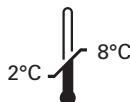


Kreatech™ FISH probes Product Information Sheet

IVD

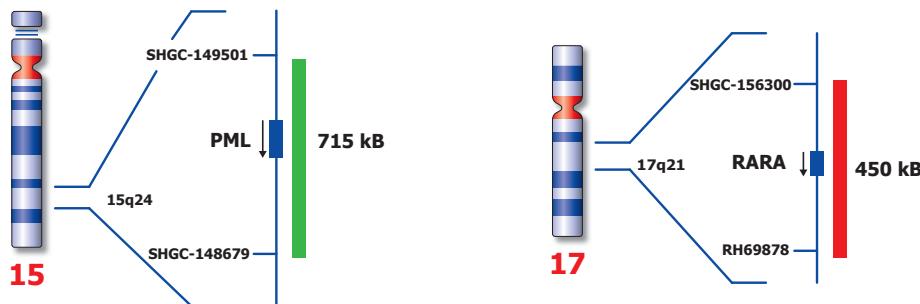
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Not to scale

Kreatech™ PML/RARA t(15;17) Fusion FISH probe

Introduction:	Acute myeloid leukemia (AML) is characterized by several recurrent chromosome anomalies, including the translocation t(15;17)(q24;q21). This translocation juxtaposes the promyelocytic leukemia (PML) gene on chromosome 15 and the retinoic acid receptor-alpha (RARA) gene on chromosome 17. AML with t(15;17) are usually assigned to a prognostic favorable group.							
Intended use:	The PML/RARA t(15;17) Fusion specific FISH probe is optimized to detect the reciprocal translocation t(15;17)(q24;q21) in a dual-color, dual-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 RARA (17q21) specific FISH probe is direct-labeled with PlatinumBright™550.							
Control region 2 (green):	The PML (15q24) specific FISH 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 PML/RARA t(15;17) Fusion FISH probe is designed as a dual-fusion probe to detect both rearranged chromosomes der(15) and der(17) by two co-localized red/green or yellow fusion signals (F). Single color red (R) and green (G) signals will identify the normal chromosomes 17 and 15 respectively. Signal patterns other than those described above may indicate variant translocations, deletions on der(15) or der(17) or other complex rearrangements.							
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;"></th> <th style="text-align: center;">Normal Signal Pattern</th> <th style="text-align: center;">t(15;17)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Expected Signals</td> <td style="text-align: center;">2R2G</td> <td style="text-align: center;">2F1R1G</td> </tr> </tbody> </table>			Normal Signal Pattern	t(15;17)	Expected Signals	2R2G	2F1R1G
	Normal Signal Pattern	t(15;17)						
Expected Signals	2R2G	2F1R1G						
References:	Grimwade D et al, 1997, Blood, 90; 4876-4885 Mancini M et al, 1995, Br J Haematol, 91; 878-884							
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 .							