



A Sysmex Group Company



Instructions For Use

REF: HB 500L, HB 1000L, HI 1000L

Hybridisation Solution B / Hybridisation Solution I

PRODUCT FOR GENERAL LABORATORY USE

FOR LABORATORY USE

PROFESSIONAL USE ONLY



ogt.com/IFU

Further information and other languages available at ogt.com/IFU

Intended Purpose

Hybridisation Solutions B and I are reagents intended for use in fluorescence *in situ* hybridisation (FISH) with DNA FISH probes.

This product is intended for general laboratory use or use 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/I

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

This Hybridisation Solution B or I kit contains only one of the three products noted above.

Materials Provided

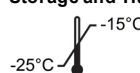
Hybridisation Solution B: 500µl per vial or 1000µl per vial or

Hybridisation Solution I: 1000µl per vial

Warnings and Precautions

- Product for General Laboratory Use. For laboratory professional use only.
- USA: General Purpose Reagent (GPR). For Laboratory Use.
- Hybridisation Solution contains formamide, which is a teratogen; do not breathe fumes or allow skin contact. Handle with care; wear gloves and a lab coat.
- Do not use if the vial(s) are damaged, or the vial contents are compromised in any way.
- 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.
- 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.

Storage and Handling

 The Hybridisation Solution 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 protocol of your own validated LDT for any additional equipment and materials necessary but not supplied.

Fluorescence Microscope Recommendation

Consult 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 protocol of your own validated LDT.

Additional Information

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

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Symbols Glossary

EN ISO 15223-1:2021 - "Medical devices - Symbols to be used with information to be supplied by the manufacturer - 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: Consult electronic 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 Cytozell Limited.



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IFU Version History

V001 2020-11-09: New IFU for HI 1000L.

V002 2022-05-26: Addition of HB 500L and HB 1000L.