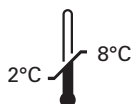


Kreatech™ FISH probes

Product Information Sheet

KBI-10307

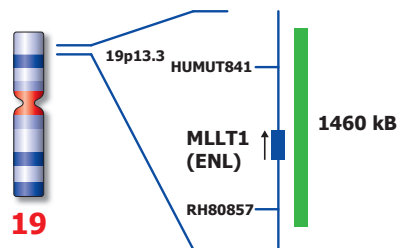
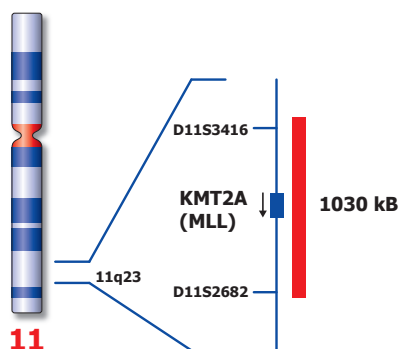
KMT2A/MLLT1 t(11;19) Fusion



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Not to scale

Kreatech™ KMT2A/MLL1 t(11;19) Fusion FISH probe

Introduction:

One of the relatively frequently (around 10 %) observed translocations in human Acute Myeloid Leukemia (AML) and Acute Lymphoblastic Leukemia (ALL) involves the genes KMT2A (previously known as MLL) and MLLT1 (aka ENL) at 11q23 and 19p13. The KMT2A/MLLT1 translocation results in the generation of fusion protein that retains the KMT2A N-terminus, including both an A-T hook domain and a region similar to mammalian DNA methyltransferase. There are several breakpoints within the MLLT1 gene described, without clear differences in clinicohematologic features. Patients with AML and the KMT2A/MLLT1 translocation carry a poor prognosis, but noninfant children with ALL and KMT2A/MLLT1 fusion may have a favorable prognosis.

Intended use:

The **KMT2A/MLLT1 Fusion FISH** probe is optimized to detect translocations involving the KMT2A and MLLT1 gene regions at 11q23 and 19p13 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 **MLLT1 (19p13.3)** 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/MLLT1 t(11;19) Fusion FISH** probe is designed as a dual fusion probe to detect both rearranged chromosomes der(11) and der(19) 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) 11 and 19 (2R2G). Translocations involving only the KMT2A region at 11q23 without the MLLT1 gene region as a fusion partner are seen as a gain of 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 MLLT1	Translocation involving KMT2A without MLLT1
Expected Signals	2R2G	2F1R1G	3R2G

References:

Mitterbauer-Hohdanner G et al, 2004, Eur J Clin Invest, 34; 12-24
 Meyer C et al, 2009, Leukemia, 23; 1490-1499
 Fu JF et al, 2007, Am J Clin Pathol, 127; 24-30

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.