

Kreatech™ FISH probes

Product Information Sheet

KBI-40003

RB1 (13q14)/RCAN1 (21q22)

IVD

DANGER



FORMAMIDE

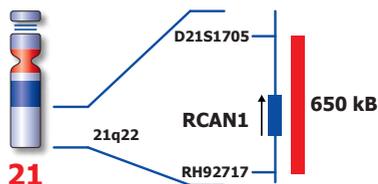
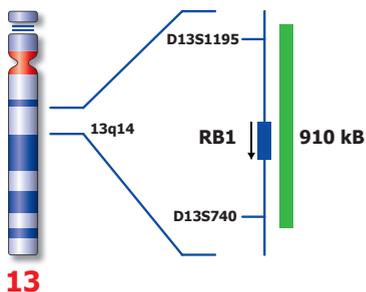
CE 2797



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

Published August 2020

PI-KBI-40003_D2.0



Kreatech™ RB1 (13q14)/RCAN1 (21q22) FISH probe

Intended Purpose:

The intended purpose of the device is to aid in the diagnosis of a trisomy 21 and trisomy 13, using uncultured amniotic cells as a sample. The probes are intended to be used in a semi-quantitative fluorescence in situ hybridization (FISH) assay to determine the following:

The **RCAN1 (21q22)** specific FISH probe is optimized to detect copy numbers of chromosome 21 at 21q22 on uncultured amniotic cells. The **RB1 (13q14)** specific FISH probe is optimized to detect copy numbers of chromosome 13 at 13q14 on uncultured amniotic cells.

Warnings and Limitations:

This product is not intended for use on any type of cells/tissue other than uncultured amniotic cells. This test should never be used as a standalone test, but always in conjunction with other results/follow-up testing. This FISH assay will not detect the presence of structural chromosome abnormalities that can also result in birth defects.

Indications for use:

Trisomy 21 is one of the most common chromosomal abnormalities in live born children and causes Down syndrome, a particular combination of phenotypic features that includes mental retardation and characteristic facies. Molecular analysis has revealed that the 21q22.1-q22.3 region appears to contain the gene(s) responsible for the congenital heart disease observed in Down syndrome. Trisomy 13, also called Patau syndrome, is a chromosomal condition that is associated with severe mental retardation and certain physical abnormalities. The critical region has been reported to include 13q14-13q32 with variable expression, gene interactions, or interchromosomal effects.

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 **21q22 specific** FISH probe is direct-labeled with PlatinumBright™550.

Critical region 2 (green):

The **13q14 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 **RB1 (13q14)/RCAN1 (21q22)** FISH probe is designed as a dual-color assay to detect gains of chromosome 21 and 13. Trisomy 21 will be detected by three red signals at the 21q22 region and two green signals for chromosome 13 (3R2G). Trisomy 13 will be detected by 3 green signals at the 13q14 region and two red signals for chromosome 21 (2R3G). Two single color red (R) and green (G) signals will identify the normal chromosomes 13 and 21 (2R2G).

	Normal Signal Pattern	Trisomy 21	Trisomy 13
Expected Signals	2R2G	3R2G	2R3G

References:

Korenberg J. et al, 1994, Proc. Nat. Acad. Sci. 91; 4997-5001

Spathas D et al, 1994, Prenat Diagn. 14(11); 1049-1054

Tepperberg et al, 2001, Prenat Diagn 21(4); 293-301

Safety data sheet: 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 formaldehyde 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.