



QUALITYXPLOER (RUO) INSTRUCTIONS FOR USE

I. DESCRIPTION

The QualityXplorer is a product for research use only (RUO) and is to be used as quality control for monitoring specified limits (process control charts) in combination with the ALEX² test procedure.

These Instructions for Use are applicable for the following product:

Basic UDI-DI	REF	Product
91201229231JX	31-0800-02	QualityXplorer (RUO)

II. INTENDED PURPOSE

The QualityXplorer is a product for research use only (RUO) to examine and monitor the processing of ALEX² Allergy Xplorer. The product contains a mixture of antibodies that react with defined allergens on the ALEX² Allergy Xplorer and is used by trained laboratory staff.



Important information for users!

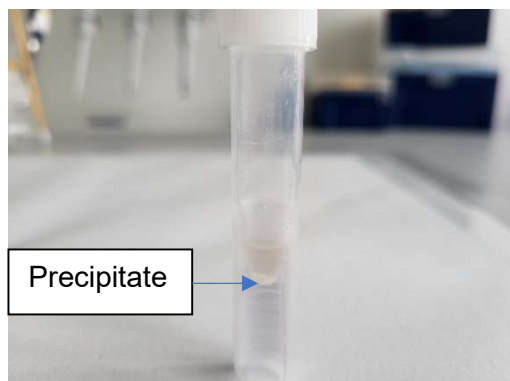
For the correct use of the QualityXplorer, it is necessary for the user to carefully read and follow these instructions for use. The manufacturer assumes no liability for any use of this product which is not described in this document or for modifications by the user of the product.

III. SHIPMENT AND STORAGE

The shipment of the QualityXplorer takes place at ambient temperature conditions. Nevertheless, the QualityXplorer must be stored, after spinning down of the liquid, in an upright position immediately upon delivery at 2-8°C. Stored correctly it can be used until the indicated expiration date.

QualityXplorer precipitates

If you encounter precipitates (see image below) in your QualityXplorer sample tube, please **shortly vortex and spin down** before use. This way, reliable results can be assured.



QualityXplorer precipitate

	<p>The QualityXplorer is only intended for one determination per vial. Before opening, briefly spin down the liquid in the vials. After opening the vials, they are to be used immediately for analysis.</p>
	<p>The human blood components used in the manufacture of the QualityXplorer have been tested and found negative for HBsAG, HCV and antibodies to the HI virus.</p>

IV. WASTE DISPOSAL

Dispose the used QualityXplorer sample with laboratory chemical waste. Follow all national, state, and local regulations regarding disposal.

V. GLOSSARY OF SYMBOLS

	<p>For Research Use Only</p>
	<p>Catalogue number</p>
	<p>Sufficient for <n> tests</p>
	<p>Indicates a control material that is intended to verify the results in the expected positive range</p>




	Do not use if packaging is damaged
	Lot code
	Consult instructions for use
	Manufacturer
	Do not re-use
	Use-by date
	Temperature limit
	Important note
	MacroArray Diagnostics (MADx)

VI. REAGENTS AND MATERIAL

The QualityXplorer is packaged separately. Expiration date and storage temperature are indicated on the label. The reagents are not to be used after their expiry date.



	<p>The use of the QualityXplorer is not lot-dependent and can therefore be used independently of the ALEX² Kit lot used.</p>
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Item	Quantity	Properties
QualityXplorer (RUO) (REF 31-0800-02)	8 vials à 200 µl Sodium Azide 0,05%	Ready to use. Store at 2-8°C until expiry date.

The composition of the QualityXplorer and the corresponding acceptance intervals of the individual antibodies are stored in the RAPTOR SERVER Analysis Software for each lot of the QualityXplorer. Using the QC module in RAPTOR SERVER Analysis Software, the results of the QualityXplorer measurements can be displayed in tabular or graphical form.

After a minimum number of measurements (e.g. 20 measurements), instrument-specific intervals (2 and 3 standard deviations) can be displayed via the QC module in RAPTOR SERVER Analysis Software. In this way, the laboratory-specific intervals for each allergen can be determined more precisely.

VII. WARNINGS AND PRECAUTIONS

- It is recommended to wear hand and eye protection as well as lab coats and follow good laboratory practices (GLP) when preparing and handling reagents and samples.
- In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions as patient samples. The starting material is partially prepared from human blood sources. The product was tested non-reactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Hepatitis C (HCV) and antibodies to HIV-1 and HIV-2.
- The reagents are for research use only (RUO). They are 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@madx.com) or your local distributor. Do not use damaged kit components, this may affect kit performance.
- Do not use expired kit components.

VIII. WARRANTY

The herein presented performance data were obtained using the procedure outlined in these Instructions for Use. Any change or modification in the procedure may affect the results and MacroArray Diagnostics disclaims all warranties expressed (including the implied warranty of



merchantability and fitness for use) in such an event. Consequently, MacroArray Diagnostics and its local distributors shall not be liable for damages indirect or consequential in such an event.

CHANGE HISTORY

Version	Description	Replaces
05	Information on precipitates added to chapter III; RUO symbol added at the end; Correction of typos	04



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