ZytoLight® SPEC ETV6 Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC ETV6 Dual Color Break Apart Probe (PL135) is intended to be used for the qualitative detection of translocations involving the human ETV6 gene at 12p13.2 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 ETV6 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 12p13.2* (chr12:12,054,737-12,634,328) proximal to the ETV6 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 12p13.2* (chr12:11,393,774-11,808,608) distal to the ETV6 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

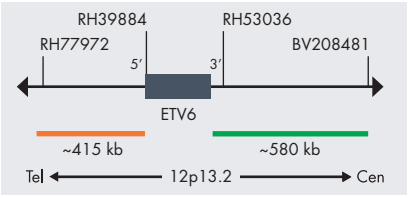
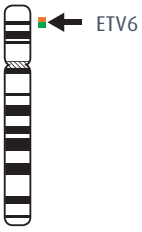


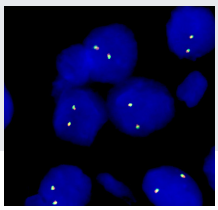
Fig. 1: SPEC ETV6 Probe map (not to scale)



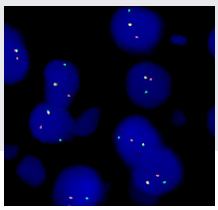
Ideogram of chromosome 12 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without a translocation involving the ETV6 gene region, two green/orange fusion signals appear.
Aberrant situation: One ETV6 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: MASC tissue section of the salivary glands with translocation of the ETV6 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.
●|●	12	CE/IVD	5 (50 µl)	**Z-2176-50**
			20 (200 µl)	**Z-2176-200**

ZytoLight® SPEC KRAS/CEN 12 Dual Color Probe

Intended Purpose

The ZytoLight SPEC KRAS/CEN 12 Dual Color Probe (PL72) is intended to be used for the qualitative detection of amplifications involving the human KRAS gene as well as chromosome 12 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 KRAS/CEN 12 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 12p12.1* (chr12:24,916,728-25,839,353) harboring the KRAS gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1,5 ng/µl), which target sequences mapping in 12p11.1-q11 specific for the alpha satellite centromeric region D12Z3 of chromosome 12.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

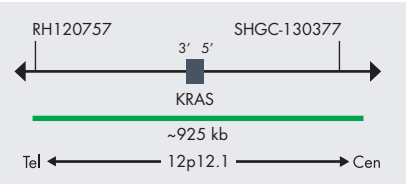
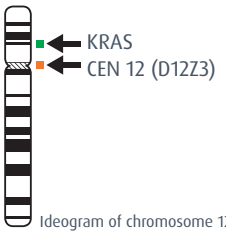


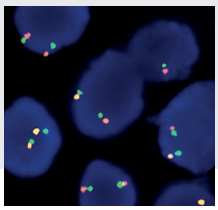
Fig. 1: SPEC KRAS Probe map (not to scale)



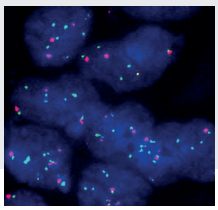
Ideogram of chromosome 12 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the KRAS gene region, two green and two orange signals appear.
Aberrant situation: In cells with an amplification of the KRAS 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 amplification of the KRAS gene (green).

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	12	CE/IVD	20 (200 µl)	**Z-2115-200**

Image kindly provided by Prof. Diebold, Lucerne, Switzerland.