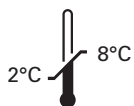


Kreatech™ FISH probes

Product Information Sheet

KBI-10404

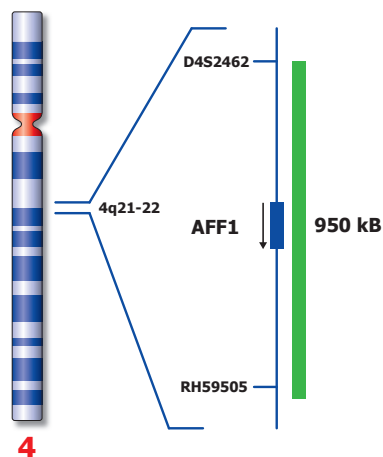
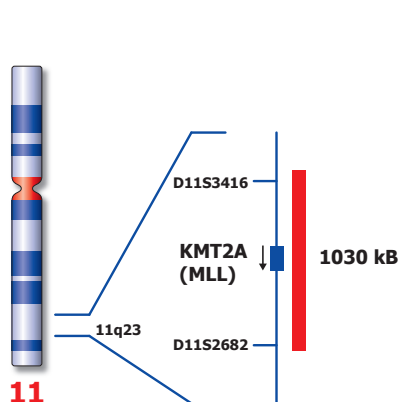
KMT2A/AFF1 t(4;11) Fusion



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Not to scale

Kreatech™ KMT2A/AFF1 t(4;11) Fusion FISH probe

Introduction: The t(4;11) is the most frequently (approximately 66% according to Meyer et al.) observed translocation involving the KMT2A (previously known as MLL) gene resulting in Acute Lymphoblastic Leukemia (ALL). The KMT2A-AFF1 translocation results in the generation of fusion proteins KMT2A-AFF1 and AFF1-KMT2A; both seem to have leukemogenic properties. Patients with ALL and the KMT2A-AFF1 translocation are associated with a high risk of treatment failure.

Intended use: The **KMT2A/AFF1 Fusion FISH probe** is optimized to detect translocations involving the KMT2A and AFF1 gene regions at 4q21-22 and 11q23 in a dual-color, fusion assay on metaphase/interphase spreads, blood smears and bone marrow cells.

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 1 (red): The **KMT2A (11q23)** gene region probe is direct-labeled with PlatinumBright™ 550.
Critical region 2 (green): The **AFF1 (4q21-22)** gene region probe 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 **KMT2A/AFF1 t(4;11) Fusion FISH probe** is designed as a dual fusion probe to detect both rearranged chromosomes der(4) and der(11) by two co-localized red/green or yellow fusion signals (F). Only red and green signals which are less than one signal diameter apart from each other are counted as a fusion. Separate red and green signals identify the normal chromosome(s) 4 and 11 (2R2G). Translocations involving only the KMT2A region at 11q23 without the AFF1 gene region as a fusion partner are visible as a gain of one red signal by breaking of one of the red signals (3R2G).

Signal patterns other than those described above may indicate variant translocations or other complex rearrangements. Investigators are advised to analyze metaphase cells for the interpretation of atypical signal patterns.

	Normal Signal Pattern	Translocation involving KMT2A and AFF1	Translocation involving KMT2A without AFF1
Expected Signals	2R2G	2F1R1G	3R2G

References: Harrison CJ et al, 2010, Br J Haem, 151; 132-142
 Arai S et al, 2011, Blood, 117; 6304-6314
 Meyer C et al, 2009, Leukemia, 23; 1490-1499

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.