ITALIA

Empowering Personalized Cancer Treatment

ERBB2/Cen17 DNA-FISH Probe

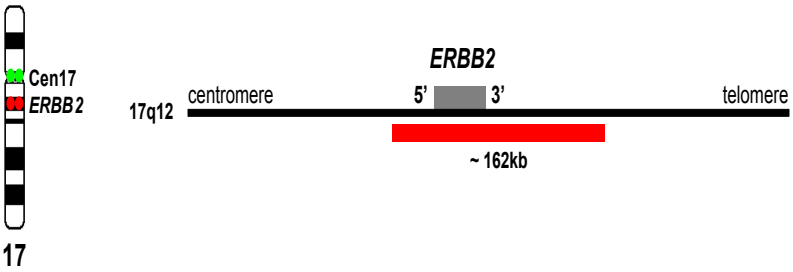
Two Color, Enumeration Probe CE

Ref: 22-003

ERBB2/ Cen17

Intended Use

The *ERBB2*/Cen17 DNA-FISH Probe is designed to detect the amplification of the *ERBB2* gene (also named *HER2/neu*) on chromosome 17q12 relative to the control Cen17 using fluorescence *in situ* hybridization (FISH) in formalin-fixed, paraffin-embedded (FFPE) breast cancer tissues. Overexpression of the *ERBB2* gene occurs in 25-30% of human breast carcinomas, and ~90-95% of these cases result directly from gene amplification.[1] Patients showing such an amplification are at high-risk for relapse and lower overall survival.[1-3] Amplification of the *ERBB2* gene predicts a favorable response to certain chemotherapy regimens and selective monoclonal antibody therapy with trastuzumab.[1-5] *ERBB2* amplification is also seen in other solid tumors such as gastric, esophageal, gynecologic, bladder, and non-small cell lung cancer and correlates with a poor prognosis.[6]



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Schematic of the *ERBB2*/Cen17 DNA-FISH Probe:

The horizontal red bar indicates the region covered by the probe (approximate to scale, NCBI Build 36.1/ Hg18/2006). The ideogram of chromosome 17 illustrates the respective locations of the hybridizations. The directly labeled Cen17 probe (green) hybridizes to the satellite DNA at 17p11.1-q11. The directly labeled *ERBB2* probe (red) spans the entire gene as indicated on the above schematic.

Signal Interpretation

In normal diploid metaphase chromosomes and interphase nuclei the probes generate two green and two red signals corresponding to the two normal homologous chromosomes 17 (Figure 1). In cells with amplification or copy number increases, the number of red (*ERBB2*) signals is increased relative to the number of green (Cen17) signals (Figure 2). Amplification may also be present in the form of an hsr (homogenously staining region), observed as a brightly fluorescing mass of red signals. An *ERBB2*:Cen17 ratio with a value of 2.2 or more is defined as amplification; ratios with a value between 1.8 and 2.2 are considered borderline and should be subjected to discussion between the pathologist and the clinician.[6]

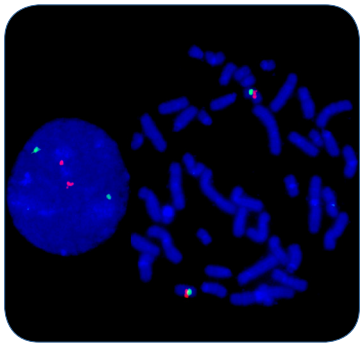

Figure 1: Normal diploid metaphase and interphase nucleus with 2 red (*ERBB2*) and 2 green (Cen17) signals.

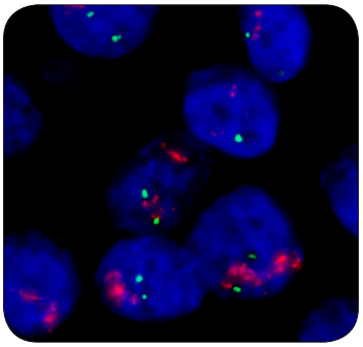

Figure 2: Interphase nuclei (from paraffin section) with green (Cen17) signals along with 5-6 red (*ERBB2*) signals and hsr signal pattern of red (*ERBB2*).

References

1. Pauletti, G., et al. J Clin Oncol, 2000. 18(21):3651-64.
2. Harries, M., et al. Endocr Relat Cancer, 2002. 9(2):75-85.
3. Kallioniemi, O. P., et al. Proc Natl Acad Sci USA, 1992. 89(12):5321-5.
4. Slamon, D. J., et al. Science, 1987. 235(4785):177-82.
5. Wolff, et al. J Clin Oncol, 2007. (1):118-145.
6. Mano, M. S., et al. Cancer Treat Rev, 2007. 33(1):64-77.

Fluorescence Microscopy Filter Requirements

Fluorophore	Excitation $_{max}$	Emission $_{max}$
Green	496 nm	520 nm
Red	580 nm	603 nm
DAPI	360 nm	460 nm

Instructions for use are available at www.cancergeneticsitalia.com

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