



A Sysmex Group Company



Instructions For Use

REF: HB 500L, HB 1000L

Hybridisation Solution B



FOR LABORATORY USE

PROFESSIONAL USE ONLY



www.cytocell.com

Further information and other languages available at www.ogt.com

Intended Use

Hybridisation Solution B is an accessory intended for use in fluorescence *in situ* hybridisation (FISH) with DNA FISH probes.

This product is intended to be used with certain CE marked CytoCell FISH Probe Kit IVDs or in a Laboratory Developed Test (LDT). If used as part of an LDT, it is the responsibility of the laboratory developing the test to validate the test before use in a clinical setting.

Table 1: Hybridisation Solution B

Catalogue Number	Description	Volume
HB 500L	Hybridisation Solution B (Formamide, Dextran Sulphate, SSC)	500µl
HB 1000L	Hybridisation Solution B (Formamide, Dextran Sulphate, SSC)	1000µl

This Hybridisation Solution B kit contains only one of the two products noted above.

Materials Provided

Hybridisation Solution B: 500µl per vial or 1000µl per vial

Warnings and Precautions

- For *in vitro* diagnostic use. For laboratory professional use only.
- USA: General Purpose Reagent (GPR). For Laboratory Use.
- Hybridisation Solution B contains formamide, which is a teratogen; do not breathe fumes or allow skin contact. Handle with care; wear gloves and a lab coat.
- Follow local disposal regulations for your location along with recommendations in the Safety Data Sheet to determine the safe disposal of this product.

Storage and Handling

The Hybridisation Solution B should be stored between -25°C to -15°C in a freezer until the expiry date indicated on the label.

Equipment and Materials Necessary but not Supplied

Calibrated equipment must be used:

- Variable volume micropipettes and tips range 1µl - 200µl.
- Consult the relevant CytoCell FISH Probe Kit IFU or the protocol of your own validated LDT for any additional equipment and materials necessary but not supplied.

Fluorescence Microscope Recommendation

Consult the relevant CytoCell FISH Probe Kit IFU or the protocol of your own validated LDT for the appropriate microscope filter(s) to use.

Check the fluorescence microscope before use to ensure it is operating correctly. Use immersion oil that is suitable for fluorescence microscopy and formulated for low auto fluorescence. Avoid mixing DAPI antifade with microscope immersion oil as this will obscure signals. Follow manufacturers' recommendations in regards to the life of the lamp and the age of the filters.

FISH Protocol

(Note: Ensure that exposure of the probe and counterstain to laboratory lights is limited at all times).

- Consult the relevant CytoCell FISH Probe Kit IFU or the protocol of your own validated LDT for the appropriate protocol to use.

Adverse Event Reporting

If you believe this device has malfunctioned or suffered a deterioration in its performance characteristics which may have contributed to an adverse event (e.g. delayed or misdiagnosis, delayed or inappropriate treatment), this must be reported immediately to the manufacturer (email: vigilance@ogt.com).

If applicable, the event should also be reported to your national competent authority. A list of vigilance contact points can be found at: <https://ec.europa.eu/growth/sectors/medical-devices/contacts/>.

Additional Information

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

T: +44 (0)1223 294048

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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: Use-by date	5.1.4
	en: Batch code	5.1.5
	en: Catalogue number	5.1.6
	en: Temperature limit	5.3.7
	en: Consult instructions for use	5.4.3
	en: Caution	5.4.4
	en: <i>In vitro</i> diagnostic medical device	5.5.1
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.

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