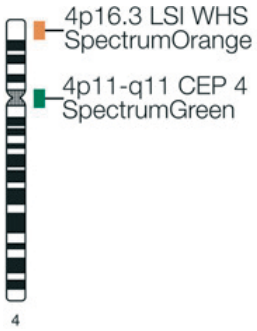


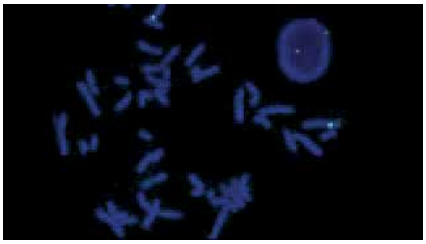
**Abnormal hybridization:** Metaphase and interphase cells hybridized with LSI ELN. Absence of the orange signal on one chromosome 7 indicates a deletion of the Williams Region.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Williams Region Probe - LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen Probe Kit **(CE)** | 20 µL | 06N28-020 | 00884999011564 |
| Vysis Williams Region Probe - LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen Probes **(ASR)** | 20 µL | 05J30-045 | 00884999025615 |

# Vysis Wolf-Hirschhorn Region Probe - LSI WHS SpectrumOrange/CEP 4 SpectrumGreen



**Abnormal hybridization:** Metaphase spread containing one chromosome with the CEP 4 SpectrumGreen but without the LSI WHS SpectrumOrange signal.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis Wolf-Hirschhorn Region Probe - LSI WHS SpectrumOrange/CEP 4 SpectrumGreen **(ASR)** | 20 µL | 05J29-074 | 00884999011533 |

POSTNATAL GENETICS: TOTELVYSION

# Vysis TotelVysion


## PRODUCT DESCRIPTION

ToTelVysion_Product_Image.jpgToTelVysion consists of 41 TelVysion probes, including various LSI and CEP probes (64 probes in total).

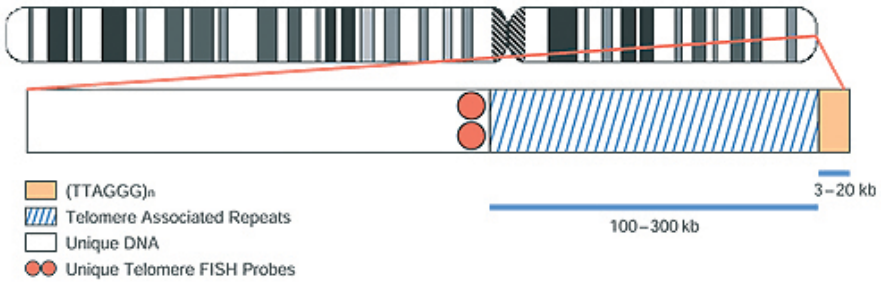
- The 41 TelVysion probes are specific to:
- p and q subtelomeres of chromosomes 1-12 and 16-20
- q subtelomeres of the acrocentric chromosomes (13, 14, 15, 21, and 22)
- Xp/Yp and Xq/Yq pseudo-autosomal region subtelomeres
- A unique region within 300 kb of each chromosome telomere

The probes in ToTelVysion are provided in 15 mixtures. All probes are direct labeled, providing bright signals with minimal background noise. By utilizing SpectrumOrange, SpectrumGreen, SpectrumAqua, and a combination of SpectrumOrange and SpectrumGreen (to yield a yellow signal), each probe within a mixture is labeled with a unique color.

## VYSIS TELVYSION PROBES

Telomeres are DNA-protein complexes that cap the ends of eukaryotic chromosomes. Every telomere contains 3 to 20 kb of tandem TTAGGG repeats. The telomere associated repeats (TAR), also known as the subtelomeric repeats, are immediately proximal to the TTAGGG repeats. They contain regions of shared homology between subsets of certain chromosomes.

Each TelVysion targeted site is a unique, chromosome specific DNA located approximately 100 to 300 kb from the chromosome end.




Schematic of the make-up of human chromosome telomeric regions. Diagram courtesy of C. Lese and D. Ledbetter, University of Chicago.

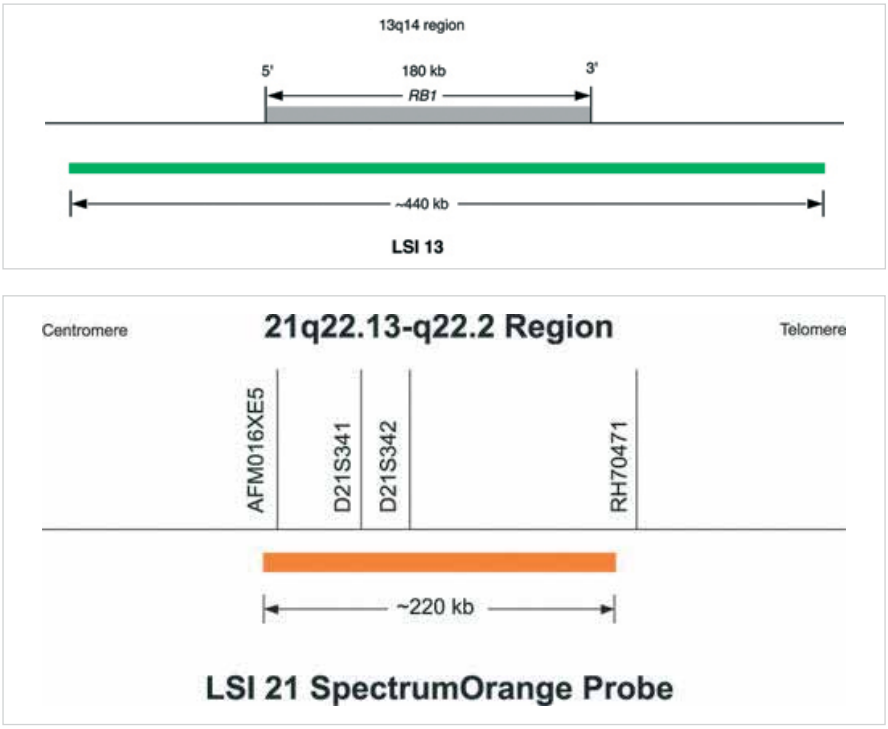
In the context of constitutional chromosome analysis, the most distal region of unique DNA on a chromosome arm commonly is referred to as the "subtelomere." Subtelomeres are known to contain a high concentration of genes as compared to other chromosome regions.Yet, subtelomere abnormalities can be difficult, if not impossible, to detect by routine G-band analysis because subtelomeres stain negative (light).

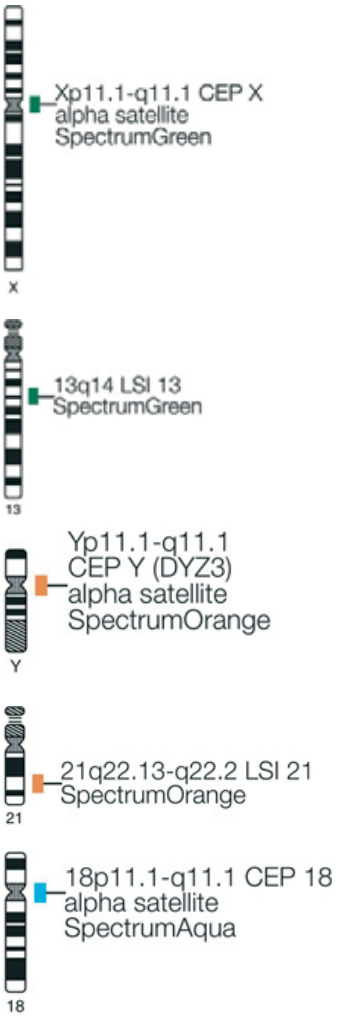
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |

PRENATAL GENETICS

# AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21)

ANEUVYSION




## PRODUCT DESCRIPTION

AneuVysion, which utilizes patented fluorescence in situ hybridization (FISH) technology applied to uncultured amniocytes, provides detection of trisomies 13, 18, and 21 (Down syndrome) and sex chromosome aneusomies in as little as 24 hours. Together these conditions account for nearly twothirds of all abnormalities identified at the time of amniocentesis, and 85-90% of clinically significant chromosomal abnormalities detected in live-born infants. Review of AneuVysion testing of over 29,000 amniotic fluid samples has found that the test is 99.9% accurate for the detection of trisomies 13, 18, 21, and aneusomies of X and Y.

There are several benefits of the AneuVysion Test. Results are rapidly available, within 24 hours after the amniocentesis sample is received in the laboratory (rather than 7-22 days for routine chromosome analysis). In accordance with professional standards, the availability of AneuVysion results along with consistent clinical information (i.e., fetal anomalies detected by ultrasonography) allows for pregnancy management options that otherwise might not be available due to late gestational age. Finally, in the rare case of a culture failure when standard cytogenetic results cannot be obtained, information on chromosome number for the most likely aneusomies is available.

## PROBE MIXTURE #1

- **CEP 18:** D18Z1 alpha satellite DNA probe corresponding to 18p11.1-q11.1 labeled with SpectrumAqua
- **CEP X:** DXZ1 alpha satellite DNA probe corresponding to Xp11.1-q11.1 labeled with SpectrumGreen
- **CEP Y:** DYZ3 alpha satellite DNA probe corresponding to Yp11.1-q11.1 labeled with SpectrumOrange

## PROBE MIXTURE #2

- **LSI 18:** DNA probe corresponding to the RB1 gene (13q14) labeled with SpectrumGreen.
- **LSI 21:** DNA probe corresponding to loci D21S259, D21S341, and D21S342(21q22.13-q22.2) labeled with SpectrumOrange.

Mixture #1 is complete with labeled probes and non-labeled blocking DNA in hybridization buffer.

## RELATED PRODUCTS

Products for use with AneuVysion

ProbeChek Prenatal Control Slides for Amniocyte;

- Male Amniocyte Control
- 30-805010 — 5 Slides
- Fixed biological specimen derived from normal human male amniocytes applied to glass microscope slides.

ProbeChek Prenatal Control Slides for Positive Control

- 30-805017 — 5 Slides
- Fixed biological specimen derived from human triploid fibroblast cells applied to glass microscope slides.
- Control slides are excellent training and validation tools for the AneuVysion Test.

## INTENDED USE

For In Vitro Diagnostic Use

The AneuVysion (Vysis CEP 18, X, Y-alpha satellite, LSI 13 and 21) Multicolor Probe Panel is intended to use CEP 18/X/Y probe to detect alpha satellite sequences in the centromere regions of chromosomes 18, X, and Y, and LSI 13/21 probe to detect the 13q14 region and the 21q22.13 to 21q22.2 region. The AneuVysion kit is indicated for identifying and enumerating chromosomes 13, 18, 21, X, and Y via fl uorescence in situ hybridization (FISH) in metaphase cells and interphase nuclei obtained from amniotic fl uid in subjects with presumed high risk pregnancies. It is not intended to be used as a stand alone assay for making clinical decisions. FISH results are intended to be used as an aid in the diagnosis of numerical abnormalities of chromosomes 13, 18, 21, X and/or Y in conjunction with other information currently used in prenatal diagnosis, consistent with professional standards of practice [1]. This device is intended for use only with amniocyte cells; it is not intended for and has not been validated for use with other test matrices. This FISH assay will not detect the presence of structural chromosome abnormalities that can also result in birth defects. This FISH assay will be performed in cytogenetics laboratories.

## LIMITATIONS

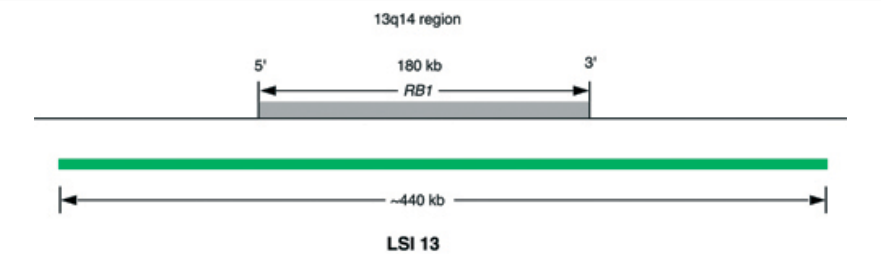
1. The AneuVysion kit has been characterized only for identifying targeted regions of chromosomes X,Y,18,13, and 21 in interphase nuclei from cultured and uncultured amniocyte specimens.
2. The clinical interpretation of any test result(s) should be made in conjunction with other diagnostic laboratory test results and should be evaluated within the context of the patient's medical history and current risk factors. Patient management decisions should be made based on information from two or three of the following parameters: FISH results, routine chromosome analysis, or clinical information [1].
3. FISH assay results may not be informative if the specimen quality and/or specimen slide preparation is inadequate.
4. This assay will not detect the presence of structural abnormalities frequently associated with birth defects. The frequency of these occurrences may be population and gestational age dependent.
5. This assay should not be performed on amniocyte specimens with moderate to severe maternal cell contamination. FISH test results on amniocyte specimens with mild maternal cell contaminations should be interpreted with caution.
6. No irreversible therapeutic action should be initiated based on the FISH assay lone. Positive results should be further characterized using traditional chromosome analysis to determine the mutational mechanism accounting for the abnormality detected by FISH. This information may aid in the counseling for the risk that the detected abnormality may occur in future pregnancies [1].

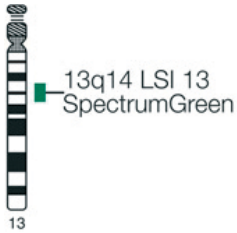
7. Physicians, counselors, and other healthcare providers should understand the risk of abnormalities that the test is not designed to detect. The patient should be informed that there is still a very small risk of low level mosaicsim, cryptic translocations, or other undetectable events that may not be demonst4rated by FISH or standard cytogenetic. Additionally, there is a very small risk that some individuals carry a genetic polymorphism that may affect the intensity, presence or absence of the probe signal that may result in a missed diagnosis [17].
8. When the specimen volume is not sufficient to meet the minimum requirements for processing both FISH and standard cytogenetic procedures, the user must carefully weigh the risks and benefits of utilizing any material for FISH. Consultation between the laboratory geneticist and or genetic counselor and the patient's physician may aid in clarifying what information is desired, and which testing method should be used [1].
9. Technologists performing the FISH signal enumeration must be capable of visually distinguishing between orange, green and aqua signals.
10. Although the probe for enumerating chromosome 13 spans the Rb1 locus, this probe has not been validated for detecting mutations associated with retinoblastoma. In rare cases, the Rb1 locus may be deleted; this could complicate interpretation of FISH test results.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE & FDA IVD)** | 10 Assays | 05J38-010 | 00884999011694 |
| | 30 Assays | 05J38-030 | 00884999011700 |
| | 50 Assays | 05J38-050 | 00884999011717 |

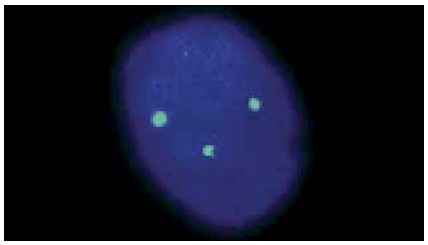
# Vysis LSI 13 (13q14) SpectrumGreen Probe




## PRODUCT DESCRIPTION

LSI 13 (13q14) consists of a set of overlapping clones that contain the RB1 gene and flanking regions. The RB1 gene is 180 kb. The probe extends beyond the gene for 110-170 kb in the 5' direction and approximately 120 kb in the 3' direction. The entire probe is approximately 440 kb in size.

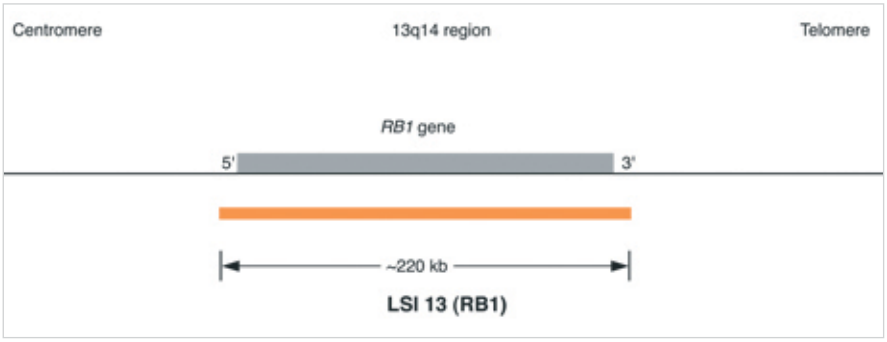


**Abnormal hybridization:** LSI 13 (13q14) SpectrumGreen hybridized to an amniocyte. Three green signals indicate three copies of chromosome 13

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 13 (13q14) SpectrumGreen Probe **(CE)** | 20 µL | 08L67-020 | 00884999031579 |

PRENATAL GENETICS

# Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe





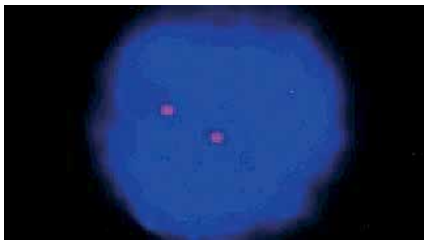
## PRODUCT DESCRIPTION

The LSI 13 (RB1) 13q14 SpectrumOrange Probe contains unique DNA sequences specific to the RB1 gene within the 13q14 region of chromosome 13. The presence or absence of the RB1 gene region may be detected using the LSI 13 (RB1) 13q14 Probe. This probe may be used to detect deletion (not mutation) of the RB1 gene locus.

