ZytoLight® SPEC D13S319/13q34/CEN 12 Triple Color Probe

CE IVD

Background

The ZytoLight® SPEC D13S319/13q34/CEN 12 Triple Color Probe (PL116) is intended to be used for the qualitative detection of deletions involving the human D13S319 region as well as the detection of chromosome 13q34 specific sequences and chromosome 12 alpha satellites in cytologic specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight® FISH-Cytology Implementation Kit (Prod. No. Z-2099-20).

The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

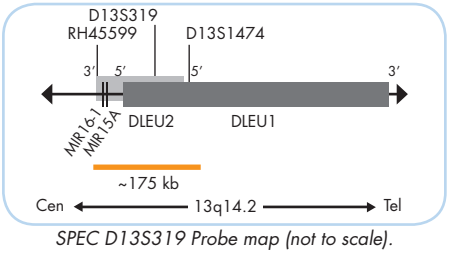
The probe is intended to be used as an aid to the differential diagnosis of various cancers and therapeutic measures should not be initiated based on the test result alone.

Ideograms of chromosomes 13 (above) and 12 (below) indicating the hybridization locations.

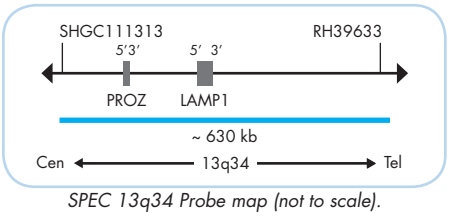
Probe Description

The ZytoLight® SPEC D13S319/13q34/CEN 12 Triple Color Probe is composed of:

- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 13q14.2** (chr13:50,607,438-50,781,256) harboring the D13S319 locus.
- ZyBlue (excitation at 418 nm and emission 467 nm) labeled polynucleotides (~37 ng/µl), which target sequences mapping in 13q34** (chr13:113,691,216-114,323,467) harboring the LAMP1 gene region.
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 12p11.1-q11 specific for the alpha satellite centromeric region D12Z3 of chromosome 12.
- Formamide based hybridization buffer



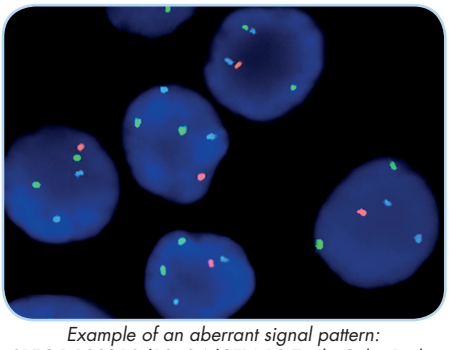
SPEC D13S319 Probe map (not to scale).



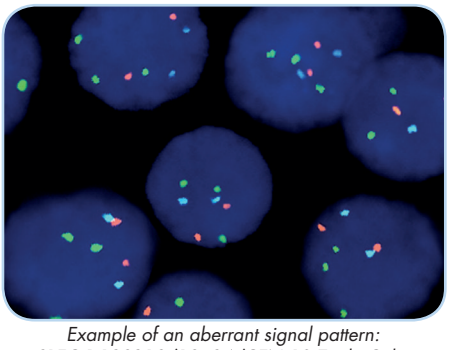
SPEC 13q34 Probe map (not to scale).

Results

Using the SPEC D13S319/13q34/CEN 12 Triple Color Probe in a normal interphase nucleus, two orange, two green, and two blue signals are expected. In a cell with deletions affecting the D13S319 locus, a reduced number of orange signals will be observed. Deletions affecting only parts of the D13S319 locus might result in a normal signal pattern with orange signals of reduced size. In a cell with trisomy or polysomy 12, three or more copies of the green signal will be observed, respectively.



Example of an aberrant signal pattern: SPEC D13S319/13q34/CEN 12 Triple Color Probe hybridized to bone marrow biopsy section with deletion of the D13S319 locus as indicated by one orange signal and two blue signals in each nucleus.



Example of an aberrant signal pattern: SPEC D13S319/13q34/CEN 12 Triple Color Probe hybridized to bone marrow smear with trisomy of chromosome 12 as indicated by three green signals in each nucleus.

Prod. No.	Product	Label	Tests* (Volume)
Z-2160-50	ZytoLight SPEC D13S319/13q34/CEN 12 Triple Color Probe CE IVD	●/●/●	5 (50 µl)
Z-2160-200	ZytoLight SPEC D13S319/13q34/CEN 12 Triple Color Probe CE IVD	●/●/●	20 (200 µl)
Related Products			
Z-2099-20	ZytoLight FISH-Cytology Implementation Kit CE IVD Incl. Cytology Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 50 ml; 10x $MgCl_2$, 50 ml; 10x PBS, 50 ml; Cytology Stringency Wash Buffer SSC, 500 ml; Cytology Wash Buffer SSC, 500 ml; DAPI/DuraTect-Solution, 0.8 ml		20

** Using 10 µl probe solution per test. IVD labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

***According to Human Genome Assembly GRCh37/hg19*