ZytoLight® SPEC FGFR2/CEN 10 Dual Color Probe

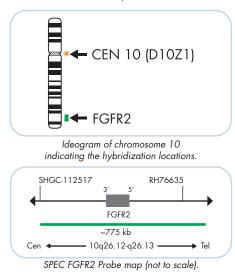
Background

The ZytoLight ® SPEC FGFR2/CEN 10 Dual Color Probe (PL79) is intended to be used for the qualitative detection of amplifications involving the human FGFR2 gene as well as chromosome 10 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 gualified 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 FGFR2/CEN 10 Dual Color Probe is composed of:

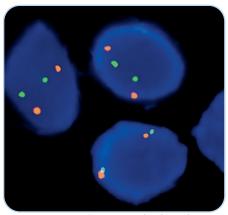
- · ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 10q26.12-q26.13** (chr10:122,908,224-123,682,373) harboring the FGFR2 gene region.
- · ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1.5 ng/µl), which target sequences mapping in 10p11.1-q11.1 specific for the alpha satellite centromeric region D10Z1 of chromosome 10.
- · Formamide based hybridization buffer



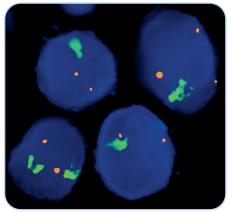
Results

In a normal interphase nucleus, two orange and two green signals are expected. Nuclei with amplification of the FGFR2 gene locus 10q26.12-q26.13, or aneuploidy of chromosome 10 will show multiple copies of the green signal or large green signal clusters.

IVD



SPEC FGFR2/CEN 10 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: Breast cancer tissue section with amplification of the FGFR2 gene as indicated by green signal clusters in each nucleus.

Prod. No.	Product	Label	Tests* (Volume)
Z-2122-200	Zyto <i>Light</i> SPEC FGFR2/CEN 10 Dual Color Probe ⊂ € 0124 IVD	•/•	20 (200 µl)
Related Pro	ducts		
Z-2028-20	Zyto <i>Light</i> FISH-Tissue Implementation Kit C E 👓 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
**According to Human (tion per test. VD labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information. enome Assembly GRCh37/hg19	ZYT	OVISION ar diagnostics simplified

FE046-1-25