The LSI 13 (RB1) 13q14 SpectrumOrange Probe is approximately 220 kb and contains sequences that target the entire RB1 gene.

## RESULTS OF HYBRIDIZATION

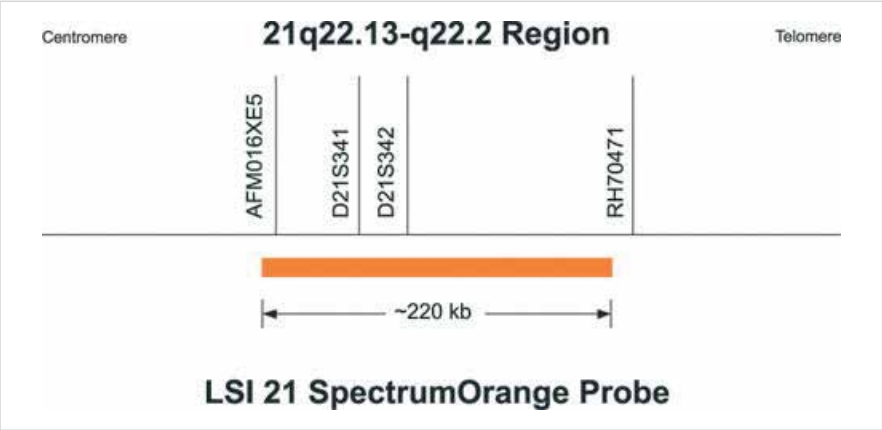
In a normal cell, the expected result for a nucleus hybridized with the LSI 13 (RB1) probe is a two orange (2O) signal pattern. In a hybridized abnormal cell containing the deletion, a one orange (1O) signal pattern will be observed.



**Normal hybridization:** LSI 13 (RB1) 13q14 Probe hybridized to a normal nucleus showing a two orange (2O) signal pattern.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 13 RB1 (13q14) SpectrumOrange Probe **(CE)** | 20 µL | 08L65-020 | 00884999031555 |

# Vysis LSI 21 SpectrumOrange Probe Kit

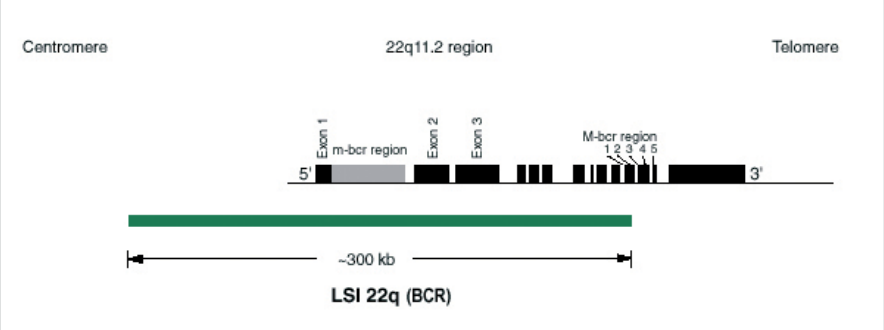




| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 21 SpectrumOrange Probe Kit **(CE)** | 20 µL | 08L54-020 | 00884999031449 |

PRENATAL GENETICS

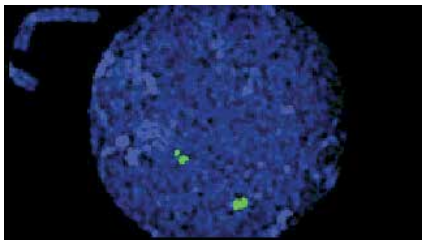
# Vysis LSI 22 (BCR) SpectrumGreen Probe





## PRODUCT DESCRIPTION

The LSI 22 (BCR) Probe is an approximately 300 kb SpectrumGreen probe corresponding to 22q11.2.

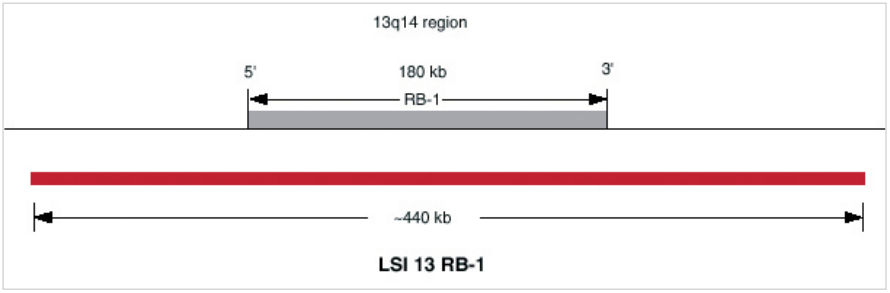


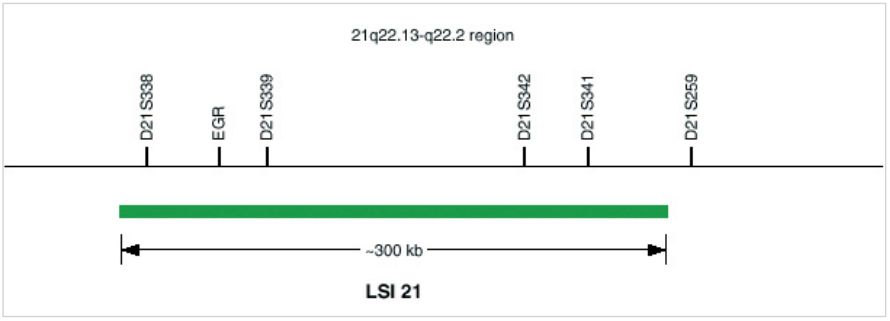
**Normal hybridization:** LSI 22 (BCR) SpectrumGreen hybridized to an interphase cell.

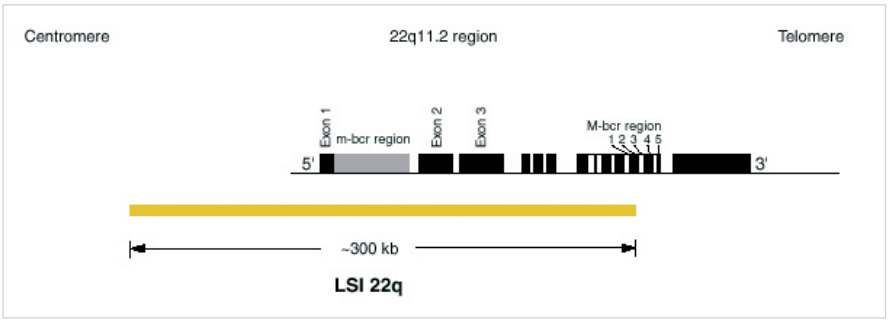
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI 22 (BCR) SpectrumGreen Probe **(ASR)** | 20 µL | 05J17-024 | 00884999011236 |

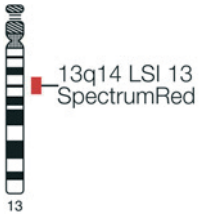
 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Vysis MultiVysion PB Multi-color Probe







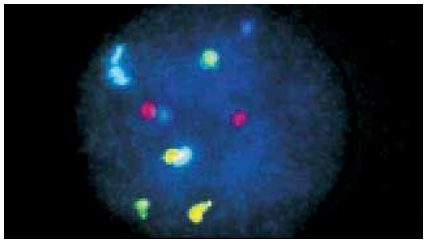

## PRODUCT DESCRIPTION

MultiVysion PGT and MultiVysion PB fluorescence in situ hybridization (FISH) probe sets are designed for determination of chromosome copy number in single cells.

Unlabeled DNA is included with both probe sets to block sequences contained within the target loci that are common to other chromosomes. This probe set is premixed in Hybridization Buffer.

## PROBE MIXTURE

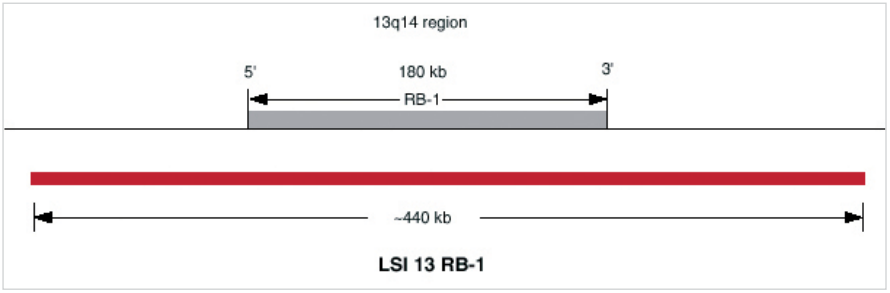
- **LSI 13:** DNA probe spanning the RB1 (13q14) labeled with SpectrumRed.
- **CEP 16:** D16Z3 satellite II DNA probe corresponding to 16q11.2 labeled with SpectrumAqua.
- **CEP 18:** D18Z1 alpha-satellite DNA probe corresponding to 18p11.1-q11.1 labeled with SpectrumBlue.
- **LSI 21:** DNA probe corresponding to loci D21S341, D21S342, D21S339, EGR, and D21S338 (21q22.13-q22.2) labeled with SpectrumGreen.
- **LSI 22:** DNA probe corresponding to the BCR locus (22q11.2) labeled with SpectrumGold.

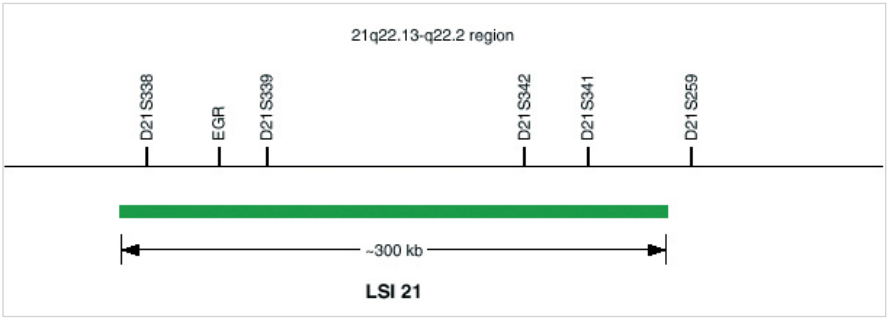


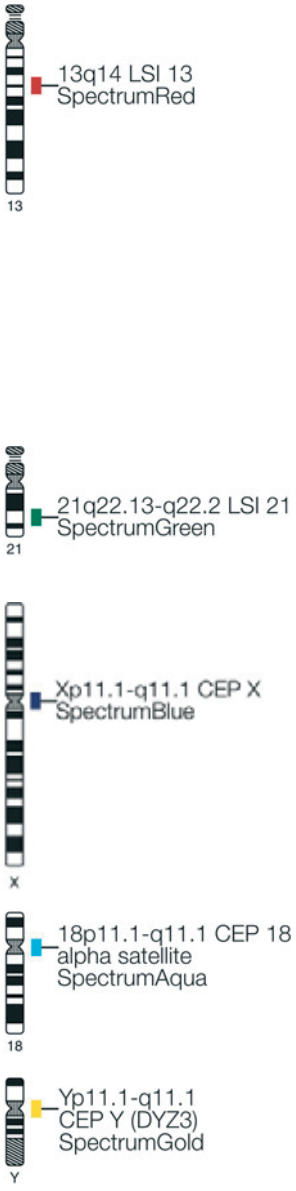
**Normal hybridization:** MultiVysion PB hybridized to an embryonic cell.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis MultiVysion PB Multi-color Probe **(CE)** | 60 µL | 08L62-020 | 00884999031524 |

# Vysis MultiVysion PGT Multi-color Probe



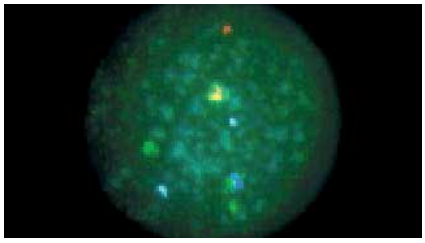

## PRODUCT DESCRIPTION

MultiVysion PGT and MultiVysion PB fluorescence in situ hybridization (FISH) probe sets are designed for determination of chromosome copy number in single cells.

Unlabeled DNA is included with both probe sets to block sequences contained within the target loci that are common to other chromosomes. This probe set is premixed in Hybridization Buffer.

## PROBE MIXTURE

- **LSI 13:** DNA probe spanning the RB1 (13q14) labeled with SpectrumRed.
- **CEP X:** DXZ1 alpha-satellite DNA probe corresponding to Xp11.1-q11.1 labeled with SpectrumBlue.
- **CEP 18:** D18Z1 alpha-satellite DNA probe corresponding to 18p11.1-q11.1 labeled with SpectrumAqua.
- **LSI 21:** DNA probe corresponding to loci D21S341, D21S342, D21S339, EGR, and D21S338 (21q22.13-q22.2) labeled with SpectrumGreen.
- **CEP Y:** DYZ3 alpha-satellite DNA probe corresponding to Yp11.1-q11.1 labeled with SpectrumGold.



**Normal hybridization:** MultiVysion PGT hybridized to an embryonic cell.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis MultiVysion PGT Multi-color Probe **(CE)** | 30 µL | 08L69-010 | 00884999031593 |

# VYSIS FISH: INSTRUMENTS

Automation is essential for laboratories interested in reducing the amount of hands-on-time required to run FISH assays, while increasing laboratory throughput, flexibility, reproducibility and productivity. Abbott Molecular is pleased to offer FISH automation options to suit the needs of your laboratory.

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

## VYSIS FISH INSTRUMENTS PROVIDES THE FOLLOWING ADVANTAGES:

- Our VP 2000 Processor is designed to automate tedious front end FISH preparation procedures such as de-paraffinization and slide pretreatment. With the flexibility to perform batches of up to 50 slides at a time, and 3 heated and 12 ambient temperature basins, the VP 2000 is well suited for the needs of today's FISH laboratory.

- The ThermoBrite Slide Processing System is a temperature programmable, humidity controlled instrument designed to automate denaturation and hybridization steps for FISH. Rapid temperature ramping and accuracy within +/– 1 °C ensure superior temperature uniformity across all 12 slide positions. Up to 40 user defined protocols and 3 operating modes ensure ease of use and flexibility.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **BIOVIEW AUTOMATED IMAGING AND ANALYSIS SYSTEM (CE)** | | | | |
| Accord Plus Automated Scanner with Single Slide Motorized Stage | 1 | Contact Us | - | - |
| Accord Semi-Automatic Scanner (Manual Stage) | 1 | Contact Us | - | - |
| Allegro Plus Automated Scanner with 8 Slides Stage | 1 | Contact Us | - | - |
| Amniotic Fluid Scanning Applications | 1 | 08N52-26 | 07290107653039 | 334 |
| AneuVysion Application | 1 | 08N52-36 | 07290107653091 | 334 |
| Automated Brightfield Scanning | 1 | 08N52-16 | 07290107652971 | 334 |
| Bladder Cancer Scanning Application | 1 | 08N52-53 | 07290107653244 | 334 |
| Cell Suspension Target FISH Dual Mode Application | 1 | 08N52-31 | 07290107653060 | 334 |
| Cervical Probe Scanning application includes Oral Cancer Scanning | 1 | 08N52-39 | 07290107653121 | 334 |
| Consecutive Cut Tissue FISH Application | 1 | 08N52-32 | 07290107653077 | 334 |
| Duet 3 Automated Scanner with 50 slides loader | 1 | Contact Us | - | - |
| Encore 100 Automatic Motorized 100 Slide Loader | 1 | Contact Us | - | - |
| Encore 200 Automatic Motorized 200 Slide Loader | 1 | Contact Us | - | - |
| ERG Probe Scanning Application | 1 | 08N52-41 | 07290107653145 | 334 |
| Fluorescent TMA mapping application | 1 | 08N52-44 | 07290107653176 | 334 |
| G/R-Band automated high resolution metaphase capture for Karyotyping | 1 | 08N52-45 | 07290107653183 | 334 |
| G/R-Band Brightfield Metaphase Finder | 1 | 08N52-17 | 07290107652988 | 334 |
| Hematological Scanning Application | 1 | 08N52-54 | 07290107653251 | 334 |
| ImmunoFluorescence Applications | 1 | 08N52-42 | 07290107653152 | 334 |
| Karyotyping Software | 1 | 08N52-24 | 07290107653015 | 334 |
| Manual Brightfield Imaging | 1 | 08N52-14 | 07290107652957 | 334 |
| Manual Karyotype Capture | 1 | 08N52-15 | 07290107652964 | 334 |
| Post-Natal Scanning Applications | 1 | 08N52-40 | 07290107653138 | 334 |
| Research Aid Software | 1 | 08N52-43 | 07290107653169 | 334 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| SOLO WEB for 10 Concurrent Users | 1 | 08N52-55 | 07290107652940 | 334 |
| Sperm Scanning Applications FL | 1 | 08N52-38 | 07290107653114 | 334 |
| Sub-telomeric Application | 1 | 08N52-37 | 07290107653107 | 334 |
| Tissue Samples – Vysis ALK | 1 | 08N52-47 | 07290107653206 | 334 |
| Tissue Samples - PathVysion | 1 | 08N52-52 | 07290107653237 | 334 |
| UroVysion Scanning Application | 1 | 08N52-46 | 07290107653190 | 334 |
| **THERMOBRITE** | | | | |
| ThermoBrite - 110/120 VAC **(CE)** | 1 | 07J91-010 | 00884999029507 | 339 |
| ThermoBrite - 200/240 VAC **(CE)** | 1 | 07J91-020 | 00884999029514 | 339 |
| ThermoBrite Humidity Strips | 10 pk | 07J68-001 | 00884999029101 | 339 |
| **VP2000** | | | | |
| VP 2000 Accessories 12 Basins with Carrier and Lid | | 02J11-075 | 00884999002098 | 341 |
| VP 2000 Accessories 50 slide basket | | 02J11-007 | 00884999001947 | 341 |
| VP 2000 Accessories Charcoal Filter Replacement Cassette | | 02J11-022 | 00884999001992 | 341 |
| VP 2000 Accessories Charcoal Filter with Blower Fan | | 02J11-019 | 00884999001985 | 341 |
| VP 2000 Accessories Heated Basin Lids | 3 pk | 02J11-034 | 00884999002050 | 341 |
| VP 2000 Accessories Heated Reagent Basin | | 02J11-013 | 00884999001961 | 341 |
| VP 2000 Accessories Printer | | 02J11-025 | 00884999002012 | 341 |
| VP 2000 Accessories Standard Reagent Basin | 6 pk | 02J11-010 | 00884999001954 | 341 |
| VP 2000 Accessories Straight Adapter Vent Tube Kit | | 02J11-016 | 00884999001978 | 341 |
| VP 2000 Processor - 100 VAC, 50/60 HZ **(CE)** | 1 | 02J11-060 | 00884999002074 | 341 |
| VP 2000 Processor - 117 VAC, 50/60 HZ **(CE)** | 1 | 02J11-001 | 00884999001916 | 341 |
| VP 2000 Processor - 230 VAC, 50/60 HZ **(CE)** | 1 | 02J11-004 | 00884999001930 | 341 |

