ZytoLight® SPEC ROS1/CEN 6 Dual Color Probe

Intended Purpose

The Zyto*Light* SPEC ROS1/CEN 6 Dual Color Probe (PL118) is intended to be used for the qualitative detection of amplifications involving the human ROS1 gene as well as the detection of chromosome 6 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 Zyto*Light* 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 Zyto*Light* SPEC ROS1/CEN 6 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 6q22.1* (chr6:117,431,278-117,894,830) harboring the ROS1 gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1,5 ng/µl), which target sequences mapping in 6p11.1-q11 specific for the alpha satellite centromeric region D6Z1 of chromosome 6.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

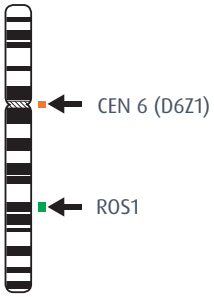
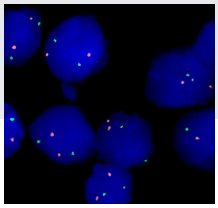


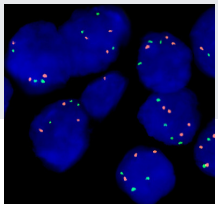
Fig. 1: SPEC ROS1 Probe map (not to scale); Right: Ideogram of chromosome 6 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the ROS1 gene region, two green and two orange signals appear.
Aberrant situation: In cells with an amplification of the ROS1 gene region, an increased number of green signals or green signal clusters will be observed.



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



Example of an aberrant signal pattern: Lung cancer tissue section with interphase cells showing a polysomy of chromosome 6 as indicated by multiple orange (CEN 6) and green (ROS1) signals in each nucleus.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	6	CE/IVD	20 (200 µl)	**Z-2162-50**

ZytoLight® SPEC MYB Dual Color Break Apart Probe

Intended Purpose

The Zyto*Light* SPEC MYB Dual Color Break Apart Probe (PL100) is intended to be used for the qualitative detection of translocations involving the human MYB gene at 6q23.3 in cytologic or formalin-fixed, paraffin-embedded specimens, such as adenoid cystic carcinoma (ACC), by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with Zyto*Light* 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 ACC and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The Zyto*Light* SPEC MYB 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 6q23.2-q23.3* (chr6:134,840,690-135,483,752) proximal to the MYB breakpoint region (see Fig.1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 6q23.3* (chr6:135,728,667-136,390.142) distal to the MYB breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

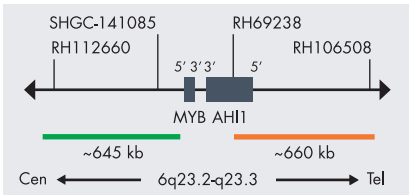
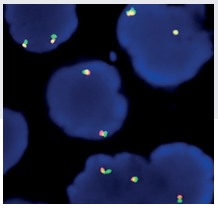


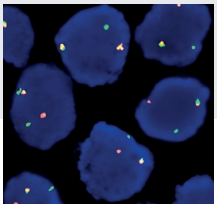
Fig. 1: SPEC MYB Probe map (not to scale);
Right: Ideogram of chromosome 6 indicating the hybridization locations

Results

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



Adenoid cystic carcinoma tissue section with translocation affecting the 6q23.3 locus as indicated by one orange/green fusion (non-rearranged) signal, one orange signal, and one separate green signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	6	CE/IVD	5 (50 µl)	**Z-2143-50**
			20 (200 µl)	**Z-2143-200**