ZytoLight® SPEC FGFR1 Dual Color Break Apart Probe

CE IVD

Background

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).

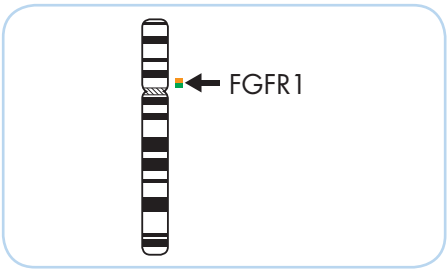
The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

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.

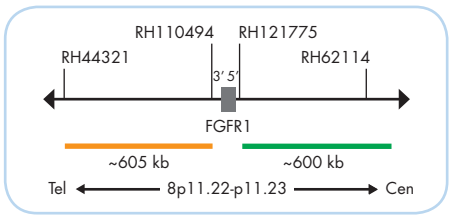
Probe Description

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.
- 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.
- Formamide based hybridization buffer



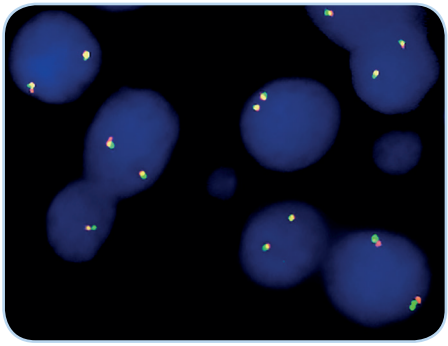
Ideogram of chromosome 8 indicating the hybridization locations.



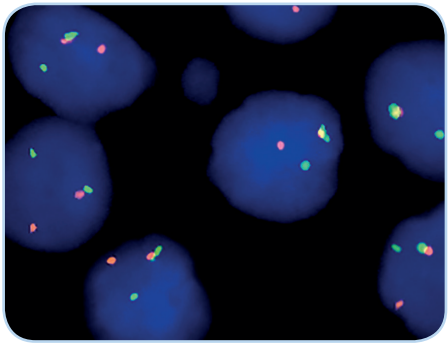
SPEC FGFR1 Probe map (not to scale).

Results

In an interphase nucleus of a normal cell lacking a translocation involving the 8p11.23-p11.22 band, two orange/green fusion signals are expected representing two normal (non-rearranged) 8p11.23-p11.22 loci. A signal pattern consisting of one orange/green fusion signal, one orange signal, and a separate green signal indicates one normal 8p11.23-p11.22 locus and one 8p11.23-p11.22 locus affected by a translocation.



SPEC FGFR1 Dual Color Break Apart Probe 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.

Prod. No.	Product	Label	Tests* (Volume)
Z-2168-50	ZytoLight SPEC FGFR1 Dual Color Break Apart Probe CE IVD	●/●	5 (50 µl)
Z-2168-200	ZytoLight SPEC FGFR1 Dual Color Break Apart Probe CE IVD	●/●	20 (200 µl)
Related Products			
Z-2099-20	ZytoLight FISH-Cytology Implementation Kit CE IVD Incl. Cytology Pepsin Solution, 4 ml; 20x Wash Buffer TBS, 50 ml; 10x $MgCl_2$, 50 ml; 10x PBS, 50 ml; Cytology Stringency Wash Buffer SSC, 500 ml; Cytology Wash Buffer SSC, 500 ml; DAPI/DuraTect-Solution, 0.8 ml		20

** Using 10 µl probe solution per test. IVD labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

***According to Human Genome Assembly GRCh37/hg19*