# BioView


## PRODUCT OVERVIEW

BioView provides innovative automated cell imaging and analysis solutions for use in cytology, cytogenetics, hematology, pathology and oncology laboratories

## BIOVIEW APPLICATION SUITE

- Amniotic Cells
- CTC
- Hematopoietic Cells
- Karyotyping
- PathVysion
- Tissue Matching
- TMA
- UroVysion
- Vysis ALK

## MAIN CONSIDERATIONS

- Operator control on the critical steps:
  - Selection of tumor regions (Tissue)
  - Review and approval of scan results (Tissue/Cells Suspension)
  - Report generation containing all pertinent data
- Standardization of analysis and results
- Local and remote review/analysis for interpretation, consultation and training

## TISSUE FISH

- Automated FISH analysis for all probes hybridized to FFPE tissue sections
- Applications for Abbott's PathVysion and Vysis ALK are CE marked
- Supports matching between parallel tissue sections

## HEMATOLOGY FISH

- Automated FISH analysis for all probes hybridized to Bone Marrow / Peripheral blood samples
- BioView's Hematology application is CE marked
- Supports automation of multiple regions hybridized with different probes on same slide (Panels)

## UROVYSION

- Automated FISH analysis for Urine samples hybridized with UroVysion Kit
- BioView's UroVysion application is CE marked
- Automation filtration of white blood cells
- Automatic identification and exclusion of clumps

## WORKFLOW DURATION (IN MINUTES)

| | Hematology | Tissue | UroVysion |
|---|---|---|---|
| **Slide Setup** | 0 | 3 | 0 |
| **Unattended Scan** | 3-8 | 5 | 20 |
| **Review and Analysis** | 5-10 | 5-10 | 10 |
| **Report** | 1 | 1 | 1 |
| **Operator Time per Sample** | 6-11 | 9-14 | 11 |

| | ENCORE | DUET-3 | ALLEGRO-PLUS | ACCORD-PLUS | ACCORD |
|---|---|---|---|---|---|
| **Fully Unattended Scanning** | + | + | + | + | Semi-automated |
| **Fluorescent Microscope and Filters** | + | + | + | + | + |
| **Oil Immersion Objectives for Automated Fluorescent Scanning** | + | + | + | + | + |
| **Slide Load Capacity of Motorized Stage** | Up to 100/200 | Up to 50 | Up to 8 | Single | Single |
| **Integrated Automated 2D Barcode Reader** | + | + | N.A. | N.A. | N.A. |
| **Integrated Automated Oil Dispenser** | + | + | - | - | - |
| **Fluorescent Light Source** | Metal-Halide/Mercury | | | | |
| **Bright Field Light Source** | Optional | | | | |
| **Digital Camera** | 2048 x 2048 Monochrome or Color | | | | |
| **UPS** | + | | | | |
| **Monitor** | 24" LCD or 22" Touch screen LCD | | | | |
| **SoloWeb Compatibility** | + | | | | |
| **Supported Applications** | • FISH<br>• Parallel tissue matching<br>• Digital pathology<br>• TMA<br>• FL Metaphase detection and capture<br>• Rare cells detection<br>• Circulating tumor cells detection and characterization mRNA imaging and analysis | | | | |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Accord Plus Automated Scanner with Single Slide Motorized Stage | 1 | Contact Us | - |
| Accord Semi-Automatic Scanner (Manual Stage) | 1 | Contact Us | - |
| Allegro Plus Automated Scanner with 8 Slides Stage | 1 | Contact Us | - |
| Amniotic Fluid Scanning Applications | 1 | 08N52-26 | 07290107653039 |
| AneuVysion Application | 1 | 08N52-36 | 07290107653091 |
| Automated Brightfield Scanning | 1 | 08N52-16 | 07290107652971 |
| Bladder Cancer Scanning Application | 1 | 08N52-53 | 07290107653244 |
| Cell Suspension Target FISH Dual Mode Application | 1 | 08N52-31 | 07290107653060 |
| Cervical Probe Scanning application includes Oral Cancer Scanning | 1 | 08N52-39 | 07290107653121 |
| Consecutive Cut Tissue FISH Application | 1 | 08N52-32 | 07290107653077 |
| Duet 3 Automated Scanner with 50 slides loader | 1 | Contact Us | - |
| Encore 100 Automatic Motorized 100 Slide Loader | 1 | Contact Us | - |
| Encore 200 Automatic Motorized 200 Slide Loader | 1 | Contact Us | - |
| ERG Probe Scanning Application | 1 | 08N52-41 | 07290107653145 |
| Fluorescent TMA mapping application | 1 | 08N52-44 | 07290107653176 |
| G/R-Band automated high resolution metaphase capture for Karyotyping | 1 | 08N52-45 | 07290107653183 |
| G/R-Band Brightfield Metaphase Finder | 1 | 08N52-17 | 07290107652988 |
| Hematological Scanning Application | 1 | 08N52-54 | 07290107653251 |
| ImmunoFluorescence Applications | 1 | 08N52-42 | 07290107653152 |
| Karyotyping Software | 1 | 08N52-24 | 07290107653015 |
| Manual Brightfield Imaging | 1 | 08N52-14 | 07290107652957 |
| Manual Karyotype Capture | 1 | 08N52-15 | 07290107652964 |
| Post-Natal Scanning Applications | 1 | 08N52-40 | 07290107653138 |
| Research Aid Software | 1 | 08N52-43 | 07290107653169 |
| SOLO WEB for 10 Concurrent Users | 1 | 08N52-55 | 07290107652940 |
| Sperm Scanning Applications FL | 1 | 08N52-38 | 07290107653114 |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Sub-telomeric Application | 1 | 08N52-37 | 07290107653107 |
| Tissue Samples – Vysis-ALK | 1 | 08N52-47 | 07290107653206 |
| Tissue Samples – PathVysion | 1 | 08N52-52 | 07290107653237 |
| UroVysion Scanning Application | 1 | 08N52-46 | 07290107653190 |

# ThermoBrite

ThermoBrite StatSpin®


## PROGRAMMABLE TEMPERATURE CONTROLLED SLIDE PROCESSING SYSTEM

The ThermoBrite System provides an easy, safe, system for in-situ hybridization procedures. This programmable, open system automates the denaturation and hybridization steps in slide-based FISH procedures and provides walk-away convenience for laboratory personnel.

The low cost unit accepts a wide range of sample types, is easy to use and reduces hands-on time by more than 50% while ensuring overall precision and accuracy in all slide-based assays.

## USER PROGRAMMABLE SETTINGS

- 40 user defined protocols and 3 operating modes
- Easy to read backlit display
- Numeric keypad allows for easy programming
- Can be used as a fixed temperature slide warmer

## EASY TO USE

- Eliminates manual steps and reduces hands-on time during FISH procedures
- Slides do not need to be fully loaded to maintain temperature accuracy
- Slide guide keeps slides in place and allows for one hand removal
- Humidity Control Cards inside the lid maintain a humid environment

## MORE STRINGENT TEMPERATURE CONTROL

- Rapid temperature ramp-up and accuracy of ± 1° C
- Temperature uniformity across all slide positions
- Heats slide to temperatures ideal for FISH procedures

## THERMOBRITE SLIDE PROCESSING SYSTEM

The StatSpin ThermoBrite System holds up to 12 slides. The lid seals tightly when closed providing optimal chamber humidity. The system maintains uniform temperture across all slide positions. Slides can be easily added or removed with one hand. The numeric keypad allows for easy programming with 40 user programmable settings and 3 modes of operation; Denaturation/ Hybridization, Hybridization, and Fixed Temperature.

## TECHNICAL SPECIFICATIONS

| | |
|---|---|
| **Dimensions** | Height 146 mm (5 5/16 inches)<br>Width 228 mm (8 5/16 inches)<br>Depth 451 mm (17 3/4 inches)<br>Weight 8.5 kg (18.7 lbs) |
| **Capacity** | 12 Slides |
| **Processing Time** | Programmable 0 to 100 hours; Continuous mode |
| **Power** | 120 VAC at 3Aw<br>240 VAC at 1.6A |
| **Temperature Control** | Programmable 30-99° C |
| **Ambient Operating Temperature** | 5-40° C(41-104° F) |
| **Ambient Operating Humidity** | 20-80% relative |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| ThermoBrite - 110/120 VAC **(CE)** | 1 | 07J91-010 | 00884999029507 |
| ThermoBrite - 200/240 VAC **(CE)** | 1 | 07J91-020 | 00884999029514 |
| ThermoBrite Humidity Strips | 10 pk | 07J68-001 | 00884999029101 |

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# VP 2000 Processor


## PRODUCT DESCRIPTION

Now you can perform deparaffinization, pretreatment, histology/cytology staining, special stains (G-banding and other), and routine slide washing with a single system. The VP 2000 Processor easily processes slides using pre-programmed Vysis protocols for fluorescence in situ hybridization (FISH) for applications such as paraffin removal and the specimen pretreatment protocols for the Vysis UroVysion Bladder Cancer Kit.

The easy-to-operate user interface of the VP 2000 allows the user to enter and save user-defined protocols for various staining procedures and specimen pretreatment procedures.

This flexibility provides your laboratory with an instrument that can be utilized for multiplefunctions within a single workday. As your laboratory adds high-volume FISH testing to your menu of routine services, the Vysis VP 2000 Processor provides a flexible and cost-effective solution.

## ADVANTAGES OF THE VP 2000 PROCESSOR:

- Convenient walk-away automation to reduce laboratory labor and costs
- Performs more consistent and standardized FISH assay deparaffinization and pretreatment
- Validated for use with Vysis FISH pretreatment protocols including solid tumor and cytological specimens, such as amniocytes and bladder tumor cells
- Full user programmability of events for maximum flexibility
- Open system is compatible with reagents used in today's laboratories
- Bulk reagents available for added economy and ease-of-use
- Driven by a PC with Windows user interface (included in package)
- Five-way safety protection
- Reliability to stay on the job processing slides, year after year

## THE VYSIS SYSTEMS APPROACH TO AUTOMATED FISH TESTING

The VP 2000 Processor, in conjunction with the Vysis ThermoBrite Denaturation/Hybridization unit provides a modular systems approach to automated FISH testing.

## TECHNICAL SPECIFICATIONS

| | |
|---|---|
| **Software** | Proprietary VP 2000 |
| **Slide Capacity per Run** | 50 |
| **Ambient Reagent Basins** | 12 |
| **Heated Reagent Basins** | 3 |
| **Program Capacity** | >1000 |
| **Events per Program** | >100 |
| **Water Bath Flow Rate** | 1L/min |
| **Dimensions (L x W x H) Processing Unit** | 31 x 24 x 22 in. (79 x 61 x 56 cm) |
| **Weight - Processing Unit** | 115 VAC - 127 lb. (58 kg)<br>100/230 VAC - 140 lb. (64. kg) |
| **Computer Configuration** | Pentium Class PC, 600 MB or greater |
| **Heated Reagent Basin Temperature** | Ambient to 80 °C |
| **Operating Temperature** | 15-30 °C |
| **Drying Station Temperature** | Ambient to 80 °C |
| **Systems** | 117 VAC, 50/60 Hz<br>230 VAC, 50/60 Hz<br>100 VAC, 50/60 Hz |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| VP 2000 Accessories 12 Basins with Carrier and Lid | | 02J11-075 | 00884999002098 |
| VP 2000 Accessories 50 slide basket | | 02J11-007 | 00884999001947 |
| VP 2000 Accessories Charcoal Filter Replacement Cassette | | 02J11-022 | 00884999001992 |
| VP 2000 Accessories Charcoal Filter with Blower Fan | | 02J11-019 | 00884999001985 |
| VP 2000 Accessories Heated Basin Lids | 3 pk | 02J11-034 | 00884999002050 |
| VP 2000 Accessories Heated Reagent Basin | | 02J11-013 | 00884999001961 |
| VP 2000 Accessories Printer | | 02J11-025 | 00884999002012 |

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| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| VP 2000 Accessories Standard Reagent Basin | 6 pk | 02J11-010 | 00884999001954 |
| VP 2000 Accessories Straight Adapter Vent Tube Kit | | 02J11-016 | 00884999001978 |
| VP 2000 Processor - 100 VAC, 50/60 HZ **(CE)** | 1 | 02J11-060 | 00884999002074 |
| VP 2000 Processor - 117 VAC, 50/60 HZ **(CE)** | 1 | 02J11-001 | 00884999001916 |
| VP 2000 Processor - 230 VAC, 50/60 HZ **(CE)** | 1 | 02J11-004 | 00884999001930 |
| VP 2000 Processor Software Version 1.1 | 1 | 03N07-01 | 00884999003774 |
| VP 2000 Reagents Pretreatment Reagent **(GPR)** | 500 mL | 02J06-030 | 00884999001862 |
| VP 2000 Reagents Protease Buffer **(GPR)** | 500 mL | 02J07-030 | 00884999001879 |
| VP 2000 Reagents Protease I **(GPR)** | 250 mg x 2 | 02J08-032 | 00884999001886 |
| VP 2000 Reagents Protease II **(GPR)** | 750 mg | 06J93-001 | 00884999023468 |
| VP 2000 Reagents 20X SSC **(GPR)** | 500 g | 02J10-032 | 00884999001909 |
| VP 2000 Reagents 2M MgCL 2 **(GPR)** | 120 mL | 02J09-030 | 00884999001893 |

# VYSIS FISH: ACCESSORIES/ GENERAL PURPOSE REAGENTS

Abbott Molecular delivers best in class products and services to meet the diverse needs of your laboratory. In addition to FISH automation, Abbott Molecular provides quality instrumentation and reagents that optimize laboratory effectiveness when processing FISH probes.

