Kreatech™ FISH probes

Product Information Sheet

KBI-10746

ALK (2p23) / EML4 t(2;2) inv (2) Fusion

IVD

DANGER

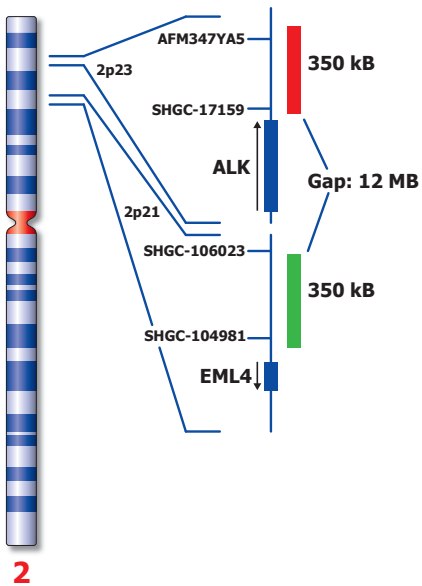
FORMAMIDE

2°C 8°C

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

PI-KBI-10746_D1.1

Published March 2015



Not to scale

KBI-10746

Kreatech™ ALK (2p23) / EML4 t(2;2) inv (2) Fusion FISH probe

Introduction:

The inversion in 2p21 and 2p23 leading to a fusion of the kinase domain of ALK (anaplastic lymphoma kinase) and EML4 (echinoderm microtubule associated protein like 4) has been described in 5-7% of non-small cell lung cancer (NSCLC) cases. ALK and EML4 are ~12 MB apart in opposite directions; a simple inversion generates the fusion gene. Promising results with specific ALK Kinase inhibitors have been obtained in patients carrying the fusion gene.

Intended use:

The **ALK (2p23) / EML4 t(2;2) inv (2) Fusion** FISH probe is optimized to detect the fusion of the ALK gene with the EML4 gene by paracentric inversion with breakage and reunion occurring at bands 2p21 and 2p23 in a dual color fusion assay on FFPE tissue sections.

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 distal **ALK** gene region is direct-labeled with Platinum*Bright*™550.
Critical region 2 (green): The distal **EML4** gene region is direct-labeled with Platinum*Bright*™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 **ALK (2p23) / EML4 t(2;2) inv (2) Fusion** FISH probe is designed as a dual-color assay to detect fusion of the ALK and EML4 gene regions by paracentric inversion. The normal pattern should show two red and two green signals (2R2G), while a fusion between ALK and EML4 results in one fusion, one red and one green signal (1F1R1G).
The **ALK (2p23) / EML4 t(2;2) inv (2) Fusion** FISH probe can not be accurately used to detect ALK translocations involving other partners than EML4 unless the analysis is performed on metaphase spreads.

	Normal Signal Pattern	Fusion of the ALK-EML4
Expected Signals	2R2G	1F1R1G

References:

Soda et al., Nature, 2007, 448, 561-566
Koivunen et al. Clin Cancer Res, 2008, 14, 4275-4283

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.