MACRO ARRAY DIAGNOSTICS

ALEX AIR

INSTRUCTION FOR USE

Contents [hide]

LANGUAGE DISCLAIMER

This Instruction for Use (IFU) is provided in multiple languages according to regulation (EU) 2017/746. In the event of any discrepancies or inconsistencies between the English version and any translated version, the English version shall prevail and be considered the authoritative reference.

LIABILITY STATEMENT

This IFU has been reviewed for accuracy. The instructions for the ALEX Air were correct at the time of publication. Subsequent versions of this guide may be updated without prior notice.

The ALEX Air kit is an in-vitro diagnostic device intended for use by trained laboratory personnel only. The ALEX Air kit may only be used for its intended purpose in accordance with this IFU. The IFU must be observed without exception. If you are unfamiliar with the use of the ALEX Air kit, you are obliged to obtain information from MacroArray Diagnostics (MADx) before using it. MADx assumes no liability for improper use of the ALEX Air kit. MADx shall only be liable for any harm or damage to property directly or indirectly resulting from errors in this IFU in the event of gross negligence or intent, and for personal injury only within the scope of the mandatory statutory provisions.

If any term or provision in this IFU shall be held to be illegal or unenforceable, in whole or in part, under any enactment or rule of law, such term or provision or part shall to that extent be deemed not to form part of this IFU but the enforceability of the remainder of this IFU shall not be affected.

DESCRIPTION

The ALEX Air is an Enzyme-Linked Immunosorbent Assay (ELISA) – based in-vitro diagnostic test for the quantitative measurement of allergen-specific IgE (sIgE).

This Instruction for Use is applicable for the following product:

Basic UDI-DI	REF	Product
91201229206JY	06-5001-01	ALEX Air for 50 Analyses

INTENDED PURPOSE

The ALEX Air test system is a quantitative in vitro diagnostic test for the measurement of 59 allergen specific IgE (sIgE) of inhalative allergens and a semi-quantitative in vitro diagnostic test for the measurement of total IgE (tIgE) in human serum or plasma

(exception EDTAplasma).

⚠ The test is intended for automatic analysis only.

SUMMARY AND EXPLANATION OF THE TEST

Allergic reactions are immediate type I hypersensitivity reactions and are mediated by antibodies belonging to the IgE class of immunoglobulins. After exposure to specific allergens, IgE-mediated release of histamine and other mediators from mast cells and basophils results in clinical manifestation such as asthma, allergic rhino-conjunctivitis, atopic eczema and gastrointestinal symptoms [1]. Therefore, a detailed sensitization pattern to specific allergens assists in the evaluation of allergic patients [2-6]. There is no restriction on the test population.

When developing IgE assays, age and sex are typically not considered as critical factors because IgE levels, which are measured in these assays, do not significantly vary based on these demographics.

All major type I inhalative allergen sources are covered by ALEX Air. A complete list of ALEX Air allergen extracts and molecular allergens can be found at the bottom of this instruction.

Important information for the user!

For the correct use of ALEX Air, 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 test system which is not described in this document or for modifications by the user of the test system.

Attention: The ALEX Air kit variant 06-5001-01 (50 arrays) is to be used for automated processing with MAX 9k (REF 17-0000-01) as well as MAX 45k (REF 16-0000-01) only, under no circumstance with the ImageXplorer device (REF 11-0000-01).

If needed, the Washing Solution (REF 00-5003-01) and Stop Solution (REF 00-5007-01) can be ordered separately. All further product information can be found in the corresponding instructions for use: https://www.madx.com/extras.

PRINCIPLE OF THE PROCEDURE

ALEX Air is an immunoassay test based on Enzyme-Linked Immunosorbent Assay (ELISA). Allergen extracts or molecular allergens, which are coupled to nanoparticles, are deposited in a systematic fashion onto a solid-phase forming a macroscopic array.