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THE FOLLOWING SECTION HIGHLIGHTS FISH ACCESSORIES BY PRODUCT CATEGORY:

- **FISH Pretreatment Reagent** Kits include ready-to-use reagents used to prepare specimens for hybridization.
- **In Situ Hybridization Reagents** offer an a la carte menu of reagents essential to FISH processing.
- **Fluorescence Labeling Reagents** used in nick translation protocols to incorporate individual fluorophore-conjugated dUTPs into DNA.
- **FISH Assay Control Slides** serve as controls and training tools to ensure high quality specimen processing and accurate enumeration.
- **VP 2000 Reagents** are specifically designed for automated deparaffinization and pre-treatment protocols for Vysis FISH assays.
- **Filter Sets** are custom-manufactured to meet the exact specifications of Abbott Molecular FISH products and your microscope.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **COMPARATIVE GENOMIC HYBRIDIZATION REAGENTS** | | | | |
| CGH Metaphase Target Slides; 10 slides | 10 Slides | 06J96-001 | 00884999023512 | - |
| CGH Nick Translation Kit with control DNA (MPE 600) | 50 Reactions | 06J40-020 | 00884999020207 | - |
| Control DNA Unlabeled | 15 µL | 06J40-001 | 00884999020177 | - |
| Human COT-1 DNA | 250 µL | 06J31-001 | 00884999019379 | - |
| SpectrumGreen Control DNA | 25 µL | 06J45-001 | 00884999021587 | - |
| **CONTROL SLIDES** | | | | |
| CGH Metaphase Target Slides; 10 slides | 10 Slides | 06J96-001 | 00884999023512 | - |
| ProbeChek ALK Positive Control Slides **(CE)** | 5 slides | 06N38-010 | 00884999025738 | - |
| ProbeChek Control Slides for CEP X/Y Assay; Control low-level female: 95% XY, 5% XX; 5 slides **(CE)** | 5 Slides | 07J21-011 | 00884999027053 | - |
| ProbeChek Control Slides for CEP X/Y Assay; Control low-level male: 95% XX, 5% XY; 5 slides **(CE)** | 5 Slides | 07J21-012 | 00884999027060 | - |
| ProbeChek Control Slides for FISH using CEP 8 and CEP 12 Assay, Negative Control 0%, trisomy 8/12 **(CE)** | 5 Slides | 07J21-001 | 00884999027039 | - |
| ProbeChek Control Slides for FISH using CEP 8 and CEP 12 Assay, Positive Control 10%, trisomy 8/12 **(CE)** | 5 Slides | 07J21-002 | 00884999027046 | - |
| ProbeChek MultiVysion Control Slides 5 slides **(CE)** | 5 Slides | 05J07-001 | 00884999010864 | - |
| ProbeChek Prenatal Control Slides for Amniocyte; Male Amniocyte Control Slides; 5 slides **(CE)** | 5 Slides | 05J39-005 | 00884999011731 | - |
| ProbeChek Prenatal Control Slides for Positive Control; 5 slides | 5 Slides | 05J36-005 | 00884999011663 | - |
| **FISH PRETREATMENT KITS** | | | | |
| FISH Pretreatment Reagent Kit **(CE)** | 1 Kit | 02J03-032 | 00884999001817 | - |
| Paraffin Pretreatment Reagent Kit I **(CE)** | 1 Kit | 02J02-032 | 00884999001800 | - |
| Paraffin Pretreatment Reagent Kit II | 1 Kit | 07J02-002 | 00884999026186 | - |
| Paraffin Pretreatment Reagent Kit III | 1 Kit | 07J02-003 | 00884999026193 | - |
| VP2000 Pretreatment Kit, Intended use with 06N38-050 | 1 Kit | 08N16-001 | 00884999038189 | - |
| Vysis Paraffin Pretreatment IV & Post-Hybridization Wash Buffer Kit **(CE)** | 1 Kit | 01N31-005 | 00884999000735 | - |

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| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **GENERAL PURPOSE REAGENTS / VP2000 REAGENTS** | | | | |
| 20X SSC | 500 g | 02J10-032 | 00884999001909 | - |
| 2M MgCl 2 | 120 mL | 02J09-030 | 00884999001893 | - |
| Protease Buffer II, 2 x 62.5 ml | 2 x 62.5 ml | 1N9901 | 00884999001404 | - |
| Protease IV **(CE)** | 75 mg x 5 | 06N46-001 | 00884999035843 | - |
| Protease IV **(CE)** | 750 mg x 5 | 06N46-002 | 00884999035850 | - |
| VP 2000 Reagents Pretreatment Reagent | 500 mL | 02J06-030 | 00884999001862 | - |
| VP 2000 Reagents Protease Buffer | 500 mL | 02J07-030 | 00884999001879 | - |
| VP 2000 Reagents Protease I | 250 mg x 2 | 02J08-032 | 00884999001886 | - |
| VP 2000 Reagents Protease II | 750 mg | 06J93-001 | 00884999023468 | - |
| VP2000 Pretreatment Kit, Intended use with 06N38-050 | 1 Kit | 08N16-001 | 00884999038189 | - |
| **HYBRIDIZATION REAGENTS** | | | | |
| 20X SSC | 500 g | 02J10-032 | 00884999001909 | - |
| 2M MgCl 2 | 120 mL | 02J09-030 | 00884999001893 | - |
| Antifade II Solution | 60 µL x 2 | 06J29-001 | 00884999019324 | - |
| Antifade Solution | 240 µL x 2 | 06J29-010 | 00884999019331 | - |
| DAPI I Counterstain | 500 µL x 2 | 06J49-001 | 00884999021624 | - |
| DAPI II Counterstain | 500 µL x 2 | 06J50-001 | 00884999021648 | - |
| DAPI III Counterstain | 500 µL x 2 | 06J49-010 | 00884999021631 | - |
| Hybridization Buffer | 2 tubes, 6900 µL | 06L44-01 | 00884999024250 | - |
| LSI/WCP Hybridization Buffer | 2 x 150 µL | 06J67-001 | 00884999021983 | - |
| LSI/WCP Hybridization Buffer | 2 x 500 µL | 06J67-011 | 00884999021990 | - |
| NP-40 | 1000 µL x 2 | 07J05-001 | 00884999026247 | - |
| Propidium Iodide Counterstain | 500 µL x 2 | 07J06-001 | 00884999026254 | - |
| Vysis CEP Hybridization Buffer | 2 x 150 µL | 07J36-001 | 00884999027565 | - |

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **LABELING REFERENCE DNA** | | | | |
| Aqua dUTP | 50nmol, lyophilized | 02N35-050 | 00884999002944 | - |
| Gold dUTP | 50nmol, lyophilized | 05N18-050 | 00884999014640 | - |
| Green dUTP | 50nmol, lyophilized | 02N32-050 | 00884999002913 | - |
| Nick Translation Kit | 50 Reactions | 07J00-001 | 00884999025936 | - |
| Orange dUTP | 50nmol, lyophilized | 02N33-050 | 00884999002920 | - |
| Red dUTP | 50nmol, lyophilized | 02N34-050 | 00884999002937 | - |
| SpectrumGreen Normal Female Reference DNA | 300 ng/µL x 25 uL | 07J03-001 | 00884999026209 | - |
| SpectrumGreen Normal Male Reference DNA | 300 ng/µL x 25 uL | 07J03-005 | 00884999026216 | - |
| SpectrumRed Normal Female Reference DNA | 100 ng/µL x 25 µL | 07J04-001 | 00884999026223 | - |
| SpectrumRed Normal Male Reference DNA | 100 ng/µL x 25 µL | 07J04-005 | 00884999026230 | - |
| **THERMOBRITE ACCESSORIES** | | | | |
| Thermobrite Humidity Strips | 10 pk | 07J68-001 | 00884999029101 | - |
| **VP2000 ACCESSORIES** | | | | |
| VP 2000 Accessories 12 Basins with Carrier and Lid | | 02J11-075 | 00884999002098 | - |
| VP 2000 Accessories 50 slide basket | | 02J11-007 | 00884999001947 | - |
| VP 2000 Accessories Charcoal Filter Replacement Cassette | | 02J11-022 | 00884999001992 | - |
| VP 2000 Accessories Charcoal Filter with Blower Fan | | 02J11-019 | 00884999001985 | - |
| VP 2000 Accessories Heated Basin Lids | 3 pk | 02J11-034 | 00884999002050 | - |
| VP 2000 Accessories Heated Reagent Basin | | 02J11-013 | 00884999001961 | - |
| VP 2000 Accessories Printer | | 02J11-025 | 00884999002012 | - |
| VP 2000 Accessories Standard Reagent Basin | 6 pk | 02J11-010 | 00884999001954 | - |
| VP 2000 Accessories Straight Adapter Vent Tube Kit | | 02J11-016 | 00884999001978 | - |

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# VYSIS FISH PROBES BY CHROMOSOME

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| **CHROMOSOME 1** | | | |
| Vysis LSI 1p36 / LSI 1q25 and LSI 19q13/19p13 Dual-Color Probe **(CE)** | 2 vials, 200 µl each | 04N60-020 | 00884999009288 |
| Vysis LSI NTRK1 Break Apart FISH Probe Kit **(RUO)** | 20 µL | 08N43-60 | 00884999042612 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 2** | | | |
| ProbeChek ALK Negative Control Slides **(CE)** | 5 slides | 06N38-005 | 00884999025721 |
| ProbeChek ALK Positive Control Slides **(CE)** | 5 slides | 06N38-010 | 00884999025738 |
| Vysis ALK Break Apart FISH Probe Kit **(CE)** | 20 Assays | 06N38-020 | 00884999025745 |
| Vysis ALK Break Apart FISH Probe Kit (automation protocol) **(CE)** | 50 Assays | 06N38-50 | 00884999037205 |
| Vysis ALK Break Apart FISH Kit **(IVD Japan Only)** | 20 Assays | 6N38-021 | 00884999035836 |
| Vysis Paraffin Pretreatment IV & Post-Hybridization Wash Buffer Kit **(CE)** | 1 Kit | 01N31-005 | 00884999000735 |
| Vysis ProbeChek ALK Negative Control II (only use with 06N38-50) **(CE)** | 5 slides | 06N38-006 | 00884999038196 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 3** | | | |
| UroVysion Bladder Cancer Kit **(CE)** | 20 Assays | 02J27-020 | 00884999002135 |

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| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| UroVysion Bladder Cancer Kit **(CE)** | 100 Assays | 02J27-099 | 00884999002197 |
| Vysis RPN1/MECOM DF FISH Probe Kit **(CE)** | 10 µL | 06N60-010 | 00884999034914 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 4** | | | |
| Vysis 4q12 Tri-Color Rearrangement FISH Probe Kit **(CE)** | 20 µL | 05N52-020 | 00884999015005 |
| Vysis IGH/FGFR3 DF FISH Probe Kit **(CE)** | 20 µL | 01N69-020 | 00884999000834 |
| Vysis LSI 4q12 Tricolor, Rearrangement Probe **(ASR)** | 20 µL | 01N79-020 | 00884999001039 |
| Vysis LSI IGH/FGFR3 Dual Color Dual Fusion Probes **(ASR)** | 20 µL | 05J74-001 | 00884999012417 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 5** | | | |
| Vysis Cri-du-Chat Region Probe - LSI EGR1 SpectrumOrange/ LSI D5S23, D5S721 SpectrumGreen **(ASR)** | 20 µL | 05J76-001 | 00884999012455 |
| Vysis CSF1R/D5S23, D5S721 FISH Probe Kit **(CE)** | 20 µL | 05N03-020 | 00884999014336 |
| Vysis EGR1 FISH Probe Kit - SC (Specimen Characterization) **(CE)** | 20 µL | 04N37-001 | 00884999038165 |
| Vysis LSI CSF1R / D5S23, D5S721 Probes **(ASR)** | 20 µL | 05J60-001 | 00884999012189 |
| Vysis LSI D5S23, D5S721 SpectrumGreen Probe **(ASR)** | 20 µL | 04N30-020 | 00884999008274 |
| Vysis LSI D5S23, D5S721/CEP 9/CEP 15 FISH Probe Kit **(CE)** | 20 µL | 05N35-020 | 00884999014886 |
| Vysis LSI D5S23/D5S721, Vysis CEP 9, Vysis CEP 15 Multi-Color Probe **(ASR)** | 20 µL | 05J84-007 | 00884999012721 |
| Vysis LSI EGR1/D5S23, D5S721 Dual Color Probe Kit **(CE)** | 20 µL | 08L68-020 | 00884999031586 |
| Vysis PDGFRB Break Apart FISH Probe Kit **(CE)** | 10 µL | 06N24-010 | 00884999025585 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 6** | | | |
| Vysis 6q22 ROS1 Break Apart FISH Probe **(RUO)** | 20 µL | 08N29-020 | 00884999037892 |
| Vysis Melanoma FISH Probe Kit **(CE)** | 200 µL | 01N89-020 | 00884999001312 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 7** | | | |
| UroVysion Bladder Cancer Kit **(CE)** | 20 Assays | 02J27-020 | 00884999002135 |
| UroVysion Bladder Cancer Kit **(CE)** | 100 Assays | 02J27-099 | 00884999002197 |
| Vysis BRAF SpectrumGold FISH Probe Kit **(CE)** | 20 µL | 06N09-020 | 00884999025028 |
| Vysis D7S486/ Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N07-020 | 00884999014367 |
| Vysis D7S486/ Vysis CEP 7 FISH Probes **(ASR)** | 20 µL | 05J61-001 | 00884999012196 |
| Vysis D7S522/Vysis CEP 7 FISH Probe Kit **(CE)** | 20 µL | 05N08-020 | 00884999014374 |
| Vysis EGFR / CEP 7 FISH Probe Kit **(CE)** | 200 µL | 01N35-020 | 00884999000773 |
| Vysis LSI D7S522 SpectrumOrange / Vysis CEP 7 SpectrumGreen Probes **(ASR)** | 20 µL | 05J85-001 | 00884999012752 |
| Vysis LSI EGFR SpectrumRed Probe **(ASR)** | 20 µL | 04N31-020 | 00884999008281 |
| Vysis MET SpectrumRed FISH Probe Kit **(CE)** | 20 µL | 06N05-020 | 00884999024984 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| Vysis Williams Region Probe - LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen Probe Kit **(CE)** | 20 µL | 06N28-020 | 00884999025615 |
| Vysis Williams Region Probe - LSI ELN SpectrumOrange/LSI D7S486, D7S522 SpectrumGreen Probes **(ASR)** | 20 µL | 05J30-045 | 00884999011564 |
| **CHROMOSOME 8** | | | |
| Vysis 8p12 FGFR1 SpectrumRed/CEP 8 SpectrumAqua FISH **(RUO)** | 20 µL | 08N21-060 | 00884999038059 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-008 | 00884999027077 |
| Vysis CEP 8 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-008 | 00884999027008 |
| Vysis Esophageal FISH Probe Kit **(CE)** | 20 µL | 04N19-020 | 00884999008021 |
| Vysis LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probe Kit **(CE)** | 20 µL | 04N10-020 | 00884999007949 |
| Vysis LSI IGH/MYC/Vysis CEP 8 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL | 05J75-001 | 00884999012431 |
| Vysis LSI LPL SpectrumOrange Probe **(ASR)** | 20 µL | 04N34-020 | 00884999008335 |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MYC Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 01N63-020 | 00884999000827 |
| Vysis LSI MYC Dual Color Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J91-001 | 00884999012844 |
| Vysis LSI MYC SpectrumGreen Probe **(ASR)** | 20 µL | 04N36-020 | 00884999008359 |
| Vysis MYC SpectrumOrange FISH Probe Kit (8q24.12-q24.13) **(CE)** | 20 µL | 03N87-020 | 00884999006256 |
| Vysis RUNX1/RUNX1T1 DF FISH Probe Kit **(CE)** | 20 µL | 08L70-020 | 00884999031609 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 9** | | | |
| UroVysion Bladder Cancer Kit **(CE)** | 20 Assays | 02J27-020 | 00884999002135 |
| UroVysion Bladder Cancer Kit **(CE)** | 100 Assays | 02J27-099 | 00884999002197 |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 20 µL | 05N54-020 | 00884999015029 |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 50 µL | 05N54-050 | 00884999015036 |
| Vysis CDKN2A / CEP 9 FISH Probe Kit **(CE)** | 20 µL | 04N61-020 | 00884999009295 |
| Vysis Esophageal FISH Probe Kit **(CE)** | 20 µL | 04N19-020 | 00884999008021 |
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation **(ASR)** Probe | 20 µL | 05J77-001 | 00884999012462 |
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L56-050 | 00884999031463 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe **(ASR)** | 20 µL | 05J78-001 | 00884999012479 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L55-020 | 00884999031456 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 05J82-001 | 00884999012592 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe **(ASR)** | 50 µL | 05J82-010 | 00884999012615 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L10-001 | 00884999031166 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 50 µL | 08L10-002 | 00884999031173 |
| Vysis LSI BCR/ABL1/ASS1 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL | 08L79-020 | 00884999031647 |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR/ABL1/ASS1 Tri-Color Dual Fusion Probes **(ASR)** | 50 µL | 08L79-050 | 00884999031654 |
| Vysis LSI D5S23, D5S721/CEP 9/CEP 15 FISH Probe Kit **(CE)** | 20 µL | 05N35-020 | 00884999014886 |
| Vysis LSI D5S23/D5S721, Vysis CEP 9, Vysis CEP 15 Multi-Color Probe **(ASR)** | 20 µL | 05J84-007 | 00884999012721 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 10** | | | |
| 10q26 FGFR2 SpectrumOrange/CEP 10 SpectrumGreen FISH Probe Kit **(RUO)** | 20 µL | 08N42-060 | 00884999042582 |
| Vysis 10q11 RET Break-Apart FISH Probe **(RUO)** | 20 µL | 08N31-060 | 00884999038097 |
| Vysis PTEN / CEP 10 FISH Probe Kit **(CE)** | 20 µL | 04N62-020 | 00884999009301 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 11** | | | |
| LSI Cyclin D1 (11q13) SpectrumOrange/ Vysis CEP 11 SpectrumGreen **(ASR)** | 20 µL | 05J41-001 | 00884999011755 |
| Vysis BIRC3/MALT1 DF FISH Probe Kit **(CE)** | 20 µL | 05N50-020 | 00884999014985 |
| Vysis CCND1 / CEP 11 FISH Probe Kit **(CE)** | 20 µL | 03N88-020 | 00884999006263 |
| Vysis IGH/CCND1 DF FISH Probe Kit **(CE)** | 20 µL | 08L58-020 | 00884999031487 |
| Vysis LSI ATM SpectrumOrange/Vysis CEP 11 SpectrumGreen Probes **(ASR)** | 20 µL | 01N18-020 | 00884999000537 |
| Vysis LSI ATM/CEP 11 FISH Probe Kit **(CE)** | 20 µL | 05N55-020 | 00884999015043 |
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J96-001 | 00884999013445 |
| Vysis LSI CCND1 (11q13) Dual Color, Break Apart Rearrangement Probe Kit **(CE)** | 20 µL | 05N38-020 | 00884999014909 |
| Vysis LSI IGH/CCND1 Dual Color Dual Fusion Probes **(ASR)** | 20 µL | 05J69-001 | 00884999012301 |
| Vysis LSI IGH/CCND1 XT Dual Color, Dual Fusion Translocation Probes **(ASR)** | 20 µL | 05J72-001 | 00884999012370 |
| Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J90-001 | 00884999012837 |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI MLL Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L57-020 | 00884999031470 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe **(ASR)** | 20 µL | 05J83-001 | 00884999012622 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe Set **(CE)** | 20 µL | 08L53-020 | 00884999031432 |
| Vysis Melanoma FISH Probe Kit **(CE)** | 200 µL | 01N89-020 | 00884999001312 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 12** | | | |
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-012 | 00884999027084 |
| Vysis CEP 12 SpectrumOrange Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-012 | 00884999027015 |
| Vysis DDIT3 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N57-020 | 00884999005778 |
| Vysis ETV6 Break Apart FISH Probe Kit **(CE)** | 20 µL | 04N09-020 | 00884999007932 |
| Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe **(ASR)** | 20µL | 05J62-001 | 00884999012202 |
| Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L66-020 | 00884999031562 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe **(ASR)** | 20 µL | 05J83-001 | 00884999012622 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe Set **(CE)** | 20 µL | 08L53-020 | 00884999031432 |
| Vysis MDM2/CEP 12 FISH Probe Kit **(CE)** | 10 µL | 01N15-010 | 00884999035362 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 13** | | | |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 30 Assays | 05J38-030 | 00884999011700 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 50 Assays | 05J38-050 | 00884999011717 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 10 Assays | 05J38-010 | 00884999011694 |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis D13S319 (13q14.3) Probe **(ASR)** | 20 µL | 05J86-001 | 00884999012769 |
| Vysis D13s319/13q34 FISH Probe Kit **(CE)** | 20 µL | 05N37-020 | 00884999014893 |
| Vysis FOXO1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N60-020 | 00884999005808 |
| Vysis LSI 13q34 SpectrumGreen Probe **(ASR)** | 20 µL | 05J80-001 | 00884999012547 |
| Vysis LSI D13S319 SpectrumOrange/ 13q34 SpectrumGreen Probes **(ASR)** | 20 µL | 01N20-020 | 00884999000544 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe **(ASR)** | 20 µL | 05J83-001 | 00884999012622 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe Set **(CE)** | 20 µL | 08L53-020 | 00884999031432 |
| Vysis MultiVysion PB Multi-color Probe **(CE)** | 60 µL | 08L62-020 | 00884999031524 |
| Vysis MultiVysion PGT Multi-color Probe **(CE)** | 30 µL | 08L69-010 | 00884999031593 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 14** | | | |
| Vysis IGH/CCND1 DF FISH Probe Kit **(CE)** | 20 µL | 08L58-020 | 00884999031487 |
| Vysis IGH/FGFR3 DF FISH Probe Kit **(CE)** | 20 µL | 01N69-020 | 00884999000834 |
| Vysis IGH/MAF DF FISH Probes **(ASR)** | 20 µL | 05J84-004 | 00884999012691 |
| Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe **(CE)** | 20 µL | 08L63-020 | 00884999031531 |
| Vysis LSI IGH Dual Color, Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J73-001 | 00884999012394 |
| Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe **(CE)** | 20µl | 08L60-020 | 00884999031500 |
| Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe Kit **(ASR)** | 20 µL | 05J71-001 | 00884999012356 |
| Vysis LSI IGH/CCND1 Dual Color Dual Fusion Probes **(ASR)** | 20 µL | 05J69-001 | 00884999012301 |
| Vysis LSI IGH/CCND1 XT Dual Color, Dual Fusion Translocation Probes **(ASR)** | 20 µL | 05J72-001 | 00884999012370 |
| Vysis LSI IGH/FGFR3 Dual Color Dual Fusion Probes **(ASR)** | 20 µL | 05J74-001 | 00884999012417 |
| Vysis LSI IGH/MAF DF Probe Kit **(CE)** | 20 µL | 05N32-020 | 00884999014855 |
| Vysis LSI IGH/MALT1 DF FISH Probe Kit **(CE)** | 20 µL | 05N47-020 | 00884999014961 |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI IGH/MYC/CEP 8 Tri-Color Dual Fusion Probe Kit **(CE)** | 20 µL | 04N10-020 | 00884999007949 |
| Vysis LSI IGH/MYC/Vysis CEP 8 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL | 05J75-001 | 00884999012431 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| Vysis TRA/D Break Apart FISH Probe Kit (previously TCR alpha/delta Dual Color Break Apart Rearrangement Probe) **(CE)** | 20 µL | 05N41-020 | 00884999014923 |
| **CHROMOSOME 15** | | | |
| LSI SNRPN / CEP 15 (D15Z1) / LSI PML TriColor Probe **(ASR)** | 10 µL | 01N12-010 | 00884999000476 |
| Vysis LSI D5S23, D5S721/CEP 9/CEP 15 FISH Probe Kit **(CE)** | 20 µL | 05N35-020 | 00884999014886 |
| Vysis LSI D5S23/D5S721, Vysis CEP 9, Vysis CEP 15 Multi-Color Probe **(ASR)** | 20 µL | 05J84-007 | 00884999012721 |
| Vysis PML/RARA Single Fusion FISH Probe Kit **(ASR)** | 20 µL | 05J66-001 | 00884999012257 |
| Vysis PML/RARA Single Fusion FISH Probe Kit **(CE)** | 20 µL | 05N45-020 | 00884999014947 |
| Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 05J70-001 | 00884999012325 |
| Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 01N36-020 | 00884999000780 |
| Vysis LSI SNRPN / CEP 15 (D15Z1) / LSI PML TriColor Probe Kit **(CE)** | 10µL | 06N27-010 | 00884999025608 |
| Vysis Prader-Willi/Angelman Region Probe - LSI D15S10 (SO)/ Vysis CEP 15 (D15Z1) (SA)/PML (SG) **(ASR)** | 10µl | 01N13-010 | 00884999000483 |
| Vysis Prader-Willi/Angelman Region Probe - LSI D15S10 (SO)/ Vysis CEP 15 (D15Z1) (SA)/PML (SG) Kit **(CE)** | 10 µL | 05N58-010 | 00884999015067 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 16** | | | |
| Vysis CBFB Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N44-020 | 00884999014930 |
| Vysis FUS Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N58-020 | 00884999005785 |
| Vysis IGH/MAF DF FISH Probes **(ASR)** | 20 µL | 05J84-004 | 00884999012691 |
| Vysis LSI CBFB Break Apart Rearrangement Probe **(ASR)** | 20 µL | 05J65-001 | 00884999012240 |

