ZytoLight® SPEC FGFR3/4p11 Dual Color Probe

Background

The ZytoLight[®] SPEC FGFR3/4p11 Dual Color Probe (PL41) is intended to be used for the qualitative detection of amplifications involving the human FGFR3 gene as well as the detection of chromosome 4p11 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 Zyto*Light* [®] SPEC FGFR3/4p11 Dual Color Probe is composed of:

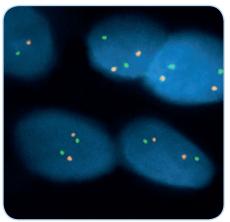
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 4p16.3** (chr4:1,531,083-2,073,649) harboring the FGFR3 gene region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 4p11** (chr4:48,329,914-48,762,386).
- · Formamide based hybridization buffer

FGFR3 4p11 Ideogram of chromosome 4 indicating the hybridization locations. D4S865 D4S2774E 5' 3 FGFR3 ~545 kb Tel 🖌 4p16.3 Cen SPEC FGFR3 Probe map (not to scale). RH67343 RH82989 5'3' ZAR1 ~435 kb Tel **-** 4p11 Cen

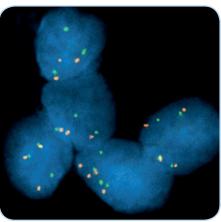
SPEC 4p11 Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. In a cell with amplification of the FGFR3 gene locus, multiple copies of the green signal or large green signal clusters will be observed.



SPEC FGFR3/4p11 Dual Color Probe hybridized to normal interphase cells as indicated by two orange and two green signals in each nucleus.



Example of an aberrant signal pattern: Bladder cancer tissue section with interphase cells showing polysomy of chromosome 4 as indicated by multiple green and orange signals in the nuclei.

Prod. No.	Product	Label	Tests* (Volume)
Z-2082-200	Zyto <i>Light</i> SPEC FGFR3/4p11 Dual Color Probe ⊂ € IVD	•/•	20 (200 µl)
Related Pro	lucts		
Z-2028-20	Zyto <i>Light</i> FISH-Tissue Implementation Kit C E ඟ Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraTect-Solution, 0.8 ml		20
0 1 1	on 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. mome Assembly GRCh37/hg19	771	

52

52

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