First, the particle-bound allergens react with specific IgE that is present in the patient's sample. After incubation, nonspecific IgE is washed off. The procedure continues by adding an enzyme-labelled anti-human IgE detection antibody which forms a complex with the particle-bound specific IgE. After a second washing step, substrate is added which is converted to an insoluble, colored precipitate by the antibody-bound enzyme. Finally, the enzyme-substrate reaction is stopped by adding a blocking reagent. The amount of precipitate is proportional to the concentration of specific IgE in the patient's sample.

The assay procedure is followed by an automated image acquisition and analysis which is integrated in the MAX device. The test results are analyzed with RAPTOR SERVER Analysis Software and reported in IgE response units (kUA/l). Total IgE results are also reported in IgE response units (kU/l). RAPTOR SERVER is available in version 1, for the full four-digit version number please refer to the RAPTOR SERVER imprint available at www.raptorserver.com/imprint.

SHIPMENT AND STORAGE

The shipment of ALEX Air takes place at ambient temperature conditions. Nevertheless, the kit must be stored immediately upon delivery at 2-8°C. Stored correctly, ALEX Air and its components can be used until the indicated expiration date.

⚠ Kit reagents are stable for 6 months after opening (at the indicated storage conditions).

WASTE DISPOSAL

Dispose the used ALEX Air cartridge and unused kit components with laboratory chemical waste. Follow all national, state, and local regulations regarding disposal.

GLOSSARY OF SYMBOLS

	Warning (GHS pictogram) Consult the Safety Data Sheet for more information.
	Catalogue number
	Sufficient for <n> tests

	Do not use if packaging is damaged
IVD	In-vitro diagnostic medical device
CE 2962	CE mark (Notified Body 2962: QMD Services GmbH, Zelinkagasse 10/ 3, 1010 Vienna, Austria)
LOT	Batch code
	Consult instructions for use
	Manufacturer
	Date of manufacture
	Do not re-use
	Use-by date
	Temperature limit
⚠	Caution
UDI	Unique device identifier
	ALEX Air Icon
MADx MACRO ARRAY DIAGNOSTICS	MacroArray Diagnostics (MADx)

KIT COMPONENTS

Each component (reagent) is stable until the date stated on each individual component's label.

Do not combine or mix reagents from different kit lots. For a list of allergen extracts and molecular allergens immobilized on the ALEX Air array, please contact support@madx.com.

Kit Components REF 06-5001-01	Content	Properties
ALEX Air Cartridge	5 Blisters à 10 ALEX Air for 50 analyses in total. Calibration via master curve available via RAPTOR SERVER Analysis Software.	Ready for use. Store at 2-8°C until expiry date.
ALEX Air Sample Diluent	1 bottle à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C (contains CCD inhibitor).
Washing Solution	4 x conc. 1 bottle à 250 ml	Store at 2-8°C until expiry date. Dilute 1 to 4 with demineralized water before use (250ml Washing Solution 4x conc. + 750 ml demineralized water). Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C.
ALEX Air Detection Antibody	1 bottle à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C.

ALEX Air Substrate Solution	1 bottle à 30 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature

Kit Components REF 06-5001-01	Content	Properties
		before use. Opened reagent is stable for 6 months at 2-8°C.
(ALEX Air) Stop Solution	1 bottle à 10 ml	Ready for use. Store at 2-8°C until expiry date. Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C. May appear as a turbid solution after prolonged storage. This has no effect on results.

REQUIRED EQUIPMENT FOR PROCESSING AND ANALYSING

- MAX device (MAX 9k or 45k)
- RAPTOR SERVER Analysis Software
- PC/Laptop with Internet connection

Required equipment, not provided by MADx:

- Demineralized Water
- Pipettes & tips (100 µl & 100 – 1000 µl)

Maintenance services according to manufacturer’s instructions.