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|---|---|---|---|
| Vysis LSI IGH/MAF DF Probe Kit **(CE)** | 20 µL | 05N32-020 | 00884999014855 |
| Vysis MultiVysion PB Multi-color Probe **(CE)** | 60 µL | 08L62-020 | 00884999031524 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 17** | | | |
| PathVysion **(FDA IVD)** | 20 Assays | 2J01-030 | 00884999001732 |
| PathVysion **(IVD Japan Only)** | 20 Tests | 2J01-031 | 00884999001749 |
| PathVysion **(FDA IVD)** | 50 Assays | 2J01-035 | 00884999001756 |
| PathVysion **(FDA IVD)** | 100 Assays | 2J01-036 | 00884999001763 |
| PathVysion HER-2 DNA Probe Kit II **(CE)** | 20 Assays | 06N46-030 | 00884999035867 |
| PathVysion HER-2 DNA Probe Kit II **(CE)** | 50 Assays | 06N46-035 | 00884999035874 |
| PathVysion HER-2 DNA Probe Kit II **(CE)** | 100 Assays | 06N46-036 | 00884999035881 |
| Protease IV **(CE)** | 75 mg x 5 | 06N46-001 | 00884999035843 |
| Protease IV **(CE)** | 750 mg x 5 | 06N46-002 | 00884999035850 |
| UroVysion Bladder Cancer Kit **(CE)** | 20 Assays | 02J27-020 | 00884999002135 |
| UroVysion Bladder Cancer Kit **(CE)** | 100 Assays | 02J27-099 | 00884999002197 |
| Vysis Esophageal FISH Probe Kit **(CE)** | 20 µL | 04N19-020 | 00884999008021 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe **(ASR)** | 20 µL | 05J83-001 | 00884999012622 |
| Vysis LSI p53 / LSI ATM and LSI D13S319 / LSI 13q34 / CEP 12 Multi-color Probe Set **(CE)** | 20 µL | 08L53-020 | 00884999031432 |
| Vysis PML/RARA Single Fusion FISH Probe Kit **(ASR)** | 20 µL | 05J66-001 | 00884999012257 |
| Vysis PML/RARA Single Fusion FISH Probe Kit **(CE)** | 20 µL | 05N45-020 | 00884999014947 |
| Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 05J70-001 | 00884999012325 |
| Vysis LSI PML/RARA Dual Color, Dual Fusion Translocation **(CE)** Probe Kit | 20 µL | 01N36-020 | 00884999000780 |
| Vysis LSI RARA Dual Color Break Apart Rearrangement Probe **(CE)** | 20 µL | 05N46-020 | 00884999014954 |



Please note some products may not be for sale in all markets. Contact your local representative for availability.

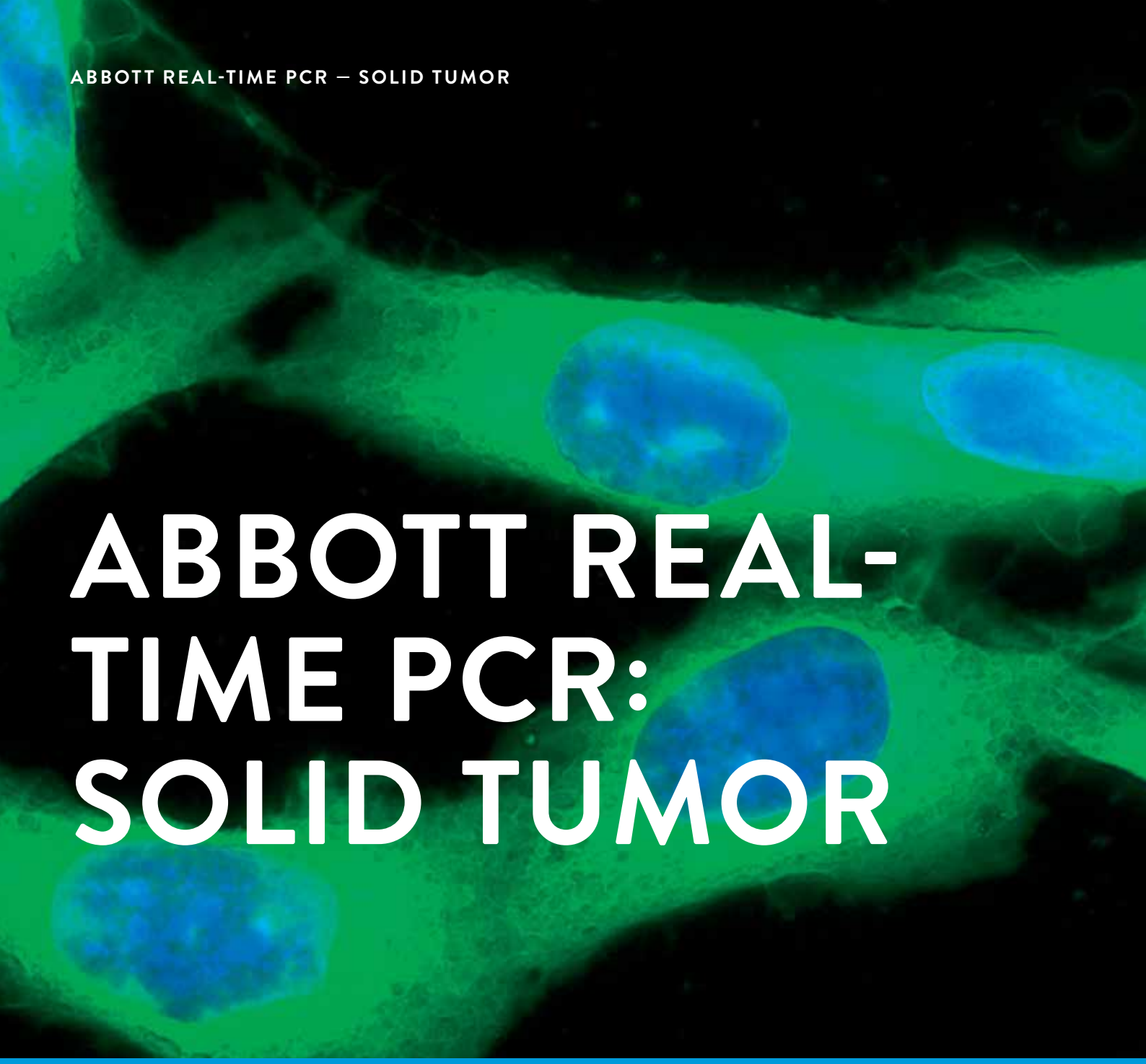
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI TP53 SpectrumOrange/ Vysis CEP 17 SpectrumGreen Probe **(ASR)** | 20 µL | 01N17-020 | 00884999000520 |
| Vysis TOP2A / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N89-020 | 00884999006270 |
| Vysis TOP2A / HER-2 / CEP 17 FISH Probe Kit **(CE)** | 200 µL | 03N90-020 | 00884999006287 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| Vysis TP53 / CEP 17 FISH Probe Kit **(CE)** | 20 µL | 05N56-020 | 00884999015050 |
| **CHROMOSOME 18** | | | |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 30 Assays | 05J38-030 | 00884999011700 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 50 Assays | 05J38-050 | 00884999011717 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 10 Assays | 05J38-010 | 00884999011694 |
| Vysis BIRC3/MALT1 DF FISH Probe Kit **(CE)** | 20 µL | 05N50-020 | 00884999014985 |
| Vysis LSI BCL2 Break Apart FISH Probe kit **(CE)** | 20 µL | 05N51-020 | 00884999014992 |
| Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe **(CE)** | 20µl | 08L60-020 | 00884999031500 |
| Vysis LSI IGH/BCL2 Dual Color, Dual Fusion Translocation Probe Kit **(ASR)** | 20 µL | 05J71-001 | 00884999012356 |
| Vysis LSI IGH/MALT1 DF FISH Probe Kit **(CE)** | 20 µL | 05N47-020 | 00884999014961 |
| Vysis LSI MALT1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 05N48-020 | 00884999014978 |
| Vysis MultiVysion PB Multi-color Probe **(CE)** | 60 µL | 08L62-020 | 00884999031524 |
| Vysis MultiVysion PGT Multi-color Probe **(CE)** | 30 µL | 08L69-010 | 00884999031593 |
| Vysis SS18 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N61-020 | 00884999005815 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 19** | | | |
| Vysis LSI 1p36 / LSI 1q25 and LSI 19q13/19p13 Dual-Color Probe **(CE)** | 2 vials, 200 µl each | 04N60-020 | 00884999009288 |

