

ZytoDot® SPEC ERBB2 Probe



Background

The ZytoDot® SPEC ERBB2 Probe (PD1) is intended to be used for the qualitative detection of amplifications involving the human ERBB2 gene in formalin-fixed, paraffin-embedded specimens, such as breast cancer, by chromogenic *in situ* hybridization (CISH). The probe is intended to be used in combination with the ZytoDot® CISH Implementation Kit (Prod. No. C-3018-40).

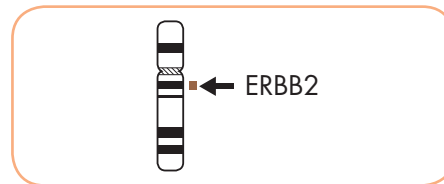
The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

The probe is intended to be used as an aid to the differential diagnosis of breast cancer and therapeutic measures should not be initiated based on the test result alone.

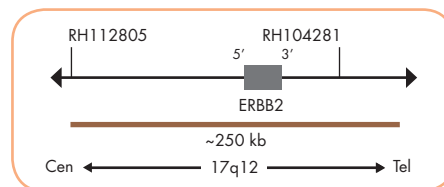
Probe Description

The ZytoDot® SPEC ERBB2 Probe is composed of:

- Digoxigenin-labeled polynucleotides (~1.8 ng/μl), which target sequences mapping in 17q12** (chr17:37,725,661-37,973,541) harboring the ERBB2 gene region.
- Formamide based hybridization buffer



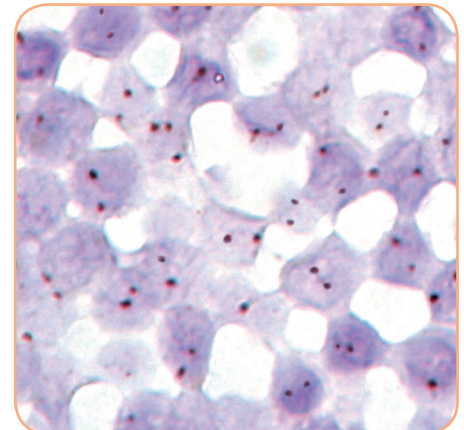
Ideogram of chromosome 17 indicating the hybridization locations.



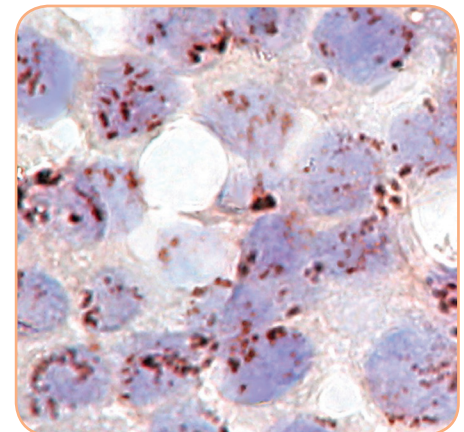
SPEC ERBB2 Probe map (not to scale).

Results

In normal cells, two distinct dot-shaped signals per nucleus will be observed. Nuclei with amplification of the ERBB2 gene locus or polysomy of chromosome 17 will show multiple dots or large signal clusters.



Normal nuclei each with two ERBB2 signals.



Breast cancer tissue section with ERBB2 amplification.

Prod. No.	Product	Label	Tests* (Volume)
C-3001-400	ZytoDot SPEC ERBB2 Probe CE 0124 IVD	DIG	40 (400 μl)
C-3003-40	ZytoDot SPEC ERBB2 Probe Kit CE 0124 IVD	DIG	40

Incl. Heat Pretreatment Solution EDTA, 500 ml; Pepsin Solution, 4 ml; Probe, 0.4 ml; Wash Buffer SSC, 560 ml; PBS/Tween, good for 2000 ml; Blocking Solution, 4 ml; Mouse-anti-DIG, 4 ml; Anti-Mouse-HRP-Polymer, 4 ml; DAB Solution A, 0.3 ml; DAB Solution B, 10 ml; Mayer's Hematoxylin Solution, 20 ml; Mounting Solution (alcoholic), 4 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