



WASHING SOLUTION INSTRUCTION FOR USE

I. DESCRIPTION

The Washing Solution is used during processing of ALEX technology-based arrays as described in their respective instructions for use. In addition, the Washing Solution can be used during the maintenance procedure as indicated in the MAX Devices Instructions for Use. The Washing Solution can be used in both manual and automated procedures by trained laboratory personnel and medical professionals.

II. INTENDED USE

The Washing Solution is an accessory for ALEX technology-based assays.

The IVD medical product is used as indicated in the respective Instruction for Use and is used by trained laboratory personnel and medical professionals in a medical laboratory.



Important information for users!

Please read the Instructions for Use thoroughly. This is the only way to ensure that the product is used correctly. The manufacturer accepts no responsibility for improper use or for modifications made by the user.



Caution!

The Washing Solution 4 x conc. is shipped as a 4-fold concentrate. Before use, the solution must be diluted 1:4 with distilled water (e.g. 250 ml + 750 ml).

III. SHIPMENT AND STORAGE

Shipment of the Washing Solution 4 x conc. takes place at ambient temperature. The reagent must be stored at 2 - 8 °C until use. If stored correctly, the reagent is stable until the stated expiry date.










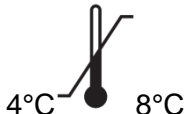

The diluted Washing Solution can be used for 6 months (at recommended storage conditions).







IV. WASTE DISPOSAL

Used and unused reagents can be disposed with laboratory waste. All national and local disposal regulations must be followed.

V. GLOSSARY OF SYMBOLS


	Manufacturer
	Date of expiry
	Batch number
	REF number
	Do not use if packaging is damaged
	Store away from light
	Store dry
	Storage temperature
	Pay attention to Instructions for use Link to download the IFU



	In vitro diagnostic medical device
	Unique device identifier
	CE mark
	Important note

VI. REAGENTS AND MATERIAL

The Washing Solution 4 x conc. is packaged separately. Expiration date and storage temperature are indicated on the label. The reagents are not to be used after their expiry date.

	The Washing Solution 4 x conc. is not batch-dependent and can therefore be applied regardless of the kit batch used (ALEX ² and/or FOX).
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Item	Quantity	Properties
Washing Solution 4 x conc. (REF 00-5003-01)	4-fold concentrated, 1 container à 250 ml	TRIS-buffered saline solution, Tween 20, 0.1 % sodium azide

Store at 2 - 8 °C until expiry date. Dilute 1:4 with distilled water before use. Before use, the solution must be brought to room temperature. The diluted and opened solution is stable for 6 months at 2 - 8 °C.



VII. WARNINGS AND PRECAUTIONS

- It is recommended to use gloves, safety goggles and a lab coat when handling patient samples and reagents, as well as to follow good laboratory practice (GLP).
- The reagents are for in vitro use only and not to be used for internal or external use in humans or animals.
- Upon delivery, the containers must be checked for damage. If any component is damaged (e.g., buffer container), please contact MADx (support@macroarraydx.com) or your local distributor. Do not use damaged kit components, this may affect kit performance.
- Do not use expired kit components

Required materials available from MADx, which are not included in the kit:

- ImageXplorer
- MAX device
- RAPTOR Server Analysis Software
- ALEX² Allergy Xplorer
- FOX Food Xplorer
- Humidity chamber
- Shaker (see ALEX²/FOX for detailed specifications)
- Array holders (optional)

Required consumables not available from MADx:

- Pipettes
- Distilled Water


VIII. PREPARATION OF REAGENTS

- I. Pour the entire contents into a 1-liter container and fill it with distilled water up to the 1-liter mark.
- II. Mix everything thoroughly.
- III. The obtained solution can be used for manual assay and/or after transfer to the Washing Solution container for automated assay.



IX. IMPLEMENTATION AND PROCEDURE

Use the Washing Solution 4 x conc. in accordance with the appropriate procedure. For further information, see the MAX devices Instructions for Use or the Instructions for Use of the corresponding MADx test kits.

	If serious incidents occur in connection with this product, they must be reported to the manufacturer at support@macroarraydx.com immediately!
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Analysis performance characteristics:

The Washing Solution is intended to be used only in combination with assays based on ALEX technology. The product does not perform an analytical or a clinical analysis on its own.

X. WARRANTY

The performance data presented here was obtained using the indicated procedure. Any change in procedure may alter results. Macro Array Diagnostics disclaims any warranty in such cases. This concerns the legal guarantee and the usability. Macro Array Diagnostics and their local distributors will not be held responsible for any damage in these cases.



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