



A Sysmex Group Company



Instructions For Use

REF: DES 500L, DES 1000L

DAPI Antifade ES



FOR LABORATORY USE

PROFESSIONAL USE ONLY



www.cytocell.com

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

Intended Use

DAPI Antifade ES counterstain solution is an accessory intended to aid visualisation of hybridised DNA fluorescence *in situ* hybridisation (FISH) probes using fluorescence microscopy.

This product is intended to be used with 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: DAPI Antifade ES

Catalogue Number	Description	Volume
DES 500L	DAPI Antifade ES (0.125µg/ml DAPI (4,6-diamidino-2-phenylindole) in glycerol-based mounting medium)	500µl
DES 1000L	DAPI Antifade ES (0.125µg/ml DAPI (4,6-diamidino-2-phenylindole) in glycerol-based mounting medium)	1000µl

This DAPI Antifade ES kit contains only one of the two products noted above.


Materials Provided

DAPI Antifade ES counterstain solution: 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.
- DAPI is a potential carcinogen. 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 DAPI Antifade ES should be stored between -25°C to -15°C in a freezer until the expiry date indicated on the label. The DAPI must be allowed to warm up at room temperature for 10 minutes prior to use.



Store the DAPI Antifade ES solution in the dark.

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.

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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: Keep away from sunlight	5.3.2
	en: Temperature limit	5.3.7
	en: Consult instructions for use	5.4.3
	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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