ZytoLight® SPEC ERBB2/D17S122 Dual Color Probe

CE IVD

Background

The ZytoLight® SPEC ERBB2/D17S122 Dual Color Probe is designed for the detection of ERBB2 gene amplification frequently observed in solid malignant neoplasms e.g. breast cancer samples.
The ERBB2 gene (a.k.a. HER2 and NEU) is located in the chromosomal region 17q12 and encodes a 185-190 kDa transmembrane glycoprotein, p185, acting as a cellular growth factor receptor. The p185 protein belongs to the EGFR (epidermal growth factor receptor) subgroup of the RTK (receptor tyrosine kinase) superfamily also including ERBB1 (HER1), ERBB3 (HER3), and ERBB4 (HER4).
Amplification of the proto-oncogene ERBB2, observed in approximately 20% of all breast cancer samples, has been correlated with a poor prognosis of the disease.
Similar results have been obtained for a variety of other malignant neoplasms e.g. ovarian cancer, stomach cancer, and carcinomas of the salivary gland.
Fluorescence *in situ* Hybridization targeting the alpha satellite centromeric regions of chromosome 17 may be misleading in some cases due to possible gains or losses of this region. For these cases, judged as equivocal according to the ASCO guidelines, reflex testing is recommended using the SPEC ERBB2/D17S122 Dual Color Probe.

References
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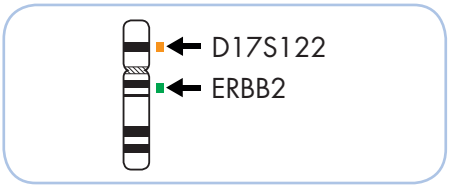
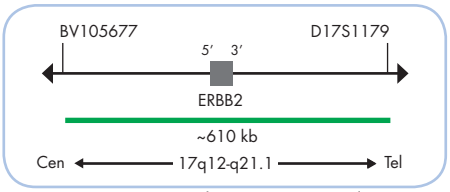
Probe Description

The SPEC ERBB2/D17S122 Dual Color Probe is a mixture of a green fluorochrome direct labeled SPEC ERBB2 probe specific for the chromosomal region 17q12-q21.1 harboring the ERBB2 gene and an orange fluorochrome direct labeled SPEC D17S122 probe specific for the chromosomal region 17p12. The SPEC D17S122 probe is designed to be used for chromosome 17 copy number detection.



Ideogram of chromosome 17 indicating the hybridization locations.

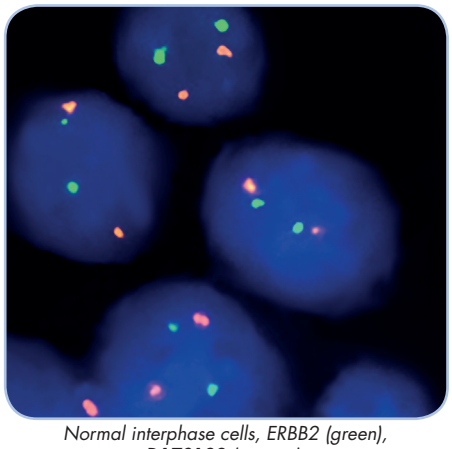


SPEC ERBB2 Probe map (not to scale).

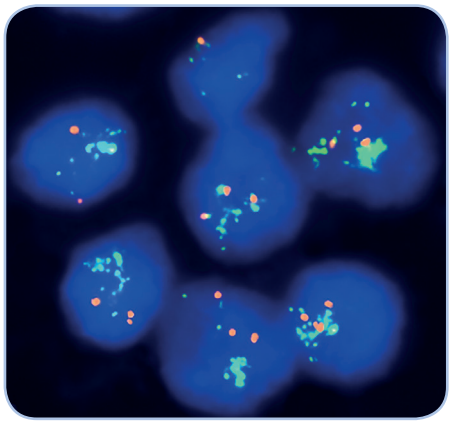
SPEC D17S122 Probe map (not to scale).

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.



Normal interphase cells, ERBB2 (green), D17S122 (orange).



Breast carcinoma tissue section, ERBB2 gene cluster (green), D17S122 (orange).

Prod. No.	Product	Label	Tests* (Volume)
Z-2190-50	ZytoLight SPEC ERBB2/D17S122 Dual Color Probe CE IVD	●/●	5 (50 µl)
Related Products			
Z-2028-5	ZytoLight FISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1ml; Wash Buffer SSC, 150 ml; 25x Wash Buffer A, 50 ml; DAPI/DuraTect-Solution, 0.2 ml		5

** Using 10 µl probe solution per test. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more information.*

FE091-1-16

ZytoLight® FISH probes are direct labeled using the unique ZytoLight® *Direct Label System II* providing improved signal intensity. Advanced specificity of the single copy SPEC probes is obtained by the unique ZytoVision® *Repeat Subtraction Technique.*

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