

# **MACROARRAY DIAGNOSTICS Stop Solution Instruction** Manual

Home » MACROARRAY DIAGNOSTICS » MACROARRAY DIAGNOSTICS Stop Solution Instruction Manual





#### **Contents**

- 1 DESCRIPTION
- **2 INTENDED USE**
- **3 SHIPMENT AND STORAGE**
- **4 WASTE DISPOSAL**
- **5 GLOSSARY OF SYMBOLS**
- **6 REAGENTS AND MATERIAL**
- **7 WARNINGS AND PRECAUTIONS**
- **8 IMPLEMENTATION AND**
- **PROCEDURE**
- 9 WARRANTY
- 10 Documents / Resources
  - 10.1 References

# **DESCRIPTION**

The Stop Solution is used during processing of ALEX technology-based arrays as described in their respective Instructions for Use. The Stop Solution can be used in both manual and automated procedures by trained laboratory personnel and medical professionals.

The Stop Solution is used during the assay to stop the color reaction on the arrays.

### **INTENDED USE**

The Stop Solution is an accessory to ALEX technology-based assays.

The IVD medical product is used as indicated in the respective Instructions 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 produc t is used correctly. The manufacturer accepts no responsibility for improper use or for modifica tions made by the user.

## SHIPMENT AND STORAGE

Shipment of the Stop Solution 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 opened Stop Solution can be used for 6 months (at recommended storage conditions).

# **WASTE DISPOSAL**

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

## **GLOSSARY OF SYMBOLS**

	Manufacturer	
	Date of expiry	
LOT	Batch number	
REF	REF number	
	Do not use if packaging is damaged	
*	Store away from light	
**	Store dry	
4°C 8°C	Storage temperature	
<b>i</b>	Pay attention to Instructions for use Link to download the IFU	
IVD	In vitro diagnostic medical device	
UDI	Unique device identifier	
CE	CE mark	
$\triangle$	Important note	
<b>!</b>	Attention (GHS hazard pictogram) Consult the Safety Data Sheet for more information.	

# **REAGENTS AND MATERIAL**

The Stop Solution 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 Stop Solution is not batch-dependent and can therefore be applied regardless of the kit b atch used (ALEX<sup>2</sup> and/or FOX).

Item	Quantity	Properties
Stop Solution (REF 00-5007-01)	1 container à 10 ml	Ethylenediaminetetraacetic acid (EDTA)-Solutio n

The Stop Solution is ready for use. Store at 2-8 °C until expiry date. Before use, the solution must be brought to room temperature. The opened solution is stable for 6 months at 2-8 °C. May become cloudy if stored for a long time. This does not affect test results.

### 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 (<u>support@macroarraydx.com</u>) 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
- ALEX<sup>2</sup> 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

### IMPLEMENTATION AND PROCEDURE

Use the Stop Solution in accordance with the appropriate procedure. For further information, see the MAX Devices Instruction 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 manufa cturer at <a href="mailto:support@macroarraydx.com">support@macroarraydx.com</a> immediately!

### **Analysis performance characteristics:**

The Stop 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.

### **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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### **Documents / Resources**



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#### References

- Macro Array Diagnostics
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