HANDLING OF ARRAYS

Do not touch the array surface. Any surface defects caused by blunt or sharp objects

can interfere with the correct readout of the results. Do not acquire ALEX Air images before array is completely dry (dry at room temperature).

WARNINGS AND PRECAUTIONS

- It is recommended to wear hand and eye protection as well as lab coats and follow good laboratory practices when preparing and handling reagents and samples.
- In accordance with good laboratory practice, all blood source material (e.g. ingredients in reagents or other components) should be considered potentially infectious and handled with the same precautions as blood samples.
- ALEX Air Sample Diluent and Washing Solution contain sodium azide (<0.1%) as a preservative and must be handled with care. Safety data sheet is available upon request.
- The (ALEX Air) Stop Solution contains Ethylenediaminetetraacetic acid (EDTA)Solution and must be handled with care. Safety data sheet is available upon request.
- For in-vitro diagnostic use only. Not for internal or external use in humans or animals.
- Only personnel trained in laboratory practice should use this kit.
- Upon arrival, check the kit components for damage. If one of the components is damaged (e.g. buffer bottles), contact MADx (support@madx.com) or your local distributor. Do not use damaged kit components, as their use may lead to poor kit performance.
- Do not use reagents beyond their expiry dates.
- Do not mix reagents from different batches.

ELISA PROCEDURE

Preparation

Preparation of samples: Serum or plasma (heparin, citrate, no EDTA) samples from capillary or venous blood can be used. Blood samples can be collected using standard procedures.

Store samples at 2–8°C for up to one week. Keep serum and plasma samples at -20°C for prolonged storage. Shipment of serum/plasma samples at room temperature is applicable.

Always allow samples to reach room temperature before use.

Preparation of Washing Solution: Pour the content of 1 vial of Washing Solution into the washing container of the MAX Device. Fill demineralized water up to the red mark and carefully mix the container several times without generating foam. Store at 2-8°C until expiry date if not in use.

Personnel using ALEX Air must be trained in handling MAX devices (MAX45k or MAX9k). Instructions on how to run a test are provided in the MAX IFU subchapters XVII.7-10 and must be followed.

Depending on the sample volume, two operation modes are available for using ALEX Air: Prediluted manually and not prediluted. Tube requirements and instructions for dilutions are available in the MAX IFU chapter XXI (Technical Specification).

The current version of the MAX IFU (Systems) can be found here: https://www.madx.com/de/extras.

Assay time is approximately 3 h 30 min.

⚠ All reagents are to be used at room temperature (20-26°C). The assay must not be performed in direct sunlight.

Assay Calibration

The ALEX Air master calibration curve was established by reference testing against serum preparations with specific IgE against different antigens covering the intended measuring range. Lot specific calibration parameters are provided by the RAPTOR SERVER Analysis Software. ALEX Air sIgE test results are expressed as kUA/l. Total IgE results are semiquantitative and calculated from an anti-IgE measurement with lot-specific calibration factors, which are provided by the RAPTOR SERVER Analysis Software and selected according to the lot-specific QR-codes.

Curve parameters for each lot are adjusted by an in-house reference testing system, against serum preparations tested on ImmunoCAP (Thermo Fisher Scientific) for specific IgE against several allergens. The ALEX Air results are therefore indirectly traceable against the WHO reference preparation 11/234 for total IgE.

Systematic variations in signal levels between lots are normalized by heterologous calibration against an IgE reference curve. A correction factor is used to systematically adjust for lotspecific measurement deviations.

Measuring Range

Specific IgE: 0.3-50 kUA/l quantitative

Total IgE: 20-2500 kU/l semi-quantitative

QUALITY CONTROL

Record keeping for each assay

According to good laboratory practice it is recommended to record the lot numbers of all reagents used.

Control Specimens

According to good laboratory practice it is recommended that quality control samples are included within defined intervals. Reference values for certain commercially available control sera can be provided by MADx upon request.

