

Kreatech[™] FISH probes Product Information Sheet

KBI-10308 KMT2A/MLLT3 t(9;11) Fusion



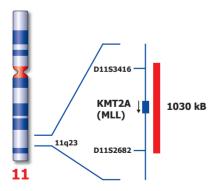


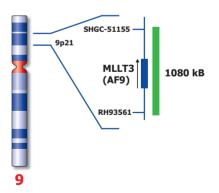


PI-KBI-10308_D1.1

Kreatech Biotechnology B.V. Vlierweg 20 1032 LG Amsterdam The Netherlands www.LeicaBiosystems.com

Published March 2015





KBI-10308

Kreatech™ KMT2A/MLLT3 t(9;11) Fusion FISH probe

Introduction:	Chromosomal rearrangements involving the KMT2A (previously known as MLL) gene at 11q23 are frequently observed in adult and childhood acute leukemia and are, in general, associated with poor prognosis. However, children with Acute Myeloid Leukemia (AML) carrying the t(9;11) KMT2A/MLLT3 (aka AF9) translocation have been described to be more sensitive to chemotherapy than patients with other 11q23 rearrangements.
Intended use:	The KMT2A/MLLT3 Fusion FISH probe is optimized to detect translocations involving the KMT2A and MLLT3 gene regions at 11q23 and 9p21 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 <u>www.LeicaBiosystems.com</u> and look for Kits & reagents)
Critical region 1 (red): Critical region 2 (green):	The KMT2A (11q23) gene region probe is direct-labeled with Platinum <i>Bright</i> ™550. The MLLT3 (9p21) gene region probe is direct-labeled with Platinum <i>Bright</i> ™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/MLLT3 t(9;11) Fusion FISH probe is designed as a dual fusion probe to detect both rearranged chromosomes der(11) and der(9) 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 should be counted as a fusion. Separate red and green signals identify the normal chromosome(s) 11 and 9 (2R2G). Translocations involving the KMT2A region at 11q23 with another fusion partner than the MLLT3 gene region are seen as gain of red signal as a result of breakage of a red KMT2A signal (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 MLLT3	Translocation involving KMT2A without MLLT3
Expected Signals	2R2G	2F1R1G	3R2G

References:	Palle J et al, 2005, Br J Haematol, 129; 189-198
	Meyer C et al, 2009, Leukemia, 23; 1490-1499
	Cavazzini F et al, 2006, Haematologica, 91; 381-5
	Balgobind BV et al, 2009, Blood, 114; 2489-96
	Keefe JG et al, 2010, J Mol Diagn, 12; 441-452

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