

Kreatech™ FISH probes

Product Information Sheet

KBI-10747
ALK (2p23) Break

IVD

DANGER



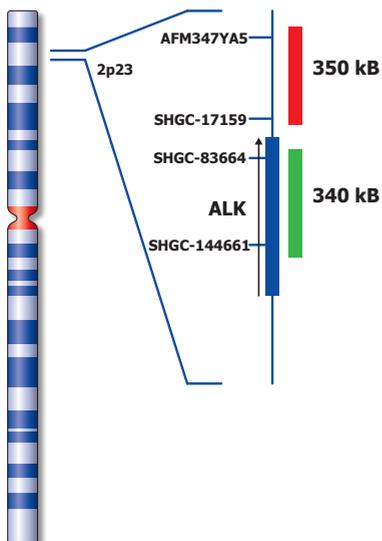
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Kreatech™ ALK (2p23) Break FISH probe

Introduction: Translocations of the **ALK** (anaplastic lymphoma kinase) gene at 2p23 have been identified in 40–60% of anaplastic lymphomas and in B-cell lymphomas, neuroblastomas and myofibroblastic tumors. The fusion genes consist of the COOH-terminal kinase domain of ALK and the NH₂-terminal portion of a fusion partner. Until now at least 21 translocation partners have been described, but 80% of the translocations involves the NPM1 gene (5q35). Activation of the ALK fusion genes typically results in aberrant activation of downstream signaling targets.

Intended use: The **ALK (2p23) Break** FISH probe is optimized to detect translocations involving the ALK gene region at 2p23 in a dual color, split assay on FFPE tissue sections.

The probe is recommended to be used in combination with one of the Kreatech Pretreatment kits providing necessary reagents to perform FISH on various sample types for optimal results. (see also www.LeicaBiosystems.com and look for Kits & reagents)

Critical region (red): The distal **ALK** gene region is direct-labeled with PlatinumBright™ 550.
Critical region (green): The proximal **ALK** gene region is direct-labeled with PlatinumBright™ 495.

Reagent: Kreatech probes are direct-labeled DNA probes provided in a ready-to-use format. Apply 10 µl of probe to a sample area of approximately 22 x 22 mm.

Please refer to the Instructions for Use for the entire Kreatech FISH protocol.

Kreatech FISH probes are REPEAT-FREE™ and therefore do not contain Cot-1 DNA. Hybridization efficiency is increased and background, due to unspecific binding, is highly reduced.

Interpretation: The **ALK (2p23) Break** FISH probe is designed as a dual-color assay to detect translocations of the ALK gene region at 2p23. The normal pattern should show two fusion signals (2F), while a translocation involving the ALK gene results in one fusion signal for the normal chromosome 2 and one red and one green signal for the translocation (1F1R1G). Consult the local or general guidelines for interpretation of signal patterns other than shown in the table.

	Normal Signal Pattern	Translocation of the ALK gene
Expected Signals	2F	1F1R1G

***) Note:** Some of the currently known fusion partners are located relatively close to the ALK gene. Especially, the inv(2)(p21;p23) ALK-EML4 will result in a distance of ~12 MB. As a result, the separate R and G signals may be located less than one signal diameter apart, possibly resulting in increased numbers of false negatives. Therefore, it is recommended to carefully define cut-off specifications in your setting. Signal patterns other than those described above may indicate variant translocations, deletions or amplifications on der(2) or other complex rearrangements.

References: Koivunen et al. Clin Cancer Res, 2008, 14, 4275-4283

Warning and precautions: In case of emergencies check SDS sheets for medical advice. SDS sheets may be obtained by either contacting Leica Technical Support or visiting www.LeicaBiosystems.com. DNA probes contain formamide which is a teratogen; do not inhale or allow skin contact. Wear gloves and a lab coat when handling DNA probes. All materials should be disposed of according to your institution's guidelines for hospital waste disposal.

Reagent Storage and Handling: Store at 2-8 °C. Reagents should not be used after the expiration date on the vial label.

TECHNICAL SUPPORT Technical support is available at www.LeicaBiosystems.com or +31 20 6919181 or via e-mail: kreatech-support@leicabiosystems.com.

CUSTOMER SERVICE Kreatech probes may be ordered through Leica Customer Service +31 20 6919181 or order via e-mail: purchase.orders@leica-microsystems.com.