ZytoLight® SPEC FGFR1 Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC FGFR1 Dual Color Break Apart Probe (PL124) is intended to be used for the qualitative detection of translocations involving the human FGFR1 gene at 8p11.22-p11.23 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.

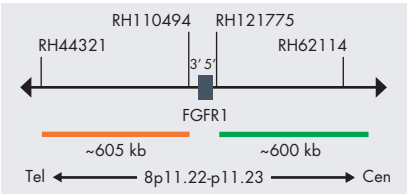
The probe is intended to be used as an aid to the differential diagnosis of various cancers and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC FGFR1 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 8p11.22* (chr8:38,352,117-38,951,783) proximal to the FGFR1 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 8p11.23* (chr8:37,635,912-38,239,669) distal to the FGFR1 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19



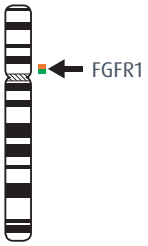
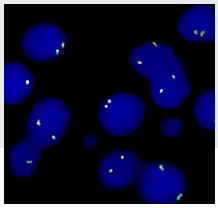


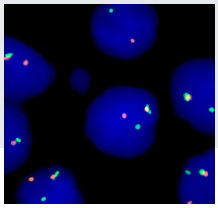
Fig. 1: SPEC FGFR1 Probe map (not to scale); Right: Ideogram of chromosome 8 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without a translocation involving the FGFR1 gene region, two green/orange fusion signals appear.
Aberrant situation: One FGFR1 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: 8p11 myeloproliferative syndrome (EMS) tissue section with translocation of the FGFR1 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.
●| ●	8	CE/IVD	5 (50 µl)	**Z-2168-50**
			20 (200 µl)	**Z-2168-200**

ZytoLight® SPEC FGFR1/CEN 8 Dual Color Probe

Intended Purpose

The ZytoLight SPEC FGFR1/CEN 8 Dual Color Probe (PL29) is intended to be used for the qualitative detection of amplifications involving the human FGFR1 gene as well as the detection of chromosome 8 alpha satellites in formalin-fixed, paraffin-embedded specimens, such as breast cancer and squamous cell lung cancer, 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.

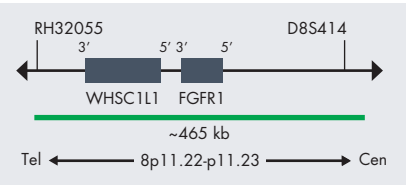
The probe is intended to be used as an aid to the differential diagnosis of breast cancer and squamous cell lung cancer and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC FGFR1/CEN 8 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 8p11.22-p11.23* (chr8:38,063,906-38,527,745) harboring the FGFR1 gene region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1.5 ng/µl), which target sequences mapping in 8p11.1-q11.1 specific for the alpha satellite centromeric region D8Z2 of chromosome 8.
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19



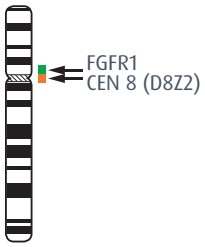
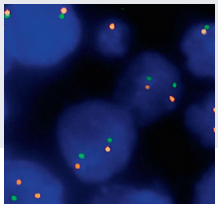


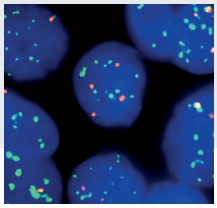
Fig. 1: SPEC FGFR1 Probe map (not to scale); Right: Ideogram of chromosome 8 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the FGFR1 gene region, two green signals and two orange signals appear.
Aberrant situation: In cells with an amplification of the FGFR1 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.



Lung carcinoma tissue section with interphase cells showing amplification of the FGFR1 gene (green) and partly polysomy 8 (orange).

Labels	Chromosome	Reg. Status	Tests	Order No.
●| ●	8	CE/IVD	5 (50 µl)	**Z-2072-50**
			20 (200 µl)	**Z-2072-200**