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 20** | | | |
| Vysis D20S108 FISH Probe Kit **(CE)** | 20 µL | 05N02-020 | 00884999014329 |
| Vysis Esophageal FISH Probe Kit **(CE)** | 20 µL | 04N19-020 | 00884999008021 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 21** | | | |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 10 Assays | 05J38-010 | 00884999011694 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 30 Assays | 05J38-030 | 00884999011700 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 50 Assays | 05J38-050 | 00884999011717 |
| Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe **(ASR)** | 20µL | 05J62-001 | 00884999012202 |
| Vysis LSI ETV6(TEL)/RUNX1(AML1) ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L66-020 | 00884999031562 |
| Vysis MultiVysion PB Multi-color Probe **(CE)** | 60 µL | 08L62-020 | 00884999031524 |
| Vysis MultiVysion PGT Multi-color Probe **(CE)** | 30 µL | 08L69-010 | 00884999031593 |
| Vysis RUNX1/RUNX1T1 DF FISH Probe Kit **(CE)** | 20 µL | 08L70-020 | 00884999031609 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME 22** | | | |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 20 µL | 05N54-020 | 00884999015029 |
| Vysis BCR/ABL1/ASS1 Tri-Color DF FISH Probe Kit **(CE)** | 50 µL | 05N54-050 | 00884999015036 |
| Vysis DiGeorge Region Probe - LSI TUPLE 1 SpectrumOrange/ LSI ARSA SpectrumGreen **(ASR)** | 20 µL | 05J21-028 | 00884999011342 |
| Vysis DiGeorge Region Probe - LSI TUPLE 1 SpectrumOrange/ LSI ARSA SpectrumGreen Probe Kit **(CE)** | 20 µL | 08L59-020 | 00884999031494 |
| Vysis EWSR1 Break Apart FISH Probe Kit **(CE)** | 20 µL | 03N59-020 | 00884999005792 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe **(ASR)** | 20 µL | 05J77-001 | 00884999012462 |
| Vysis LSI BCR, ABL Dual Color, Single Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L56-050 | 00884999031463 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe **(ASR)** | 20 µL | 05J78-001 | 00884999012479 |
| Vysis LSI BCR, ABL ES Dual Color Translocation Probe Kit **(CE)** | 20 µL | 08L55-020 | 00884999031456 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe **(ASR)** | 20 µL | 05J82-001 | 00884999012592 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe **(ASR)** | 50 µL | 05J82-010 | 00884999012615 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 20 µL | 08L10-001 | 00884999031166 |
| Vysis LSI BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit **(CE)** | 50 µL | 08L10-002 | 00884999031173 |
| Vysis LSI BCR/ABL1/ASS1 Tri-Color Dual Fusion Probes **(ASR)** | 50 µL | 08L79-050 | 00884999031654 |
| Vysis LSI BCR/ABL1/ASS1 Tri-Color Dual Fusion Probes **(ASR)** | 20 µL | 08L79-020 | 00884999031647 |
| Vysis MultiVysion PB Multi-color Probe **(CE)** | 60 µL | 08L62-020 | 00884999031524 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME X** | | | |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 50 Assays | 05J38-050 | 00884999011717 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 10 Assays | 05J38-010 | 00884999011694 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - al **(CE)** pha satellite / LSI 13/21) | 30 Assays | 05J38-030 | 00884999011700 |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-050 | 00884999027091 |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-050 | 00884999027022 |
| Vysis MultiVysion PGT Multi-color Probe **(CE)** | 30 µL | 08L69-010 | 00884999031593 |
| Vysis SRY Probe LSI SRY Spectrum Orange/Vysis CEP X Spectrum Green **(ASR)** | 20 µL | 05J27-007 | 00884999011472 |

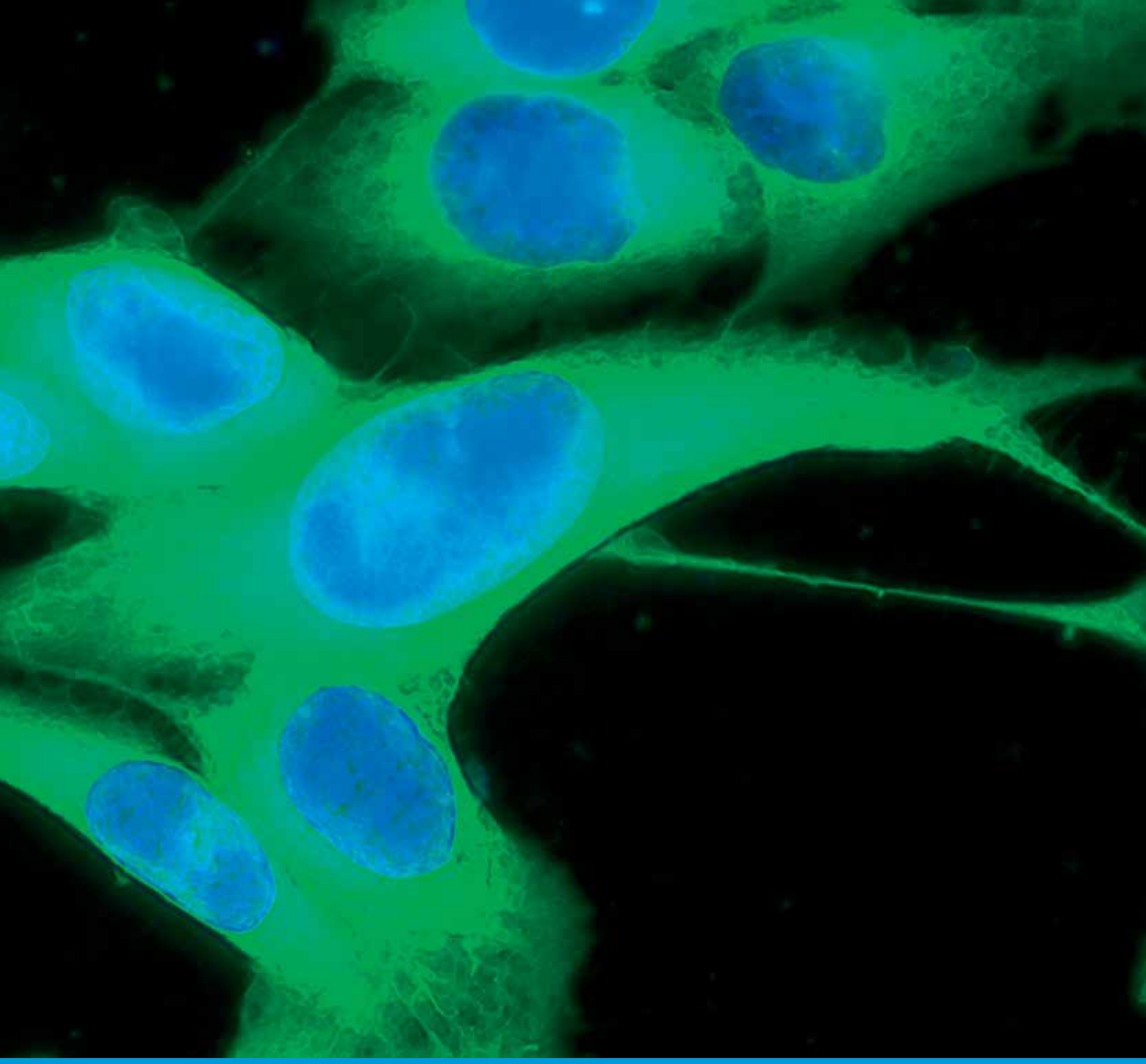
| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Vysis SRY Probe LSI SRY Spectrum Orange/Vysis CEP X Spectrum Green Probe Kit **(CE)** | 20 µL | 06N29-020 | 00884999025622 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |
| **CHROMOSOME Y** | | | |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 10 Assays | 05J38-010 | 00884999011694 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 30 Assays | 05J38-030 | 00884999011700 |
| AneuVysion Multicolor DNA Probe Kit (Vysis CEP 18/X/Y - alpha satellite / LSI 13/21) **(CE)** | 50 Assays | 05J38-050 | 00884999011717 |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit **(CE)** | 20 Assays | 07J22-050 | 00884999027091 |
| Vysis CEP X SpectrumOrange/Y SpectrumGreen Direct Labeled Fluorescent DNA Probe Kit (without control slides) **(CE)** | 20 Assays | 07J20-050 | 00884999027022 |
| Vysis MultiVysion PGT Multi-color Probe **(CE)** | 30 µL | 08L69-010 | 00884999031593 |
| Vysis SRY Probe LSI SRY Spectrum Orange/Vysis CEP X Spectrum Green **(ASR)** | 20 µL | 05J27-007 | 00884999011472 |
| Vysis SRY Probe LSI SRY Spectrum Orange/Vysis CEP X Spectrum Green Probe Kit **(CE)** | 20 µL | 06N29-020 | 00884999025622 |
| Vysis ToTelVysion **(ASR)** | 30 µL | 05J05-001 | 00884999010703 |
| Vysis ToTelVysion Probe Kit **(CE)** | 30 µL | 08L52-001 | 00884999031425 |



# ABBOTT REAL-TIME PCR: SOLID TUMOR

Abbott Real-Time PCR Technology for oncology provides more than a system. As a partner in delivering diagnostic results to the community, you get the commitment of a company with a long history of driving innovations and delivering solutions that help to improve the health of people everywhere. The performance you need is the performance we deliver, because we know you need it here and now. This philosophy fuels our commitment to your lab, the work you do, and the support we provide.

 Please note some products may not be for sale in all markets. Contact your local representative for availability.



## LEADING SCIENCE

- Precise and accurate detection ensures confidence in results
- Innovative technologies such as maxRatio data analysis increase accuracy by removing operator subjectivity

## ENABLING SOLUTIONS

- Reliable automated features result in true walkaway capability to reduce hands-on time
- Easy connection to advanced IT solutions improves data management

## TRUSTED PARTNER

- Proactive ongoing dialogue and customer collaboration ensure you and your system stay ahead of industry developments
- Rapid-response field service from certified specialists reduces system downtime
- Long-term commitment to relationships with non-government and government organizations increases adaptability, accessibility and development of new products

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| Abbott Bisulfite Modificaton Kit **(CE)** | 32 tests | 04N74-60 | 884999009677 | 368 |
| Abbott RealTime BRAF V600 E/K/D Mutations Amplification Reagent Kit **(CE)** | 24 Tests | 07N60-90 | 884999036116 | - |
| Abbott RealTime BRAF V600 E/K/D Mutations Control Kit **(CE)** | 5 Runs | 07N60-80 | 884999036109 | - |
| Abbott RealTime KRAS Amplification Reagent Kit **(CE)** | 24 Tests | 08N04-90 | 884999041646 | - |
| Abbott RealTime KRAS Control Kit **(CE)** | 5 Runs | 08N04-80 | 884999041639 | - |
| Abbott RealTime mS9 Colorectal Cancer - m2000 System ROW Combined Application CD-ROM **(CE)** | 1 CD-ROM | 04N48-01 | 884999009028 | 368 |
| Abbott RealTime mS9 Colorectal Cancer Amplification Reagent Kit **(CE)** | 4 packs, 8 tests each | 04N48-90 | 884999009042 | 368 |
| Abbott RealTime mS9 Colorectal Cancer Control Kit **(CE)** | 12 sets of 2 levels | 04N48-80 | 884999009035 | 368 |
| Abbott TargetPrep DNA FFPE Sample Prep Kit I **(CE)** | 50 Tests | 08N01-05 | 884999037786 | - |
| Abbott TargetPrep DNA FFPE Sample Prep Kit II **(CE)** | 50 Tests | 08N01-10 | 884999037793 | - |

# RealTi*me* *m*S9 Colorectal Cancer

## PRODUCT DESCRIPTION

The Abbott RealTi*me* *m*S9 Colorectal Cancer assay is an in vitro polymerase chain reaction (PCR) test for the qualitative detection of the presence of methylated Septin 9 in plasma. The Abbott RealTi*me* *m*S9 Colorectal Cancer assay may be useful as an indicator of the presence of colorectal cancer when confirmed by colonoscopy.

Colorectal cancer (CRC) is the second leading cause of cancer-related death and ranks third among most prevalent cancers worldwide. Although CRC is a serious condition, when detected early, five year survival rate can be as high as 90%. According to established guidelines, a number of screening modalities are recommended for use in an average risk population. These include, but are not limited to, fecal occult blood test, endoscopy, stool DNA and CT colonography. However, screening compliance rates are low and CRC can progress to later stages without any evident symptoms. About 55-60% of CRC's are diagnosed at an advanced stage and stage IV CRC's have a five-year survival rate of 11%.

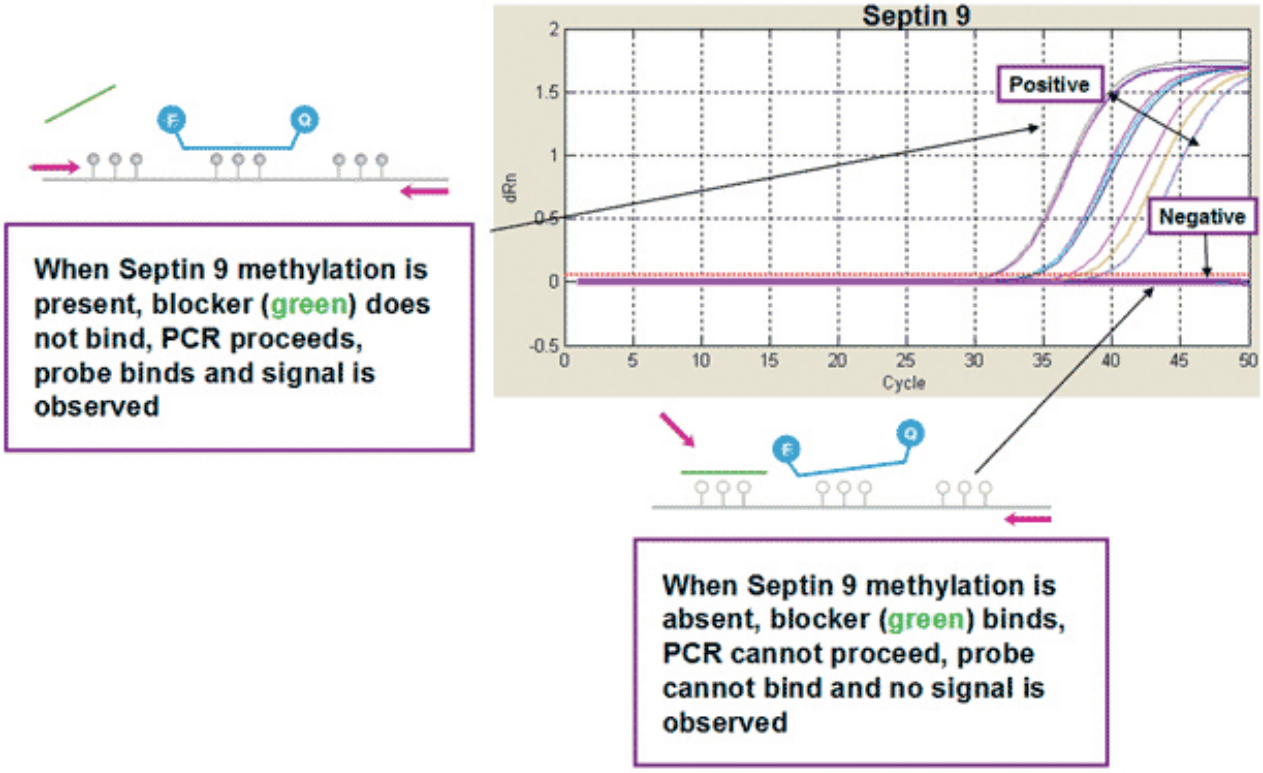
The Abbott RealTi*me* *m*S9 Colorectal Cancer assay monitors the presence of methylated Septin 9. Methylation of the Septin 9 promoter region, also termed epigenetic modification, has been associated with colorectal cancer. Determination of epigenetic events is a useful tool for early detection of disease since regulation of gene expression by aberrant DNA methylation is a well-characterized event in tumor biology, and is extensively described for CRC. Increased levels of cell-free circulating methylated DNA in the blood of cancer patients compared to healthy controls have been reported and can be used as a target for CRC detection.

## RESULTS YOU CAN TRUST

- Internal control to monitor for inhibition and sample adequacy
- Real-Time format

## AMPLIFICATION DETAILS

Product manufactured under license from Epigenomics and covered by one or more of the following patents EP1721992, US6,331,393, US7,229,759, EP1370691, and their foreign equivalents.




 Please note some products may not be for sale in all markets. Contact your local representative for availability.

## DESIGN

Reliable Results Abbott RealTi*me* *m*S9 Intended Use

The Abbott RealTi*me* *m*S9 Colorectal Cancer assay is an in vitro polymerase chain reaction (PCR) test for the qualitative detection of the presence of methylated Septin 9 in plasma. The Abbott RealTi*me* *m*S9 Colorectal Cancer assay may be useful as an indicator of the presence of colorectal cancer when confirmed by colonoscopy.

## PRODUCT DESIGN

**Instrumentation:** Extraction: *m*2000*sp*, Amplification and Detection: *m*2000*rt*

**Kit Configuration:** 32 tests per kit (4 x 8 tests/pack)

**Technology:** Multiplex Heavy Methyl RealTi*me* PCR

**Assay Performance:** Sensitivity- Stage I 52%: Stage II 76%: Stage III 76%: Stage IV 100% Specificity- 99%

**Sample Type:** Human Plasma

**Input Volume:** 4.0 ml automated / 3.5 ml manual

**Internal Control:** An endogenous Beta-actin sequence is detected as sample validity control for DNA adequacy, sample extraction and amplification efficiency.

**External Controls:** Negative control; Positive control

**Reported Results:** Qualitative detection of methylated Septin 9 - Positive or Negative

| Dyes | Probe Labels | Type Specific Probes |
|---|---|---|
| 3 | FAM | methylated Septin 9 |
| 4 | Quasar | Internal Control (Beta-actin) |
| 5 | ROX | Passive Reference |

Product manufactured under license from Epigenomics and covered by one or more of the following patents EP1721992, US6,331,393, US7,229,759, EP1370691, and their foreign equivalents.

