

ZytoLight® SPEC PIK3CA/CEN 3 Dual Color Probe



Background

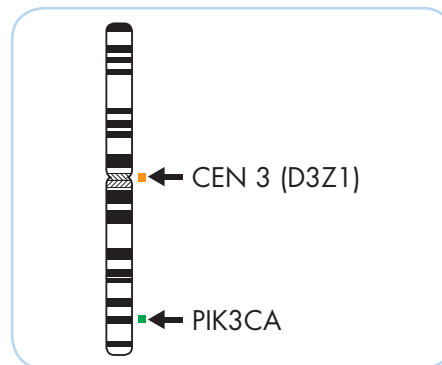
The ZytoLight® SPEC PIK3CA/CEN 3 Dual Color Probe (PL97) is intended to be used for the qualitative detection of PIK3CA gene amplifications as well as the detection of chromosome 3 alpha satellites in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe 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.

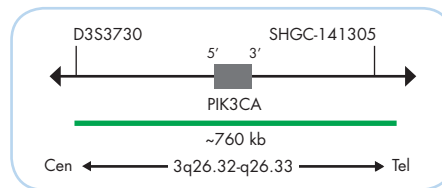
Probe Description

The ZytoLight® SPEC PIK3CA/CEN 3 Dual Color Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/μl), which target sequences mapping in 3q26.32-q26.33** (chr3:178,535,986-179,293,464) harboring the PIK3CA gene region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~1.5 ng/μl), which target sequences mapping in 3p11.1-q11.1 specific for the alpha satellite centromeric region D3Z1 of chromosome 3.
- Formamide based hybridization buffer



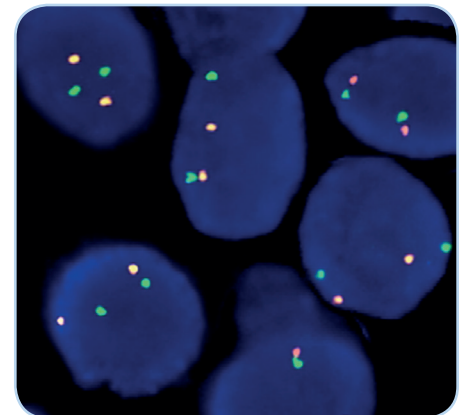
Ideogram of chromosome 3 indicating the hybridization locations.



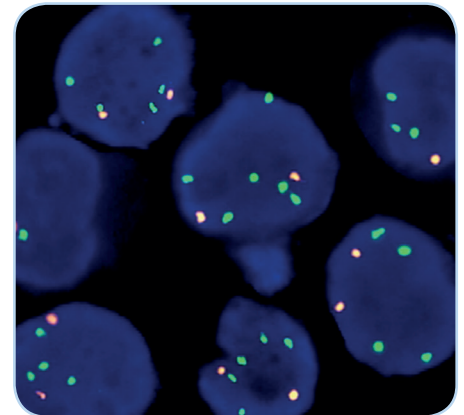
SPEC PIK3CA Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. Nuclei with amplification of the PIK3CA gene locus 3q26.32-q26.33 or aneuploidy of chromosome 3 will show multiple copies of the green signal or large green signal clusters.



SPEC PIK3CA/CEN 3 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: Human breast cancer cell line with amplification of the PIK3CA gene as indicated by multiple green signals in each nucleus.

Prod. No.	Product	Label	Tests* (Volume)
Z-2140-200	ZytoLight SPEC PIK3CA/CEN 3 Dual Color Probe CE IVD	●/●	20 (200 μl)
Related Products			
Z-2028-20	ZytoLight FISH-Tissue Implementation Kit CE IVD		20
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			

* 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