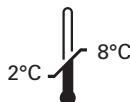


Kreatech™ FISH probes Product Information Sheet

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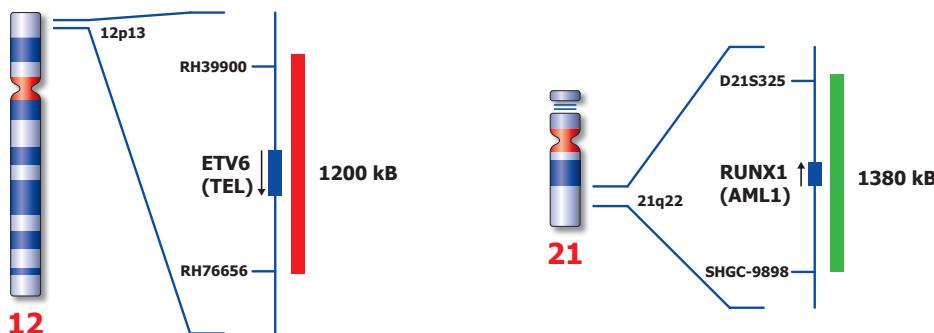
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Not to scale

Kreatech™ ETV6/RUNX1 t(12;21) Fusion FISH probe

Introduction: The ETV6/RUNX1 t(12;21)(p13;q22) is the most common genetic abnormality found in childhood acute lymphoblastic leukemias (ALL). It is closely correlated with a B-cell precursor (BCP) phenotype and is considered a favorable prognostic factor. Double ETV6/RUNX1 fusion, lack of ETV6 (previously known as TEL) signal and extra RUNX1 (previously known as AML1) signals can be detected as additional FISH abnormalities.

Intended use: The ETV6/RUNX1 t(12;21) Fusion FISH probe is optimized to detect the reciprocal translocation t(12;21) 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 ETV6 (12p13) specific FISH probe is direct-labeled with PlatinumBright™550.
Critical region 2 (green): The RUNX1 (21q22) control 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 therefore increased and background, due to unspecific binding, is highly reduced.

Interpretation: The ETV6/RUNX1 t(12;21) Fusion FISH probe is designed as a dual-fusion probe to detect both rearranged chromosomes der(12) and der(21) by two co-localized red/green or yellow fusion signals (F). Single color red (R) and green (G) signals will identify the normal chromosomes 12 and 21 respectively. Deletion of the unarranged ETV6 region at 12p13 has been described as a secondary event and will be observed as 2 fusion signals and 1 green signal at the normal chromosome 21.

Signal patterns other than those described above may indicate variant translocations, deletions on der(12) or der(21) or other complex rearrangements. Investigators are advised to analyze metaphase cells for the interpretation of atypical signal patterns.

	Normal Signal Pattern	t(12;21)	t(12;21), del(12p13)
Expected Signals	2R2G	2F1R1G	2F1G

References: Romana S et al, 1995, Blood; 3662-3670
 Ford A et al, 2001, Blood; 558-564

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.