

ZytoMation® ERBB2/CEN 17 Dual Color FISH Probe



Background

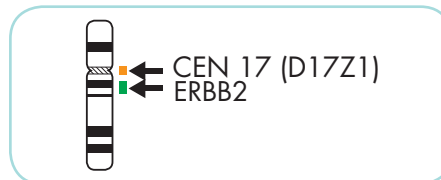
The ZytoMation® ERBB2/CEN 17 Dual Color FISH Probe (PL246) is intended to be used for the qualitative detection of amplifications involving the human ERBB2 gene as well as the detection of chromosome 17 alpha satellites in formalin-fixed, paraffin-embedded specimens, such as breast cancer and gastric/gastroesophageal junction cancer, by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the Bond FISH Kit (DS9636) on the automated Bond-MAX or Bond III system by Leica Biosystems.

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.

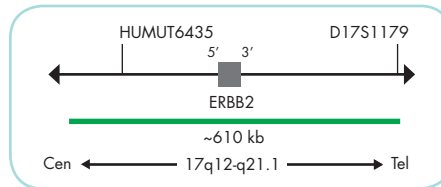
Probe Description

The ZytoMation® ERBB2/CEN 17 Dual Color FISH Probe is composed of:

- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~5.0 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 (~0.2 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



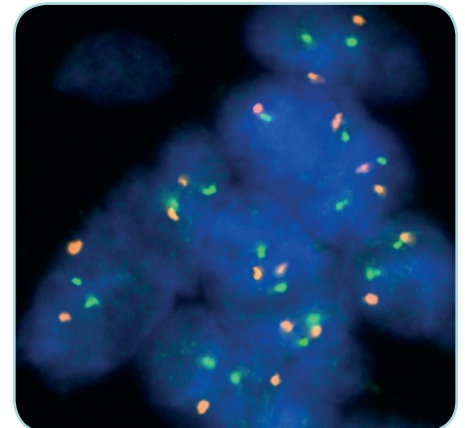
Ideogram of chromosome 17 indicating the hybridization locations.



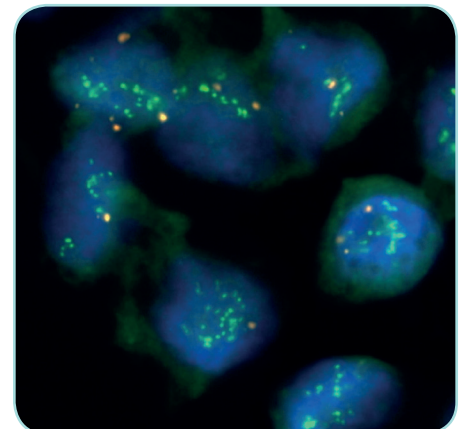
ERBB2 Probe map (not to scale).

Results

In a normal interphase nucleus, two orange and two green signals are expected. In a cell with amplification of the ERBB2 gene locus, multiple copies of the green signal or green signal clusters will be observed.



ERBB2/CEN 17 Dual Color FISH Probe hybridized to normal interphase cells as indicated by two green and two orange signals in each nucleus.



Breast cancer tissue section with amplification of the ERBB2 gene locus as indicated by multiple copies of the green signal in each nucleus.

Prod. No. Product

Z-2292-5.1ML ZytoMation ERBB2/CEN 17 Dual Color FISH Probe CE IVD

Label Tests* (Volume)

●/● up to 20 (5.1 ml)

* Using 240 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