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

Intended Purpose

The Zyto*Light* 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 Zyto*Light* 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 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 (see Fig. 1).
- 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 (see Fig. 1).
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides (~12.0 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

* according to Human Genome Assembly GRCh37/hg19

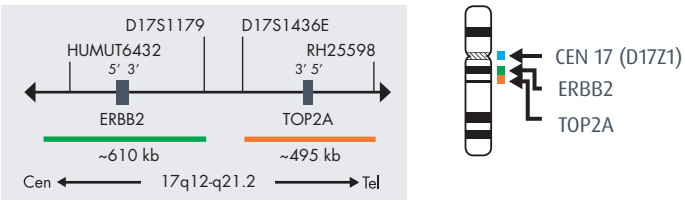
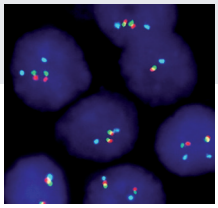


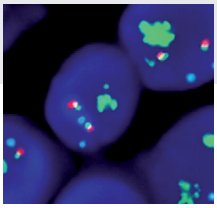
Fig. 1: SPEC ERBB2/TOP2A Probe map (not to scale); Right: Ideogram of chromosome 17 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without an amplification involving the respective gene regions, two green, two orange and two blue signals appear.
Aberrant situation: In cells with an amplification of the ERBB2 gene region an increased number of green signals or green signal clusters will be observed. In cells with an amplification of the TOP2A gene region an increased number of orange signals or orange signal clusters will be observed. Deletions affecting the TOP2A gene region result in a reduced number of orange signals.



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.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●|●	17	CE/IVD	5 (50 µl)	**Z-2093-50**
			20 (200 µl)	**Z-2093-200**

ZytoLight® SPEC COL1A1 Dual Color Break Apart Probe

Intended Purpose

The Zyto*Light* SPEC COL1A1 Dual Color Break Apart Probe (PL78) is intended to be used for the qualitative detection of translocations involving the human COL1A1 gene at 17q21.33 in formalin-fixed, paraffin-embedded specimens by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the Zyto*Light* 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 COL1A1 Dual Color Break Apart Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10 ng/µl), which target sequences mapping in 17q21.33* (chr17:47,669,218-48,223,465) distal to the COL1A1 breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/µl), which target sequences mapping in 17q21.33* (chr17:48,347,800-48,744,021) distal to the COL1A1 breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

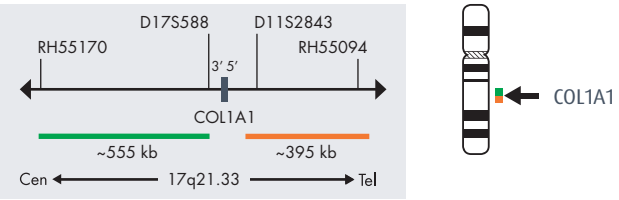
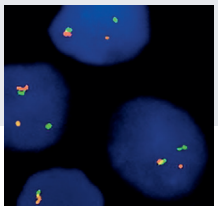


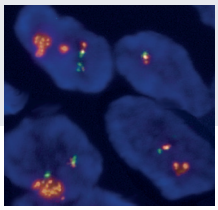
Fig. 1: SPEC COL1A1 Probe map (not to scale); Right: Ideogram of chromosome 17 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without a translocation involving the COL1A1 gene region, two green/orange fusion signals appear.
Aberrant situation: One COL1A1 gene region affected by a translocation is indicated by one separate green signal and one separate orange signal.



Example of an aberrant signal pattern: DFSP tissue section with translocation affecting the 17q21.33 locus as indicated by one non-rearranged orange/green fusion signal, one orange signal, and one separate green signal.



Example of an aberrant signal pattern: DFSP tissue section with amplification of the 17q21-qter and 22q10–q13.1 sequences probably due to a COL1A1-PDGFB fusion product on the ring chromosome.

Labels	Chromosome	Reg. Status	Tests	Order No.
●|●	17	CE/IVD	20 (200 µl)	**Z-2121-200**

Image kindly provided by Dr. Schildhaus, Essen, Germany.