The Abbott RealTi*me* *m*S9 Colorectal Cancer assay is an in vitro polymerase chain reaction (PCR) test for the qualitative detection of the presence of methylated Septin 9 in plasma. The Abbott RealTi*me* *m*S9 Colorectal Cancer assay may be useful as an indicator of the presence of colorectal cancer when confirmed by colonoscopy

| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| Abbott RealTime mS9 Colorectal Cancer Amplification Reagent Kit **(CE)** | 4 packs, 8 tests each | 04N48-90 | 00884999009042 |
| Abbott RealTime mS9 Colorectal Cancer Control Kit **(CE)** | 12 sets of 2 levels | 04N48-80 | 00884999009035 |
| Abbott RealTime mS9 Colorectal Cancer - m2000 System ROW Combined Application CD-ROM **(CE)** | 1 CD-ROM | 04N48-01 | 00884999009028 |
| Abbott Bisulfite Modificaton Kit **(CE)** | 32 tests | 04N74-60 | 00884999009677 |
| Abbott m2000 Low Residual Volume Sample Rack Posts **(CE)** | 2 Posts per pkg | 05N22-01 | 00884999014725 |
| Abbott m2000 Low Residual Volume Tube **(CE)** | 10 tubes per pkg | 05N29-01 | 00884999014831 |

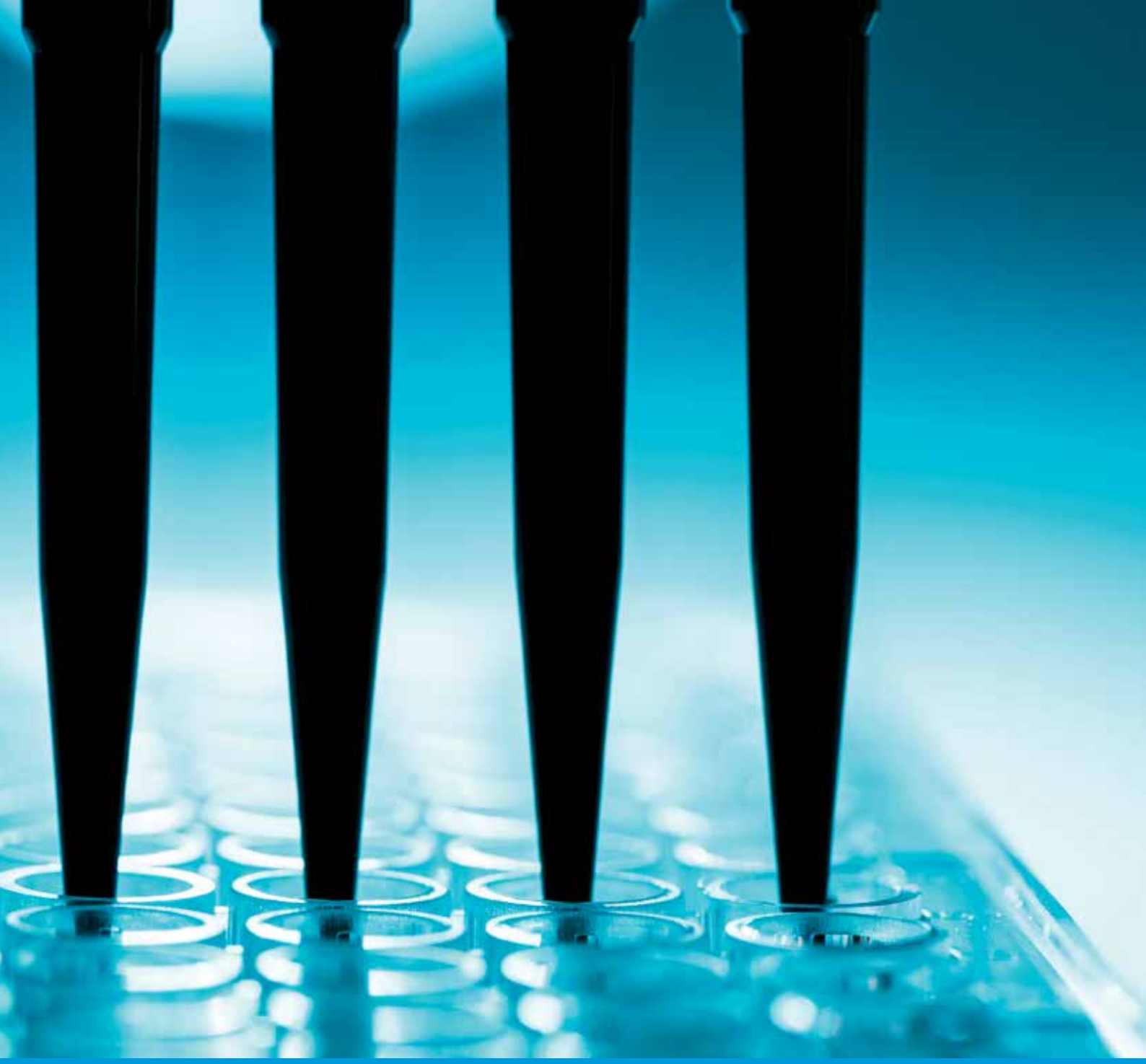
# ABBOTT REAL-TIME PCR: INSTRUMENTS

Abbott Molecular is committed to molecular diagnostics. Whether through new system software releases, innovative assay design or a constantly expanding mSystem menu, we are continuously evolving to provide flexible, automation with the laboratory in mind.

Laboratories are constantly being asked to do more and more, driving efficiency to it's absolute limits. Automation, with Abbott Molecular mSystems, provides laboratories with the ability to reduce instrument hands on time, maximize throughput and report results with confidence.

Designed with laboratorians in mind the m2000 RealTime System minimizes operator hands on time and provides automated data reduction and results reporting. Partnered with the Abbott Molecular RealTime assays, the m2000 System delivers patient results on an easy to use and reliable platform.

 Please note some products may not be for sale in all markets. Contact your local representative for availability.



| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **M2000 SYSTEMS** | | | | |
| m2000rt Instrument **(CE)** | 1 each | 09K15-01 | 00884999031814 | 374 |
| m2000rt Operations Manual Software Version 6.0 (English) | 1 each | 09K25-06 | 00884999036963 | 374 |
| m2000rt Operations Manual Software Version 6.0 (French) | 1 each | 03N51-04 | 00884999036888 | 374 |
| m2000rt Operations Manual Software Version 6.0 (German) | 1 each | 03N52-04 | 00884999036901 | 374 |
| m2000rt Operations Manual Software Version 6.0 (Italian) | 1 each | 03N56-04 | 00884999036895 | 374 |
| m2000rt Operations Manual Software Version 6.0 (Portuguese) | 1 each | 03N54-04 | 00884999036925 | 374 |
| m2000rt Operations Manual Software Version 6.0 (Russian) | 1 each | 03N55-04 | 00884999036932 | 374 |
| m2000rt Operations Manual Software Version 6.0 (Spanish) | 1 each | 03N53-04 | 00884999036918 | 374 |
| System Customer Training Guide | 1 each | 09K30-11 | 00884999038004 | 374 |
| **CONSUMABLES** | | | | |
| Abbott m2000 Low Residual Volume Sample Rack Posts **(CE)** | 2 Posts per pkg | 05N22-01 | 00884999014725 | - |
| Abbott m2000 Low Residual Volume Tube **(CE)** | 10 tubes per pkg | 05N29-01 | 00884999014831 | - |
| Abbott mSample Preparation System (DNA) **(CE)** | 4 packs, 8 tests each | 06K12-024 | 00884999023802 | - |
| m2000 Halogen Lamp, Replacement | 1 each | 09K33-01 | 00884999032071 | - |
| m2000 Optical Calibration Kit | 1 each | 04J71-93 | 00884999006577 | - |
| mSample Preparation Systems DNA | 4x24 Preps | 06K12-24 | 00884999023802 | - |
| mSample Preparation Systems RNA | 4x24 Preps | 04J70-24 | 00884999006416 | - |
| mSystems 200 mL Reagent Vessels | 90 Vessels | 04J71-60 | 00884999006515 | - |
| mSystems 5mL Reaction Vessels | 2000 Vessels | 04J71-20 | 00884999006461 | - |
| mSystems 96 Deep Well Plates | 32 Plates | 04J71-30 | 00884999006485 | - |
| mSystems 96-Well Optical Reaction Plates | 20 Plates | 04J71-70 | 00884999006522 | - |
| mSystems Biohazard Bags | 50 Bags | 04J71-45 | 00884999006492 | - |
| mSystems Disposable Tips (DiTis): 1mL | 2304 Tips | 04J71-10 | 00884999006430 | - |
| mSystems Disposable Tips (DiTis): 200µL | 2304 Tips | 04J71-17 | 00884999006454 | - |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| mSystems Master Mix Tubes/Caps | 150 Tubes/ Caps | 04J71-80 | 00884999006546 | - |
| mSystems Optical Adhesive Covers | 100 Covers | 04J71-75 | 00884999006539 | - |
| mSystems Splash Free Support Base | 5 each | 09K31-01 | 00884999032057 | - |
| mSystems Wrench | 1 each | 01N71-01 | 00884999000841 | - |
| Sequencing Consumables Kit **(GPR)** | 96 Tests/Kit | 04J94-92 | 00884999007468 | - |

# *m*2000 RealTi*m*e System

## PRODUCT DESCRIPTION

Automation is the foundation for the clinical molecular laboratory to report patient results with confidence. Abbott Molecular's m2000rt for real-time amplification and detection is a cornerstone for this process.

Abbott Molecular is committed to molecular diagnostics. Whether through new system software releases, innovative assay design or a constantly expanding mSystem menu, we are continuously evolving.

More and more is being expected of laboratories. Automation, with Abbott Molecular mSystems, provides laboratories with the ability to reduce instrument hands on time, maximize throughput and report patient results with confidence.

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

## *M*2000*RT*: REALTIME PCR

Real-time PCR Amplification and Detection

5 excitation, 5 emission filters

***max***Ratio Data Analysis

Multiple validity checks for improved confidence in patient results

Minimal Maintenance

Halogen bulb replacement

Laboratory Defined Applications

Complete flexability in defining laboratory-based real-time PCR applications

## TECHNICAL SPECIFICATIONS

| | |
|---|---|
| **Total Length** | 34 cm (13.4 in) |
| **Total Height** | 49 cm (19.3 in) |
| **Total Depth** | 45 cm (17.8 in) |
| **Weight** | 34.1 kg (75.2 lbs) |
| **Power Source** | 100-240 V |

## *M*2000 SYSTEM SOFTWARE: SIMPLIFIED DATA MANAGEMENT

Intuitive User Interface

Windows XP™

LIS Capability

Standardized interface with LIS

Data Archiving

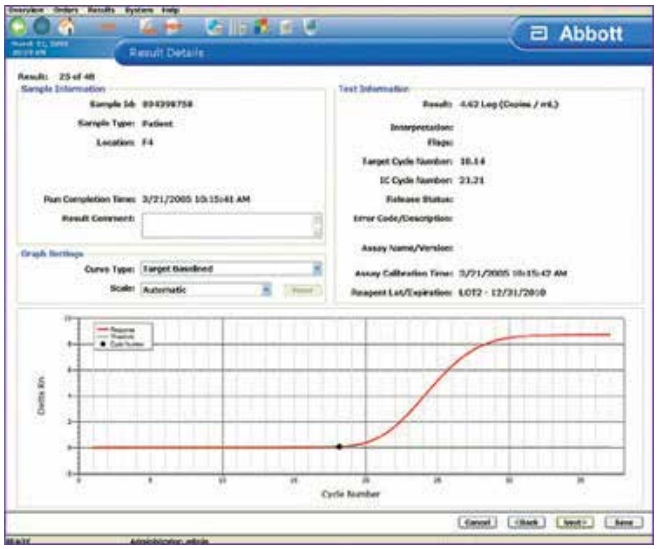
Calibrator, control, and patient data logs

Automated Quality Checks and Calibration

Provides accurate results

AbbottLink

Remote Instrument Monitoring



| PRODUCT | QUANTITY | ORDER # | GTIN |
|---|---|---|---|
| m2000rt Instrument **(CE)** | 1 each | 09K15-01 | 00884999031814 |
| m2000rt Operations Manual Software Version 6.0 (English) | 1 each | 09K25-06 | 00884999036963 |
| m2000rt Operations Manual Software Version 6.0 (French) | 1 each | 03N51-04 | 00884999036888 |
| m2000rt Operations Manual Software Version 6.0 (German) | 1 each | 03N52-04 | 00884999036901 |
| m2000rt Operations Manual Software Version 6.0 (Italian) | 1 each | 03N56-04 | 00884999036895 |
| m2000rt Operations Manual Software Version 6.0 (Portuguese) | 1 each | 03N54-04 | 00884999036925 |
| m2000rt Operations Manual Software Version 6.0 (Russian) | 1 each | 03N55-04 | 00884999036932 |
| m2000rt Operations Manual Software Version 6.0 (Spanish) | 1 each | 03N53-04 | 00884999036918 |
| System Customer Training Guide | 1 each | 09K30-11 | 00884999038004 |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.


ABBOTT
m2000rt

# ABBOTT REAL-TIME PCR: ACCESSORIES/ GENERAL PURPOSE REAGENTS

With Abbott RealTime you get more than a system. You get the commitment of a company with a long history of driving innovations and delivering solutions that help to improve the health of people everywhere: introducing the first HIV-1 diagnostic test, launching the industry's first global HIV-1 surveillance program, leading in hepatitis testing for more than 40 years, and continuing to work with organizations around the world every day to make molecular disease testing more accessible.

The performance you need is the performance we deliver, because we know you need it here and now. This philosophy fuels our commitment to your lab, the work you do, and the support we provide.

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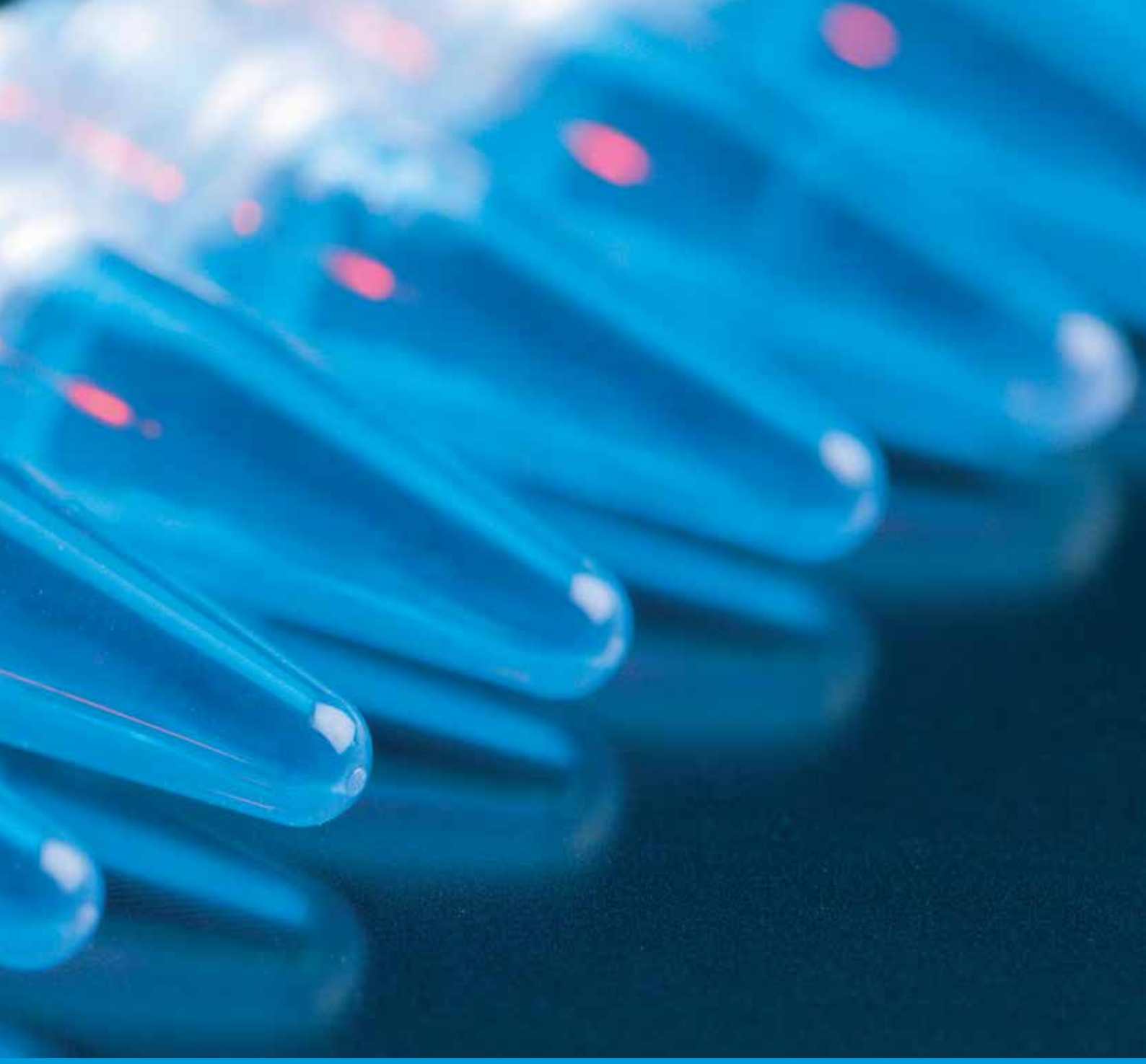


**TRUSTED PARTNER:**

- Proactive ongoing dialogue and customer collaboration ensure you and your system stay ahead of industry developments.
- Rapid-response field service from certified specialists reduces system downtime.
- Long-term commitment to relationships with non-government and government organizations increases adaptability, accessibility and development of new products.

