ZytoLight® SPEC NECTIN4/1p12 Dual Color Probe

Intended Purpose

The ZytoLight SPEC NECTIN4/1p12 Dual Color Probe (PL291) is intended to be used for the qualitative detection of amplifications involving the human NECTIN4 gene as well as the detection of chromosome 1p12 specific sequences 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 NECTIN4/1p12 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 1q23.3* (Chr1:160,773,463-161,218,427) harboring the NECTIN4 gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 1p12* (Chr1:119,537,102-119,823,147) (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

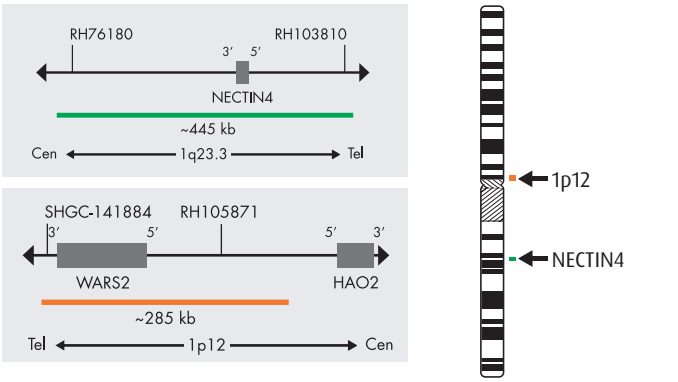
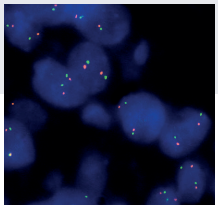


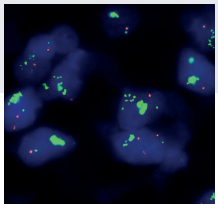
Fig. 1: Top: SPEC NECTIN4 Probe map; Bottom: SPEC 1p12 Probe map (not to scale); Right: Ideogram of chromosome 1 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the NECTIN4 gene region, two green signals and two orange signals appear.
Aberrant situation: In cells with an amplification of the NECTIN4 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: Hybridized to urothelial carcinoma tissue section with amplification of the NECTIN4 gene as indicated by green signal clusters.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	1	CE/IVD	5 (50 µl)	**Z-2331-50**
			20 (200 µl)	**Z-2331-200**

ZytoLight® SPEC ABL2 Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC ABL2 Dual Color Break Apart Probe (PL158) is intended to be used for the qualitative detection of translocations involving the human ABL2 gene at 1q25.2 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 ABL2 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 1q25.2* (chr1:179,141,608-179,659,091) distal to the ABL2 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 1q25.2* (chr1:178,496,704-179,015,312) proximal to the ABL2 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

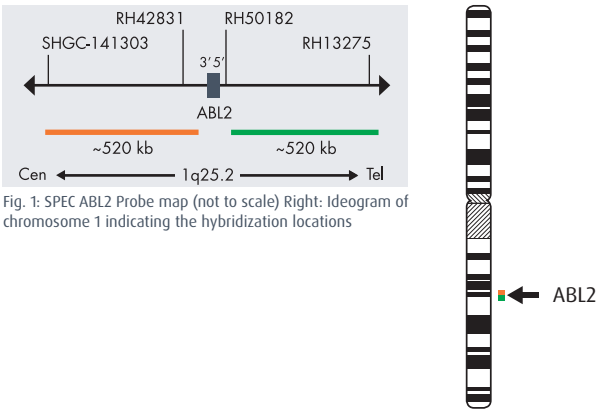
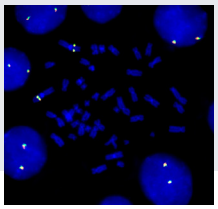


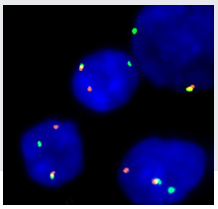
Fig. 1: SPEC ABL2 Probe map (not to scale) Right: Ideogram of chromosome 1 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without a translocation involving the ABL2 gene region, two green/orange fusion signals appear.
Aberrant situation: One ABL2 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 and to metaphase chromosomes of a normal cell.



Example of an aberrant signal pattern: Blood smear with translocation of the ABL2 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.
●|●	1	CE/IVD	5 (50 µl)	**Z-2200-50**