ZytoLight® SPEC PTEN/CEN 10 Dual Color Probe

Intended Purpose

The ZytoLight SPEC PTEN/CEN 10 Dual Color Probe (PL37) is intended to be used for the qualitative detection of deletions involving the human PTEN gene as well as the detection of chromosome 10 alpha satellites in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight FISH-Tissue Implementation Kit (Prod. No. Z-2028-5/-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 PTEN/CEN 10 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 10q23.2-q23.31* (chr10:89,440,649-89,755,790) harboring the PTEN gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1,5 ng/µl), which target sequences mapping in 10p11.1-q11.1 specific for the alpha satellite centromeric region D10Z1 of chromosome 10.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

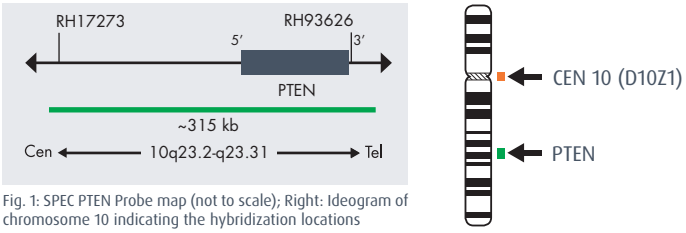
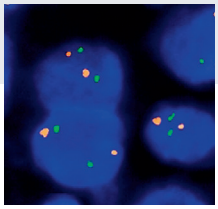


Fig. 1: SPEC PTEN Probe map (not to scale); Right: Ideogram of chromosome 10 indicating the hybridization locations

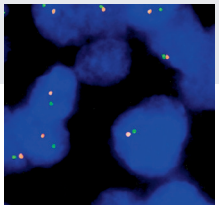
Results

Normal situation: In interphases of normal cells or cells without a deletion involving the PTEN gene region, two green and two orange signals appear.

Aberrant situation: In a cell with deletion affecting the PTEN gene region, a reduced number of green signals will be observed. Deletions affecting only parts of the PTEN gene region might result in normal signal pattern with green signals of reduced size.



Hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



Example of an aberrant signal pattern: Melanoma tissue section with chromosome 10 monosomy as indicated by one orange and one green signal in each nucleus.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	10	CE/IVD	5 (50 µl)	**Z-2078-50**
			20 (200 µl)	**Z-2078-200**

ZytoLight® SPEC FGFR2 Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC FGFR2 Dual Color Break Apart Probe (PL125) is intended to be used for the qualitative detection of translocations involving the human FGFR2 gene at 10q26.13 in formalin-fixed, paraffin-embedded specimens, such as intrahepatic cholangiosarcoma, by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the ZytoLight FISH-Tissue Implementation Kit (Prod. No. Z-2028-5/-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 intrahepatic cholangiosarcoma and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC FGFR2 Dual Color Break Apart Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 10q26.12-q26.13* (chr10:122,632,462-123,166,030) proximal to the FGFR2 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 10q26.13* (chr10:123,436,230-123,791,279) distal to the FGFR2 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

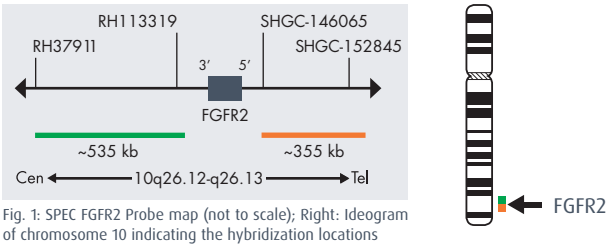
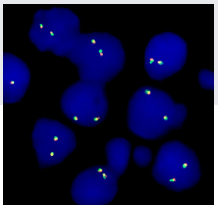


Fig. 1: SPEC FGFR2 Probe map (not to scale); Right: Ideogram of chromosome 10 indicating the hybridization locations

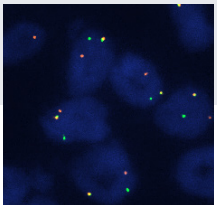
Results

Normal situation: In interphases of normal cells or cells without a translocation involving the FGFR2 gene region, two green/orange fusion signals appear.

Aberrant situation: One FGFR2 gene region affected by a translocation is indicated by one separate green signal and one separate orange signal.



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



Example of an aberrant signal pattern: Cholangiocellular adenocarcinoma tissue section with translocation of the FGFR2 gene as indicated by one non-rearranged orange/green fusion signal, one orange, and one separate green signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	10	CE/IVD	5 (50 µl)	**Z-2169-50**
			20 (200 µl)	**Z-2169-200**

Kindly provided by Prof. Dr. Büttner, Cologne, Germany.