

ZytoLight® SPEC ERBB2/TOP2A/CEN 17 Triple Color Probe



Background

The ZytoLight® SPEC ERBB2/TOP2A/CEN 17 Triple Color Probe (PL52) is intended to be used for the qualitative detection of amplifications involving the human ERBB2 gene and the human TOP2A gene as well as the detection of chromosome 17 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.

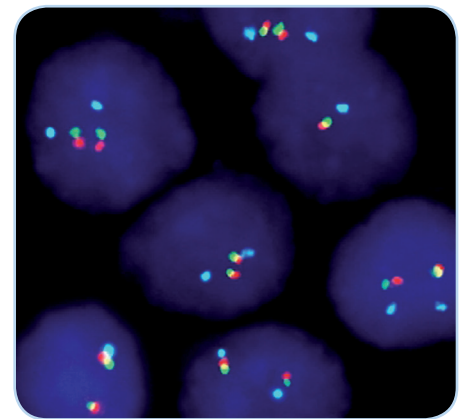
Probe Description

The ZytoLight® SPEC ERBB2/TOP2A/CEN 17 Triple Color Probe is composed of:

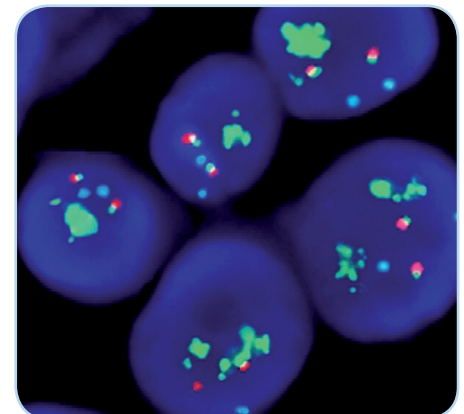
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 17q12-q21.1** (chr17:37,572,531-38,181,308) harboring the ERBB2 gene region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4.5 ng/µl), which target sequences mapping in 17q21.1-q21.2** (chr17:38,323,741-38,818,030) harboring the TOP2A gene region.
- ZyBlue (excitation at 418 nm/emission 467 nm) labeled polynucleotides (~12 ng/µl), which target sequences mapping in 17p11.1-q11.1 specific for the alpha satellite centromeric region D17Z1 of chromosome 17.
- Formamide based hybridization buffer

Results

In a normal interphase nucleus, two green, two orange, and two blue signals are expected. In a cell with amplification of the ERBB2 gene locus, multiple copies of the green signal or large green signal clusters will be observed. Amplification of TOP2A will result in multiple copies of the orange signal or large orange signal clusters. Deletion of the TOP2A gene results in a reduced number of orange signals.



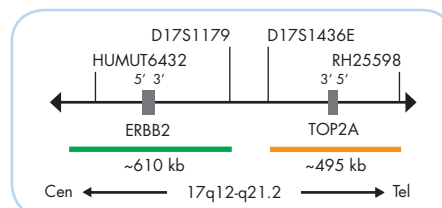
SPEC ERBB2/TOP2A/CEN 17 Triple Color Probe hybridized to normal interphase cells as indicated by two green, two orange, and two blue signals per nucleus.



Example of an aberrant signal pattern: Breast cancer tissue section with two copies of chromosome 17 (blue) and TOP2A (orange) and ERBB2 gene clusters (green) in each nucleus.



Ideogram of chromosome 17 indicating the hybridization locations.



SPEC ERBB2/TOP2A Probe map (not to scale).

Prod. No.	Product	Label	Tests* (Volume)
Z-2093-50	ZytoLight SPEC ERBB2/TOP2A/CEN 17 Triple Color Probe CE 0124 IVD	●/●/●	5 (50 µl)
Z-2093-200	ZytoLight SPEC ERBB2/TOP2A/CEN 17 Triple Color Probe CE 0124 IVD	●/●/●	20 (200 µl)
Related Products			
Z-2028-5	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTect-Solution, 0.2 ml		5
Z-2028-20	ZytoLight FISH-Tissue Implementation Kit CE IVD 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

* 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