

ZytoLight® SPEC YWHAE Dual Color Break Apart Probe

Intended Purpose

The ZytoLight SPEC YWHAE Dual Color Break Apart Probe (PL134) is intended to be used for the qualitative detection of translocations involving the human YWHAE gene at 17p13.3 in formalin-fixed, paraffin-embedded specimens, such as endometrial stromal sarcoma (ESS), 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 ESS and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC YWHAE 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 17p13.3* (chr17:1,339,752-1,716,668) proximal to the YWHAE breakpoint region (see Fig. 1).
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~4,5 ng/μl), which target sequences mapping in 17p13.3* (chr17:791,171-1,124,746) distal to the YWHAE breakpoint region (see Fig. 1).
- Formamide based hybridization buffer

* according to Human Genome Assembly GRCh37/hg19

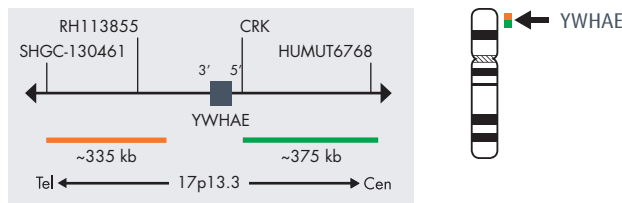
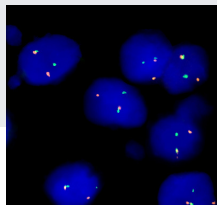


Fig. 1: SPEC YWHAE Probe map (not to scale); Right: Ideogram of chromosome 17 indicating the hybridization locations

Results

Normal situation: In interphases of normal cells or cells without a translocation involving the YWHAE gene region, two green/orange fusion signals appear.

Aberrant situation: One YWHAE gene region affected by a translocation is indicated by one separate green signal and one separate orange signal.



Endometrial stromal sarcoma tissue section with translocation affecting the YWHAE gene as indicated by one non-rearranged orange/green fusion signal, one orange, and one separate green signal.

Labels	Chromosome	Reg. Status	Tests	Order No.
	17	CE/IVD	5 (50 μl)	Z-2175-50

ZytoLight® SPEC ERBB2/CEN 17 Dual Color Probe

Intended Purpose

The ZytoLight SPEC ERBB2/CEN 17 Dual Color Probe (PL8) is intended to be used for the qualitative detection of amplifications involving the human ERBB2 gene as well as the detection of chromosome 17 alpha satellites in formalin-fixed, paraffin-embedded specimens, such as breast cancer and gastric/gastroesophageal junction cancer, 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 breast cancer and gastric/gastroesophageal junction cancer and therapeutic measures should not be initiated based on the test result alone.

Probe Description

The ZytoLight SPEC ERBB2/CEN 17 Dual 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 (~1.5 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

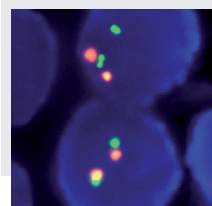


Fig. 1: SPEC ERBB2 Probe map (not to scale); Right: Ideogram of chromosome 17 indicating the hybridization locations

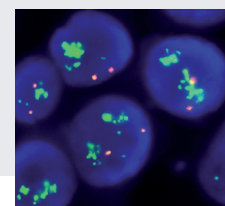
Results

Normal situation: In interphases of normal cells or cells without an amplification involving the ERBB2 gene region, two green signals and two orange 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.



Normal interphase cells, ERBB2 (green), CEN 17 (orange).



Breast carcinoma tissue section, ERBB2 gene cluster (green), CEN 17 (orange).

Labels	Chromosome	Reg. Status	Tests	Order No.
	17	CE/IVD	5 (50 μl)	Z-2015-50
			20 (200 μl)	Z-2015-200

The product is also available as a kit in two different sizes.

ZytoLight SPEC ERBB2/CEN 17 Dual Color Probe Kit	Tests	Order No.
Incl: Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; Wash Buffer SSC, 210 ml; Probe, 0.05 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTect-Solution, 0.2 ml	5	Z-2020-5
Incl: Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; Wash Buffer SSC, 560 ml; Probe, 0.2 ml; 25x Wash Buffer A, 100 ml; DAPI/DuraTect-Solution, 0.8 ml	20	Z-2020-20