ZytoLight® SPEC CBFB Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC CBFB Dual Color Break Apart Probe (PL165) is intended to be used for the qualitative detection of translocations involving the human CBFB gene at 16q22.1 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 CBFB Dual Color Break Apart Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10,0 ng/µl), which target sequences mapping in 16q22.1* (chr16:67,161,347-67,605,304) distal to the CBFB breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 16q22.1* (chr16:66,882,262-67,102,895) proximal to the CBFB breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

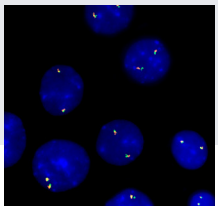
* according to Human Genome Assembly GRCh37/hg19

Fig. 1: SPEC CBFB Probe map (not to scale); Right: Ideogram of chromosome 16 indicating the hybridization locations

Results

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

Aberrant situation: One CBFB 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.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	16	CE/IVD	5 (50 µl)	**Z-2207-50**

ZytoLight® SPEC TP53/17q22 Dual Color Probe

Intended Purpose

The ZytoLight SPEC TP53/17q22 Dual Color Probe (PL156) is intended to be used for the qualitative detection of deletions involving the human TP53 gene as well as the detection of gains of chromosome 17q22 specific sequences in cytologic or formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with ZytoLight FISH Implementation Kits (Prod. No. Z-2028-5/-20, or 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 TP53/17q22 Dual Color Probe is composed of:

- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 17p13.1* (chr17:7,495,749-7,663,022) harboring the TP53 gene region (see Fig.1).
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10,0 ng/µl), which target sequences mapping in 17q22* (chr17:56,124,338-56,594,220) (see Fig.1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

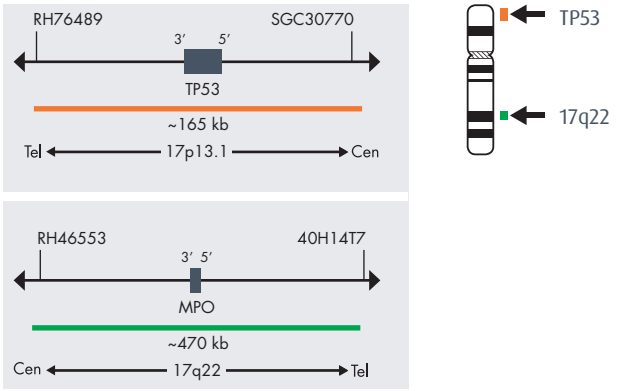
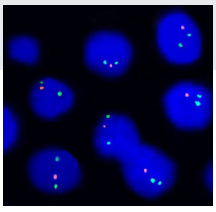


Fig. 1: Top: SPEC TP53 Probe map; Bottom: SPEC 17q22 Probe map (not to scale); Right: Ideogram of chromosome 17 indicating the hybridization locations

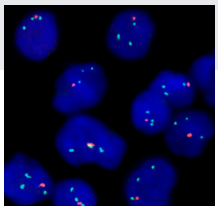
Results

Normal situation: In interphases of normal cells or cells without a deletion involving the TP53 gene region, two green and two orange signals appear.

Aberrant situation: In a cell with deletion affecting the TP53 gene region, a reduced number of orange signals will be detected. Deletions affecting only parts of the TP53 gene region might result in a normal signal pattern with orange signals of reduced size. A gain of 17q involving the 17q22 region will result in an increased number of green signals. Isochromosome 17q is indicated by three green signals and one orange signal.



Example of an aberrant signal pattern: SPEC TP53/17q22 Dual Color Probe hybridized to bone marrow tissue section with deletion of the TP53 gene as indicated by one orange signal and two green signals in each nucleus.



Example of an aberrant signal pattern: SPEC TP53/17q22 Dual Color Probe hybridized to a bone marrow smear with isochromosome 17q as indicated by three green signals and one orange signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	17	CE/IVD	5 (50 µl)	**Z-2198-50**