ZytoLight® SPEC 4p11/CEN 10/17 Triple Color Probe

Intended Purpose

The ZytoLight SPEC 4p11/CEN 10/17 Triple Color Probe (PL261) is intended to be used for the qualitative detection of human chromosome 4p11 specific sequences as well as alpha satellites of chromosomes 10 and 17 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.

Probe Description

The ZytoLight SPEC 4p11/CEN 10/17 Triple Color Probe is composed of:

- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 4p11* (chr4:48,329,914-48,762,386) (see Fig. 1).
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 10p11.1-q11.1 specific for the alpha satellite centromeric region D10Z1 of chromosome 10.
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~12 ng/µl), which target sequences mapping in 17p11.1-q11.1 specific for the alpha satellite centromeric region D17Z1 of chromosome 17.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

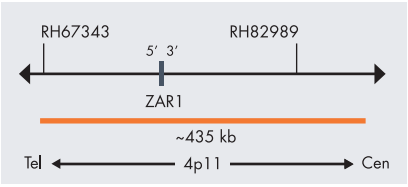
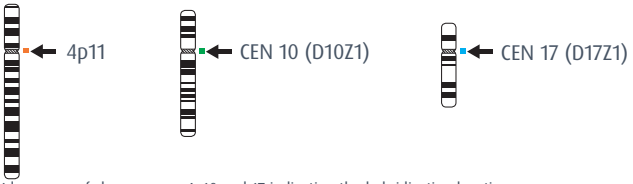


Fig. 1: SPEC 4p11 Probe map (not to scale)

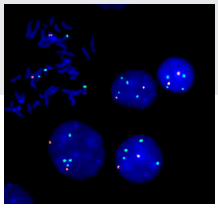


Ideograms of chromosome 4, 10 and 17 indicating the hybridization locations

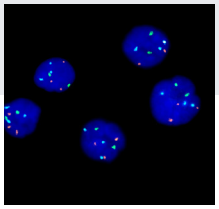
Results

Normal situation: In nterphases of normal cells or cells without an alteration of the respective chromosomes, two green, two orange, and two blue signals appear.

Aberrant situation: In a cell with aneusomy of the chromosomes 4, 10, and/or 17, an increased or a reduced number of signals of the respective color will be observed.



Hybridized to normal interphase cells as indicated by two orange, two green, and two blue signals in each nucleus and to metaphase chromosomes of a normal cell.



Example of an aberrant signal pattern: Bone marrow smear with trisomy of chromosome 4 and 17 as indicated by three orange and blue signals in each nucleus.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●|●	4, 10, 17	CE/IVD	5 (50 µl)	**Z-2307-50**

ZytoLight® SPEC PDGFRA/FIP1L1 TriCheck™ Probe

Intended Purpose

The ZytoLight SPEC PDGFRA/FIP1L1 TriCheck Probe (PL167) is intended to be used for the qualitative detection of rearrangements involving the human PDGFRA gene with and without participation of the human FIP1L1 gene in cytological 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.

Probe Description

The ZytoLight SPEC PDGFRA/FIP1L1 TriCheck Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10,0 ng/µl), which target sequences mapping in 4q12* (chr4:53,552,536-54,238,252) proximal to the FIP1L1 gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 4q12* (chr4:54,351,156-54,749,671) proximal to the PDGFRA gene region (see Fig. 1).
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~37,0 ng/µl), which target sequences mapping in 4q12* (chr4:55,185,968-55,915,442) distal to the PDGFRA gene region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

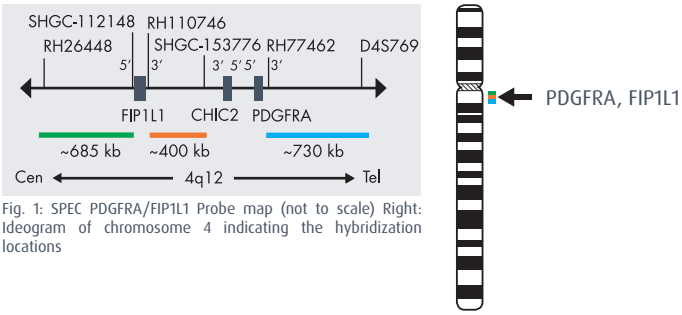
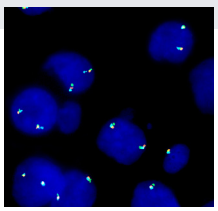


Fig. 1: SPEC PDGFRA/FIP1L1 Probe map (not to scale) Right: Ideogram of chromosome 4 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without PDGFRA-FIP1L1 rearrangements, two green/orange fusion signals appear when using an appropriate dual bandpass filter set, and two blue signals appear when using an appropriate single bandpass filter set. When using an appropriate triple color bandpass filter set, two green/orange/blue fusion signals can be observed.

Aberrant situation: A PDGFRA-FIP1L1 fusion resulting from a deletion of interstitial DNA is indicated by the loss of one orange signal leading to a separate green signal co-localizing with a blue signal. A PDGFRA translocation without involvement of FIP1L1 is indicated by a green/orange fusion signal and a separate blue signal.



Hybridized to normal interphase cells as indicated by two tricolor orange/green/blue fusion signals per nucleus.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●|●	4	CE/IVD	5 (50 µl)	**Z-2209-50**