DATA ANALYSIS

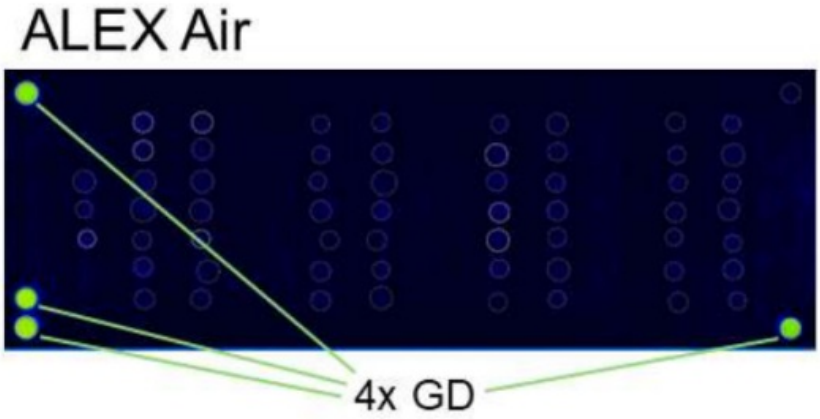
For the image analysis of processed arrays, the MAX device is to be used. ALEX Air images are automatically analyzed using RAPTOR SERVER Analysis Software and a report is generated summarizing the results for the user.

The array of the measurement with grid is displayed in the analytical image area. The software automatically identifies the position of the array in the image data based on the Guide Dots (GD). There are 4 Guide Dots on ALEX Air.

After processing, the Guide Dots have to be easily visible with the naked eye. Please also verify their correct orientation as shown in the image for ALEX Air below. If they are not visible, please contact your local distributor or MADx support on how to proceed. In case the Guide Dots are visible, the cartridge can be further analysed.

During the image acquisition of an ALEX Air cartridge, RAPTOR SERVER evaluates the signal of all Guide Dots as well as the background signal of the membrane surface. If all quality criteria are fulfilled, the “automatic QC” field under the image is set to “OK”.

In order to exclude the influence of artifacts in the automated image analysis (satellite spots, sample contaminations, dust, smeared spots, …), the images must be checked by a trained operator before the results are approved in order to exclude false results. In case of discrepancies between the processed array and the image acquired by the RAPTOR SERVER please consult your local distributor or MADx Support.



RESULTS

ALEX Air is a quantitative ELISA test for specific IgE and semi-quantitative method for total IgE. Allergen-specific IgE antibodies are expressed as IgE response units (kUA/l), total IgE results as kU/l. RAPTOR SERVER Analysis Software automatically calculates and reports sIgE results (quantitatively) and tIgE results (semi- quantitatively).

LIMITATIONS OF THE PROCEDURE

A definitive clinical diagnosis should only be made in conjunction with all available clinical findings by medical professionals and shall not be based on results of a single diagnostic method only.
In children, especially up to 2 years of age, the normal range of tIgE is lower than in adolescents and adults [7]. Therefore, it is to be expected that in a higher proportion of children younger than 2 years the total IgE-level lies below the specified detection limit. This limitation does not apply to specific IgE measurement.

EXPECTED VALUES

The close association between allergen-specific IgE antibody levels and allergic disease is well known and is described thoroughly in literature [1]. Each sensitized patient will show an individual IgE profile when tested with ALEX Air. The IgE response with samples from healthy non-allergic individuals will be below 0.3 kUA/l for single molecular allergens and for allergen extracts when tested with ALEX Air. The reference area for total IgE in adults is <100 kU/l. Good laboratory practice recommends that each laboratory establishes its own range of expected values.

PERFORMANCE CHARACTERISTICS

The Summary of Safety and Performance can be found on the MADx website: https://www.madx.com/extras.

The performance characteristics were developed based on ALEX² tests. Since ALEX Air is a derivative of ALEX², consisting of allergen subsets, these performance characteristics also apply to ALEX Air.

