ALK Break Apart DNA-FISH Probe

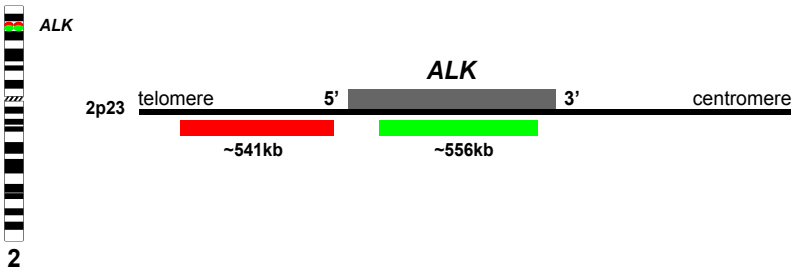
Two Color, Break Apart Probe CE

Ref: 21-002

ALK Break Apart

Intended Use

The *ALK* Break Apart DNA-FISH Probe is designed to detect the translocation between the *ALK* gene located at 2p23 and one of at least 14 known translocation partner loci using fluorescence *in situ* hybridization (FISH).[1] Translocation of the *ALK* gene occurs in ~50% of anaplastic large cell lymphoma (ALCL) cases with a form of t(2;5)(p23;q35), as determined by conventional cytogenetics; in such cases, the presence of the t(2;5)(p23;q35) form carries a better overall prognosis for ALCL patients.[2] *ALK* translocation has been observed in vesical inflammatory myofibroblastic tumors (IMT) of the bladder (>66%)[3] and serves as a diagnostic biomarker for differential diagnosis of IMT from sarcomatous lesions.[3] *ALK* translocation is observed in ~5% - 16% of non-small cell lung cancer (NSCLC) cases in the form of inv(2)(p21p23), as determined by FISH,[4] and serves as a biomarker for therapy response.[4,5] The presence of the *ALK* translocation in NSCLC patients is correlated with a marked sensitivity to pemetrexed and crizotinib treatment.[6]



Schematic of the *ALK* Break Apart DNA-FISH Probe:

Horizontal red and green bars indicate the regions covered by the probes (approximate to scale, GRCh37/Hg19/2009). The directly labeled 5' *ALK* (red) & the 3' *ALK* (green) probe flank the break-points of the gene.

Signal Interpretation

In normal diploid metaphase and interphase nucleus, two fusion signals (red/green or yellow) would be observed corresponding to the normal homologous chromosome 2 (Figures 1 and 2). In cells with chromosomal rearrangements involving the *ALK* gene, the most commonly observed pattern is one fusion signal (red/green or yellow), which represents the normal chromosome 2, and one red and one green signal, which represents the derivative chromosomes (Figure 3). It is recommended to confirm variant pattern or atypical signal patterns by metaphase analysis whenever possible.

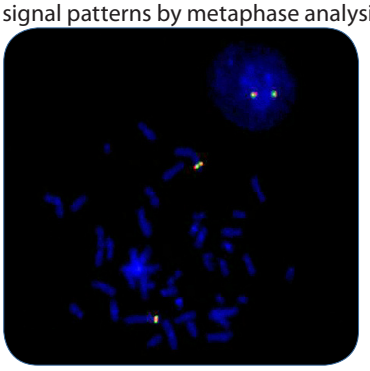


Figure 1: Normal diploid metaphase and interphase nucleus (from normal peripheral blood specimen) with 2 fusion (red/green or yellow) signals.

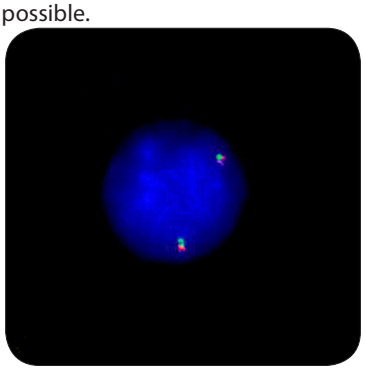


Figure 2: Normal diploid interphase nucleus (from bone marrow specimen) with 2 fusion (red/green or yellow) signals.

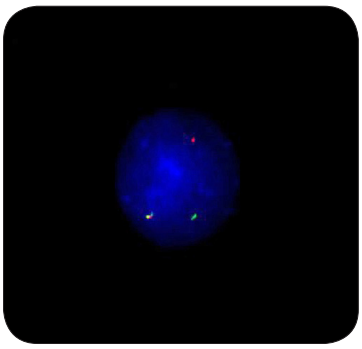


Figure 3: Interphase nucleus with 1 fusion (red/green or yellow), 1 red (5' *ALK*), and 1 green (3' *ALK*) signals.

References

1. Chiarle R., et al. Nat Rev Cancer, 2008. 8(1): 11-23.
2. Drexler, H. G., et al. Leukemia, 2000. 14(9):p.1533-59.
3. Sukov, W. R., et al. Mod Pathol, 2007. 20(5):p.592-603.
4. Kwak, E.L., et al. N Eng J Med, 2010. 363(18): p. 1693-703.
5. Gerber, D. E., et al. Cancer Cell, 2010. 18(6):p.548-51.
6. Camidge, D. R., et al. J Thorac Oncol, 2011. 6(4):p.774-80.

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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