



A Sysmex Group Company



IGK Breakpart Probe

REF: LPS 038-A

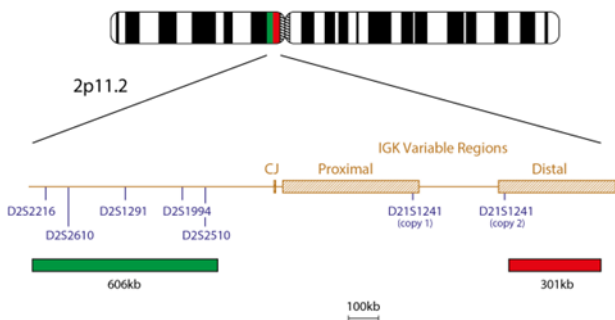
Analyte Specific Reagent: Analytical and performance characteristics are not established.

Fluorescence *in situ* hybridisation (FISH) is a technique that allows the visualisation of DNA sequences upon chromosomes. The technique uses DNA probes that hybridise to entire chromosomes or single unique sequences, and serves as a powerful adjunct to classic cytogenetics. Recent developments have meant that this valuable technique can now be applied as an essential tool in prenatal, haematological and pathological chromosomal analysis. Target DNA, after fixation and denaturation, is available for annealing to a similarly denatured, fluorescently labelled DNA probe, which has a complementary sequence. Following hybridisation, unbound and non-specifically bound DNA probe is removed and the DNA is counterstained for visualisation. Fluorescence microscopy then allows the visualisation of the hybridised probe on the target material.

Probe Specification

IGK, 2p11.2, Red
IGK, 2p11.2, Green

CMP-H034 v005.00



The IGK product consists of a 301kb probe, labelled in red, covering a part of the distal IGK Variable region and a green probe, covering a 606kb region telomeric to the Joining segments and the Constant segment of IGK. The green probe extends from a position that is telomeric to the D2S2216 marker and continues to a position that is centromeric to the D2S2510 marker.

Materials Provided

Probe: 100µl per vial.

Probe concentration: Amount of red probe 3.50-5.90ng/µl
Amount of green probe 17.1-25.6ng/µl

The probe is provided in hybridisation solution (Formamide; Dextran Sulphate; SSC) and is ready to use.

Warnings and Precautions

1. Analyte Specific Reagent. Analytical and performance characteristics are not established.
2. For professional use only.
3. Laboratories must undertake all appropriate validation of any Laboratory Developed Test (LDT), as per the CLIA Regulations.
4. Probe mixtures contain formamide, which is a teratogen; do not breathe fumes or allow skin contact. Handle with care; wear gloves and a lab coat.
5. Follow local disposal regulations for your location along with recommendations in the Safety Data Sheet to determine the safe disposal of this product. This also applies to damaged test kit contents.
6. Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.
7. Operators must be capable of distinguishing the colors red, blue, and green.

Storage and Handling

The probe vial should be stored between -25°C to -15°C in a freezer until the expiry date indicated on the label. The probe vial must be stored in the dark.



The FISH probe remains stable throughout the freeze-thaw cycles experienced during normal use (where one cycle constitutes the vial's removal from and replacement into the freezer). Exposure to light should be minimised and avoided wherever possible. Store the vial in the light proof container provided. Components used and stored under conditions other than those stated on the labelling may not perform as expected and may adversely affect the assay results. All efforts must be made to limit exposure to light and temperature changes.

Known Relevant Interferences / Interfering Substances

No known relevant interferences / interfering substances.

Known Cross-Reactivity

No known cross-reactivity.

Additional Information

For additional product information please contact the CytoCell Technical Support Department.

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Labelling according to GHS-US hazard label requirements

Hazard pictograms (GHS-US):



GHS07

GHS08

Signal word (GHS-US): Danger

Hazardous ingredients: Formamide <100%

Hazard statements (GHS-US):

H315 – Causes skin irritation

H319 – Causes serious eye irritation

H360 – May damage fertility or the unborn child

Precautionary statements (GHS-US):

P202 – Do not handle until all safety precautions have been read and understood

P280 – Wear eye protection, protective clothing, protective gloves

P302+P352 – IF ON SKIN: Wash with plenty of soap and water

P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing











P308+P313 – IF exposed or concerned: Get medical advice/attention

P362+P364 – Take off contaminated clothing and wash it before reuse

P501 – Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

Refer to Safety Data Sheet for more information.

Symbols Glossary

ISO 15223-1:2016 - "Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements" (© International Organization for Standardization)		
Symbol	Title	Reference Number(s)
	en: Manufacturer	5.1.1
	en: Date of manufacture	5.1.3
	en: Use-by date	5.1.4
	en: Batch code	5.1.5
	en: Catalogue number	5.1.6
	en: Keep away from sunlight	5.3.2
	en: Temperature limit	5.3.7
	en: Consult instructions for use	5.4.3
	en: Caution	5.4.4
EDMA symbols for IVD reagents and components, October 2009 revision		
Symbol	Title	Reference Number(s)
	en: Contents (or contains)	N/A

Patents and Trademarks

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