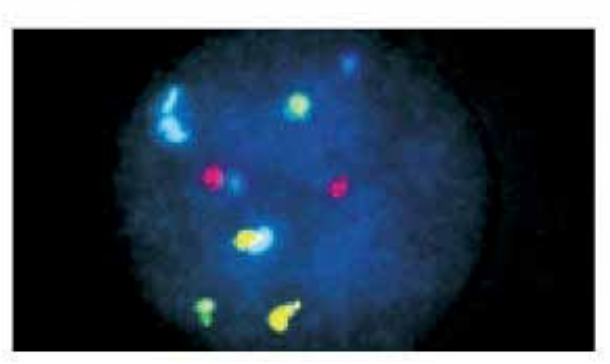
| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **CONSUMABLES** | | | | |
| Abbott m2000 Low Residual Volume Sample Rack Posts **(CE)** | 2 Posts per pkg | 05N22-01 | 884999014725 | - |
| Abbott m2000 Low Residual Volume Tube **(CE)** | 10 tubes per pkg | 05N29-01 | 884999014831 | - |
| Abbott mSample Preparation System (DNA) **(CE)** | 4 packs, 8 tests each | 06K12-024 | 884999023802 | - |
| m2000 Halogen Lamp, Replacement | 1 each | 09K33-01 | 884999032071 | - |
| m2000 Optical Calibration Kit | 1 each | 04J71-93 | 884999006577 | - |
| mSample Preparation Systems DNA | 4x24 Preps | 06K12-24 | 884999023802 | - |
| mSample Preparation Systems RNA | 4x24 Preps | 04J70-24 | 884999006416 | - |
| mSystems 200 mL Reagent Vessels | 90 Vessels | 04J71-60 | 884999006515 | - |
| mSystems 5mL Reaction Vessels | 2000 Vessels | 04J71-20 | 884999006461 | - |
| mSystems 96 Deep Well Plates | 32 Plates | 04J71-30 | 884999006485 | - |
| mSystems 96-Well Optical Reaction Plates | 20 Plates | 04J71-70 | 884999006522 | - |
| mSystems Biohazard Bags | 50 Bags | 04J71-45 | 884999006492 | - |
| mSystems Disposable Tips (DiTis): 1mL | 2304 Tips | 04J71-10 | 884999006430 | - |
| mSystems Disposable Tips (DiTis): 200µL | 2304 Tips | 04J71-17 | 884999006454 | - |
| mSystems Master Mix Tubes/Caps | 150 Tubes/ Caps | 04J71-80 | 884999006546 | - |
| mSystems Optical Adhesive | 100 Covers | 04J71-75 | 884999006539 | - |
| mSystems Splash Free Support Base | 5 each | 09K31-01 | 884999032057 | - |
| mSystems Wrench | 1 each | 01N71-01 | 884999000841 | - |
| Sequencing Consumables Kit **(GPR)** | 96 Tests/Kit | 04J94-92 | 884999007468 | - |

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

| PRODUCT | QUANTITY | ORDER # | GTIN | PG |
|---|---|---|---|---|
| **M2000RT ACCESSORIES** | | | | |
| m2000rt Operations Manual Software Version 6.0 (English) | 1 each | 09K25-06 | 00884999036963 | - |
| m2000rt Operations Manual Software Version 6.0 (French) | 1 each | 03N51-04 | 00884999036888 | - |
| m2000rt Operations Manual Software Version 6.0 (German) | 1 each | 03N52-04 | 00884999036901 | - |
| m2000rt Operations Manual Software Version 6.0 (Italian) | 1 each | 03N56-04 | 00884999036895 | - |
| m2000rt Operations Manual Software Version 6.0 (Portuguese) | 1 each | 03N54-04 | 00884999036925 | - |
| m2000rt Operations Manual Software Version 6.0 (Russian) | 1 each | 03N55-04 | 00884999036932 | - |
| m2000rt Operations Manual Software Version 6.0 (Spanish) | 1 each | 03N53-04 | 00884999036918 | - |
| System Customer Training Guide | 1 each | 09K30-11 | 00884999038004 | - |

# VYSIS MICROSCOPE FILTERS

Vysis filter sets can be specified for most microscope types and models. Some of the most common filter holders and sliders are available from Abbott Molecular. If your model is not listed, please contact your local Abbott representative. *(Abbott Molecular currently does not supply the new 8 position turret for the Olympus AX-70)*



The Vysis microscope filter sets are high-quality filter sets that are designed to provide optimal excitation and emission of the Vysis fluorophore labeled DNA FISH probes. The specific Vysis design filter sets provide a wider bandpass, steeper profile, and maximum fluorescence throughput specific for Vysis fluorophores. In addition, the Vysis filter sets carry a one year warranty against defects.

Many of the Vysis filter sets are also suitable for excitation and emission of other manufacturers' FISH probes that are labeled with the common fluorophores such as rhodamine, TexasRed®, and fluorescein.

View the Microscope Filter Order Form for ordering information at:

**ABBOTTMOLECULAR.COM/ORDER-MICROSCOPE-FILTERS**

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Single Bandpass Filter Sets

### ORANGE

The Orange filter set is designed to excite and transmit SpectrumOrange fluorescence. All of the Vysis SpectrumOrange labeled DNA FISH probes can be viewed, analyzed, and imaged using this filter set. The SpectrumRed fluorophore will be visible using this filter set, but will be dim.

### RED

The Red filter set is designed to excite and transmit SpectrumRed fluorescence. This filter set can be used to view, analyze, and image SpectrumRed labeled probes, or for TexasRed labeled DNA FISH probes that are available from other probe manufacturers. The SpectrumRed filter set is not recommended for viewing SpectrumOrange labeled probes.

### YELLOW

The Yellow filter set is designed to excite and transmit SpectrumGold fluorescence. The Vysis SpectrumGold labeled DNA FISH probes (Vysis UroVysion) can be viewed, analyzed, and imaged using this filter set. SpectrumOrange probe fluorescence will also be visible with the Yellow filter set. SpectrumRed fluorescence may be visible, yet very dim.

### GREEN

The Green filter set is designed to excite and transmit SpectrumGreen fluorescence. This filter set can be used to view, analyze, and image SpectrumGreen and fluorescence labeled DNA FISH probes.

### AQUA

The Aqua filter set is designed to excite and transmit SpectrumAqua fluorescence. This filter set is specifically required for viewing, analyzing, and imaging Vysis SpectrumAquaTM DNA probes. Filter sets that excite and transmit DAPI fluorescence are not appropriate for SpectrumAqua labeled probes. In some instances,when hybridization signal is very intense for the SpectrumAqua labeled DNA probe, the aqua fluorescence may be visible through a DAPI filter set.However, this will not provide a reliable method for analysis of SpectrumAqua labeled probes. In addition, on specimens counterstained with DAPI, extremely weak DAPI fluorescence may be observed when viewing or imaging through an Aqua single bandpass filter set.

### BLUE

The Blue filter set is designed to excite and transmit SpectrumBlue fluorescence and is useful when viewing the SpectrumBlueTM fluorophore alone.DAPI fluorescence will also be visible with this filter set. SpectrumAqua fluorescence will be visible through the Blue filter set, but will be dim. In order to view the SpectrumBlue and SpectrumAqua fluorophores simultaneously, the Aqua/Blue dual bandpass filter set should be used.

### DAPI LONGPASS

The DAPI longpass filter set is designed to excite and transmit DAPI counterstain fluorescence. This filter set transmits more in the red range of the color spectrum than the DAPI bandpass filter set.

### DAPI BANDPASS

The DAPI bandpass filter set is designed to excite and transmit DAPI counterstain. This filter set does not transmit as much of the spectrum as the DAPI Longpass filter set, and is recommended over the DAPI Longpass for imaging applications.

# Dual Bandpass Filter Sets

### DAPI/ORANGE

The DAPI/Orange filter set is designed to excite and transmit SpectrumOrange™ and DAPI counterstain fluorescence simultaneously. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the SpectrumOrange fluorophore must be viewed concurrently. This filter set is recommended for many of the Vysis® SpectrumOrange labeled DNA FISH probes that can be analyzed simultaneously while viewing the DAPI counterstain.

### DAPI/9-ORANGE (NB)

The DAPI/9-Orange (NB) filter set is designed to excite and transmit SpectrumOrange and the DAPI counterstain fluorescence simultaneously. This filter set is designed to minimize autofluorescence from paraffin-embedded specimens and is recommended for the PathVysion® HER-2 DNA Assay. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the SpectrumOrange fluorophore must be viewed concurrently.

### DAPI/GREEN

The DAPI/Green filter set is designed to excite and transmit SpectrumGreen™ and DAPI fluorescence simultaneously and is recommended for the PathVysion® DNA Assay. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the SpectrumGreen fluorophore must be viewed concurrently. This filter set is recommended for many of the Vysis SpectrumGreen labeled DNA FISH probes that can be analyzed simultaneously while viewing the DAPI counterstain.

### BLUE/AQUA

The Blue/Aqua filter set is designed to excite and transmit SpectrumBlue™ and SpectrumAquaTM fluorophores simultaneously.

# Triple Bandpass Filter Sets

### DAPI/GREEN/ORANGE

The DAPI/Green/Orange filter set is designed to excite and transmit SpectrumGreen, SpectrumOrange, and DAPI counterstain fluorescence simultaneously. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the two fluorophores SpectrumGreen and SpectrumOrange must be viewed concurrently. This filter set is recommended for most of the Vysis dual color probe mixtures when hybridized to specimens that are not imbedded in paraffin. Products such as CEP X/Y should be viewed using this filter set.

### DAPI/GREEN/ORANGE (V.2)

The DAPI/Green/Orange (V.2) filter set is designed to excite and transmit SpectrumGreen, SpectrumOrange and the DAPI counterstain fluorescence simultaneously. This filter is useful when the nuclear and chromosomal DNA, counterstained with DAPI, and the SpectrumGreen and SpectrumOrange fluorophores must be viewed simultaneously.

The DAPI/Green/Orange (V.2) filter design may provide better color distinction and brightness of the SpectrumOrange and SpectrumGreen fluorophores when viewing paraffin-embedded specimens. This filter set is not optimized for viewing dual-color translocation probes where a blending of the SpectrumGreen and SpectrumOrange fluorophores creates a yellow color. This is the recommended triple bandpass filter set for viewing and analyzing the PathVysion HER-2 DNA Assay.

### DAPI/GREEN/RED

The DAPI/Green/Red filter set is designed to excite and transmit SpectrumGreen, SpectrumRed, and the DAPI counterstain fluorescence simultaneously. This filter is optimal for viewing probes labeled with SpectrumRed fluorophore while concurrently viewing SpectrumGreen and DAPI.

 Please note some products may not be for sale in all markets. Contact your local representative for availability.

# Quad Bandpass Filter Sets

### DAPI/AQUA/GREEN/ORANGE

The quad bandpass filter set is designed to excite and transmit DAPI, SpectrumAqua, SpectrumOrange and SpectrumGreen fluorophores simultaneously. This filter set is optimal for viewing all three probe labels simultaneously, plus the DAPI counterstain. This filter set is not recommended for viewing the AneuVysion® Assay on uncultured amniocytes.

# Required Vysis Filter Set Configurations

The following filter set configurations are required for the specific Vysis Assays, as indicated. The recommended filter sets provide the most optimal viewing conditions. If not indicated, contact your local Abbott Molecular Technical Service representative for more information on appropriate filter set configurations for imaging.

## PATHVYSION HER-2 DNA ASSAY FILTER SETS

The following filter sets are recommended for viewing and enumeration of the PathVysion HER-2 Assay. These filter sets are optimized both for Vysis SpectrumGreen and SpectrumOrange fluorophores and for paraffin-embedded specimen autofluorescence. The dual bandpass filter sets allow the user to view signals of each respective individual color fluorophore and the DAPI counterstain. The triple bandpass filter set allows the user to visualize the SpectrumGreen, SpectrumOrange, and DAPI fluorescent signals simultaneously.

| VYSIS FILTER SET | FLUOROPHORES DETECTED |
|---|---|
| DAPI/9-Orange (NB) dual bandpass | SpectrumOrange and DAPI |
| DAPI/Green dual bandpass | SpectrumGreen and DAPI |
| DAPI/Green/Orange (V.2) triple bandpass | SpectrumGreen/SpectrumOrange/DAPI (specifically designed for viewing paraffin sections) |

## ANEUVYSION ASSAY FILTER SETS

The following filter set configuration provides the best microscope filter set-up for viewing and analysis of the AneuVysion Assay on uncultured amniocytes.

| VYSIS FILTER SET | FLUOROPHORES DETECTED |
|---|---|
| Aqua single bandpass | SpectrumAqua |
| Green single bandpass | SpectrumGreen |
| Orange single bandpass | SpectrumOrange |
| DAPI/Green/Orange triple bandpass | SpectrumGreen/SpectrumOrange/ DAPI |

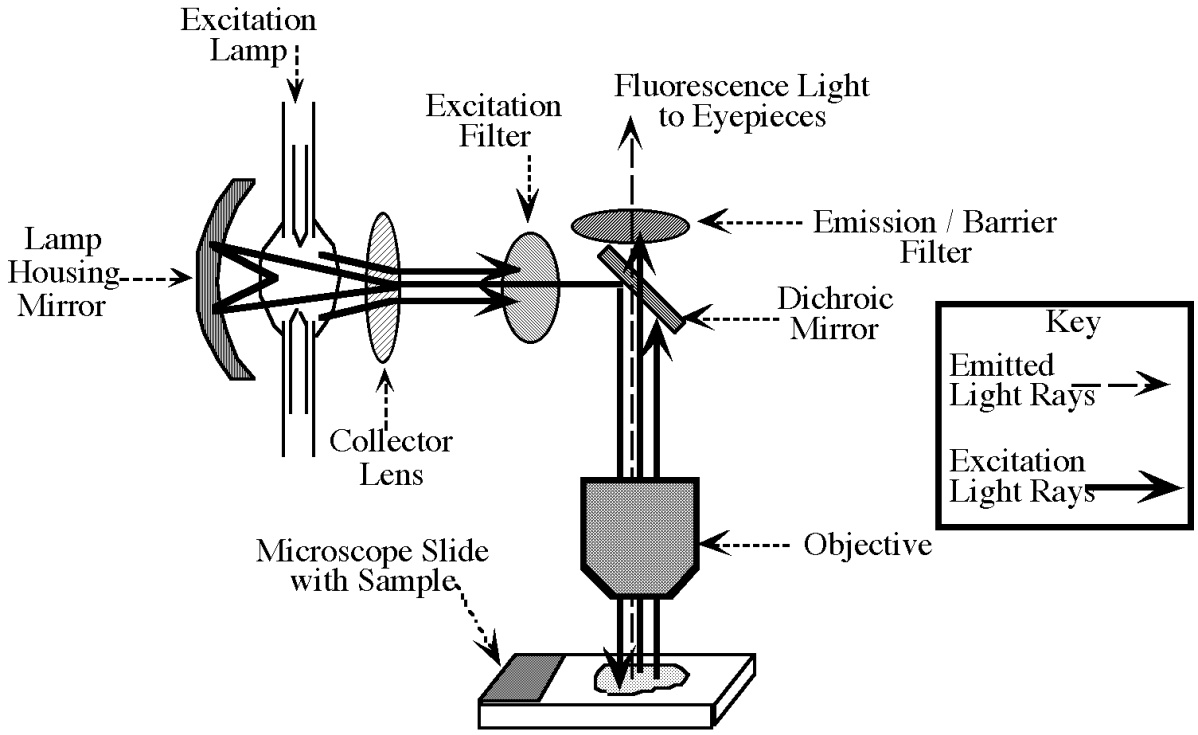
## UROVYSION ASSAY FILTER SETS

| VYSIS FILTER SET | FLUOROPHORES DETECTED |
|---|---|
| DAPI single bandpass | DAPI |
| Aqua single bandpass | SpectrumAqua |
| Yellow single bandpass | SpectrumGold |
| Red/Green dual bandpass | SpectrumRed/SpectrumGreen |

## FILTER SLIDERS/HOLDERS

Vysis filter sets can be specified for most microscope types and models. Some of the most common filter holders and sliders are available through Abbott Molecular. Abbott Molecular currently does not supply the new 8 position turret for the Olympus AX-70.

# The Fluorescence Microscope




***Key Components of the Epi-Fluorescence Microscope Optical Train***

The critical components of the fluorescence microscope optical train are depicted in the diagram above.

Microscope filter sets are custom manufactured to fit the dimensions required by each type of microscope and filter wheel. Filters are manufactured as matched sets consisting of the excitation filter, dichroic filter, and emission filter. As such, it is necessary to provide all of the required information, as requested below, when ordering filter sets. Without the appropriate information, the correct microscope filter cannot be manufactured. In addition, delays in order processing due to inaccurate or incomplete information will delay the fulfillment of the filter set order. Contact Vysis Technical Service for more information on microscope filter sets and the appropriate configuration for your laboratory's specific needs.

# ORDERING/ CONTACT INFORMATION

### AUSTRALIA
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Tel: 1-800-659-554
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### BAHRAIN
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