ITALIA

Empowering Personalized Cancer Treatment

TP53/RARA DNA-FISH Probe

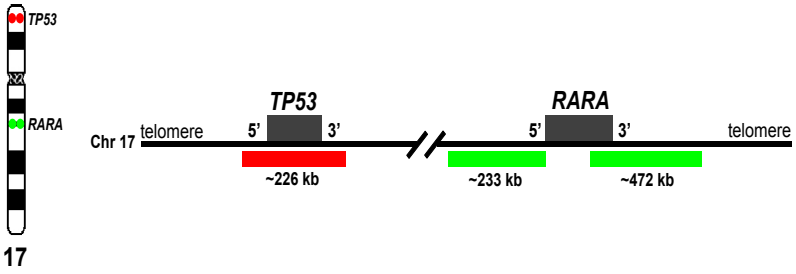
Two Color, Enumeration Probe CE

Ref: 14-015

TP53/RARA

Intended Use

The *TP53/RARA* DNA-FISH Probe is designed to detect the deletion of the *TP53* gene located on 17p13, relative to the control marker gene *RARA* located on 17q21, using fluorescence *in situ* hybridization (FISH). The *TP53* gene is a known tumor suppressor gene and is frequently deleted in a wide variety of solid tumors [1, 2] and hematologic malignancies such as mature B-cell neoplasms,[3] myeloid disorders such as acute myeloid leukemia (AML),[4] and myelodysplastic syndrome (MDS).[5] Deletion of the *TP53* gene has been associated with advanced stage, shortened survival, and resistance to treatment in several malignancies and solid tumors.[3,6] The loss of *TP53* is also found in chronic lymphocytic leukemia (CLL) cases and is associated with a very poor clinical outcome.[7,8]



Schematic of the *TP53/RARA* DNA-FISH Probe:

Horizontal red and green bars indicate the region covered by the probes (approximate to scale, NCBI 36.1/HG18/2006). The directly labeled *TP53* probe (red) spans the entire gene while the directly labeled *RARA* probe (green) hybridizes to the regions surrounding the *RARA* gene and serves as the control.

Signal Interpretation

In normal diploid interphase nuclei and metaphase chromosomes, the probe generates two red and two green signals corresponding to the two normal homologous chromosomes 17 (Figure 1). In cells with deletion of an entire chromosome 17, the number of red (*TP53*) and green (*RARA*) signals will decrease. In cells with interstitial deletion of chromosome 17, in which the *TP53* gene is deleted and the *RARA* gene is retained, one red (*TP53*) and two green (*RARA*) signals will be observed (Figures 2 and 3). If unexpected signal patterns are observed, hybridization to metaphase chromosomes is recommended.

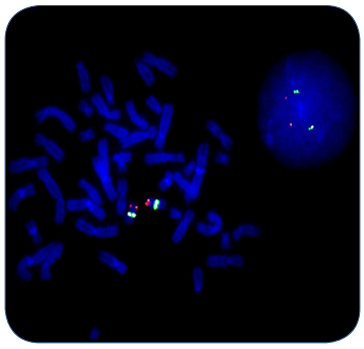


Figure 1: Normal diploid metaphase and interphase nucleus (from normal peripheral blood specimen) with 2 red (*TP53*) and 2 green (*RARA*) signals.

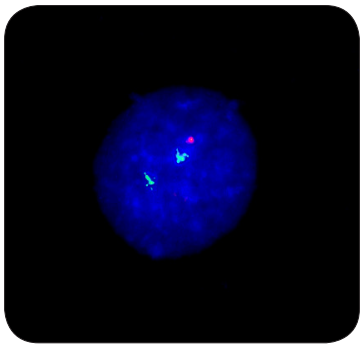


Figure 2: Interphase nuclei with 1 red (*TP53*) and 2 green (*RARA*) signals.

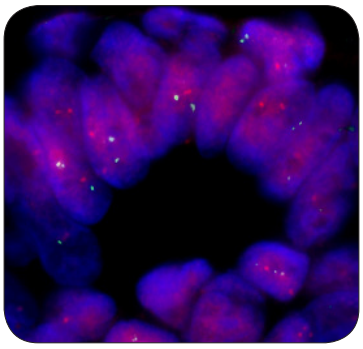


Figure 3: FFPE section, positive for *TP53* deletion, with 1 red (*TP53*) and 2 green (*RARA*) signals.

References

1. Bertheau, P., et al. Pathobiology (Review), 2008. 75(2):132-9.
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4. Seifert, H., et al. Leukemia, 2009. 23(4): 656-63.
5. Silveira, C. G., et al., Leuk Res, 2009. 33(1):19-27.
6. Hof, J., et al. J Clin Oncol. 29(23): 3185-93.
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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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IVD/14-015, v.07.19.12