



A Sysmex Group Company



## BCR/ABL Translocation, Dual Fusion Probe

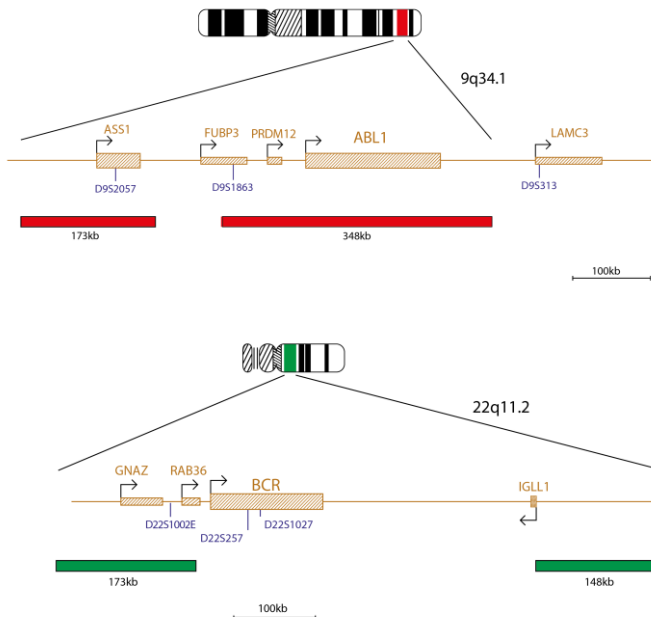
REF LPH 007-A / LPH 007-A50

**Analyte Specific Reagent. Analytical and performance characteristics are not established. For professional use only.**

**Laboratories must undertake all appropriate validation of any Laboratory Developed Test (LDT), as per the CLIA Regulations**

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**  
 ABL1, 9q34.1, Red  
 BCR, 22q11.2, Green



The green probe mix contains a 173kb probe centromeric to the BCR gene that spans the GNAZ and RAB36 genes. A second green probe covers a 148kb region telomeric to the BCR gene that spans part of the IGLL1 gene. The red probe mix contains a 348kb probe that spans the ABL1 gene and a 173kb probe that spans the ASS1 gene.

### Fluorophore Information

Fluorophore	Excitation <sub>max</sub> [nm]	Emission <sub>max</sub> [nm]
DAPI	364	454
Aqua	418	467
Green	495	521
Red	596	615

### Materials Provided

**Probe:** 100µl per vial or 500µl per vial  
**Probe concentration:** Amount of red probe 4.38-7.38ng/µl  
 Amount of green probe 12.3-18.5ng/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

The green BCR distal probe may show up to 2 cross-hybridisation signals on chromosome 7 at 7q11.2.

### Additional Information

For additional product information please contact the CytoCell Technical Support Department.  
 T: +44 (0)1223 294048  
 E: techsupport@cytoCELL.com  
 W: www.ogt.com

### 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

CytoCell is a registered trademark of CytoCell Ltd.  
This product contains technology licensed from Life Technologies Corporation that is available for human diagnostics or life science research use only.



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#### Pack Insert Version History

V16.00 2023-08-08: Update to current template. Addition of known cross reactivity.