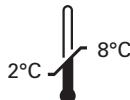


## Kreatech™ FISH probes Product Information Sheet

IVD

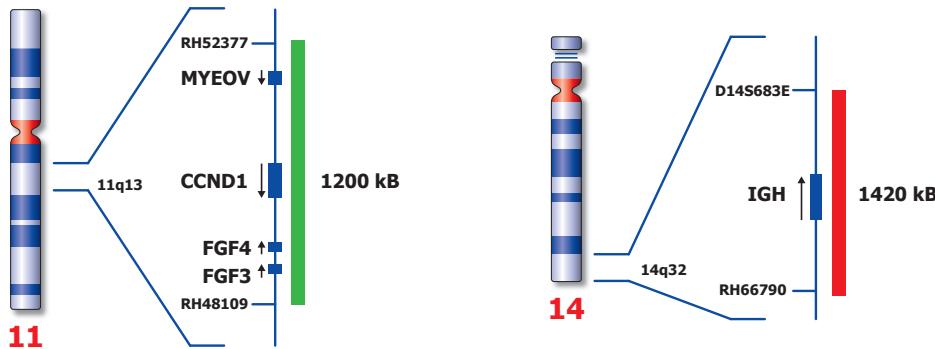
CE



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PI-KBI-10604\_D1.1

Published March 2015



Not to scale

## Kreatech™ CCND1/IGH t(11;14) Fusion FISH probe

**Introduction:**

The chromosomal translocation t(11;14)(q13;q32) is the hallmark of mantle cell lymphoma (MCL) in which it can be detected cytogenetically in about 75% of cases. The t(11;14) translocation juxtaposes the CCND1 (previously known as BCL1) locus at chromosome band 11q13 next to the IGH locus at chromosome band 14q32 and thus leads to deregulation of the cell cycle regulatory protein cyclin D1 (CCND1).

**Note:** This probe is not optimal for use in Multiple Myeloma as breakpoint regions are different. For Multiple Myeloma the MYEOV/IGH t(11;14) probe is recommended (Cat# KBI-10605).

**Intended use:**

The **CCND1/IGH t(11;14) Fusion** specific FISH probe is optimized to detect the reciprocal translocation t(11;14) 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](http://www.LeicaBiosystems.com) and look for Kits & reagents)

**Critical region 1 (red):**

The IGH (14q32) specific FISH probe is direct-labeled with PlatinumBright™ 550.

**Critical region 2 (green):**

The CCND1 (11q13) 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 **CCND1/IGH t(11;14) Fusion** FISH probe is designed as a dual-fusion probe to detect both rearranged chromosomes der(11) and der(14) by two co-localized red/green or yellow fusion signals (F). Single color red (R) and green (G) signals will identify the normal chromosomes 14 and 11 respectively.

Signal patterns other than those described above may indicate variant translocations, deletions on der(11) or der(14) or other complex rearrangements. Investigators are advised to analyze metaphase cells for the interpretation of atypical signal patterns.

	Normal Signal Pattern	t(11;14)
Expected Signals	2R2G	2F1R1G

**References:**

Vaandrager et al, 1996, Blood 88 (4); 1177-1182

Siebert, R. et al, 1998, Ann. Onc., 9; 519-526

**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](http://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](http://www.LeicaBiosystems.com) or +31 20 6919181 or via e-mail: [kreatech-support@leicabiosystems.com](mailto: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](mailto:purchase.orders@leica-microsystems.com).