1. Precision (lot-to-lot variation) with ImageXplorer The lot-to-lot variation was determined on 3 cartridge lots in three separate runs. Multisensitized samples were included in the study. The study comprised 319 allergens per sample combinations covering 191 individual allergens at 3 different levels (> 10 kUA/l, 1-10 kUA/l and 0.3-1 kUA/l). [8]

	0.3 – 1 kUA/l	**1 – 10 kUA/l**	**>1 kUA/l**	**>10 kUA/l**
Total CV%	24.7	12.1	11.3	9.6

2. **Precision with MAX devices**

   The variation between different MAX devices in the ALEX² assay was determined on three MAX 45k and MAX 9k devices in three separate runs (same ALEX² lot). Three selected multisensitized samples were tested covering the majority of priority components at 3 different levels (> 10 kUA/l, 1-10 kUA/l and 0.3-1 kUA/l). For the selected allergen components, the CV (in %) was calculated between runs and between instruments (= total CV).

	0.3 – 1 kUA/l	1 – 10 kUA/l	> 1 kUA/l	> 10 kUA/l
Total CV% MAX 45k	24.0	11.0	10.6	9.1
Total CV% MAX 9k	20.6	10.1	9.4	8.8

3. **Repeatability (within-run precision) for ImageXplorer**

In the repeatability study, multi-sensitized samples were tested 10 times by the same operator on different days. The study comprised 319 allergen per sample combinations covering 165 individual allergens at 3 different levels (>10 kUA/l, 1-10 kUA/l and 0.3 – 1 kUA/l). [9]

	0.3 – 1 kUA/l	**1 – 10 kUA/l**	**>1 kUA/l**	**>10 kUA/l**
Total CV%	25.6	13.8	13.5	10.7

4. **Homogeneity for MAX devices**

   The homogeneity of the ALEX² results within a MAX test run was tested on three separate MAX 45k and MAX 9k devices. A single multi-sensitized positive test sample was tested at all positions of the cartridge carousel.

	0.3 – 1 kUA/l	**1 – 10 kUA/l**	**> 1 kUA/l**	**> 10 kUA/l**
TotalCV% MAX 45k	33.6	12.3	11.5	9.2
TotalCV% MAX 9k	28.1	10.3	9.8	9.3

5. **Analytical sensitivity**

   The Limit Of Detection (LOD) was determined in accordance with CLSI guideline EP17-A [10] for representative allergen components and was 0.3 kUA/l for all allergen components and all allergen extracts.

6. **Analytical specificity**

   There is no detectable cross-reactivity with other human Immunoglobulins (IgA, IgG1, IgG2, IgG3, IgG4 and IgM) at normal physiological concentrations.

7. **Interference**

   There is no detectable interference with bilirubin, cholesterol/triglycerides and hemoglobin at normal physiological concentrations. Neither is there an interference with tIgE which was tested in concentrations of up to 3000 kU/l.

8. **Information on clinical performance**

   For a correlation study, around 50 positive samples covering ≥ 50 positive responses (covering the measuring range for the 9 priority allergens) were tested. These samples cover also a correlation study with total IgE covering a measuring range from 1 kU/l to

2500 kU/l. The studies demonstrated high correlation and no significant differences. Similarly, performed reproducibility studies showed consistent results, with no significant differences observed. A clinical study called “Diagnostic Accuracy of the MADx Multi Array Xplorer (MAX 45k) Automated Laboratory System and the MADx Allergy Explorer Version 2 (ALEX²) – IgE Multiplex Test for the Diagnosis of Pre-defined Groups of Specific High-priority Allergens (MADMAX)” (reference number: NCT04435678) was successfully completed in April 2022. The primary objective of the study was to assess the diagnostic accuracy (sensitivity, specificity) of the MAX 45k/ALEX² IgE multiplex test in comparison to clinical symptoms. Furthermore, the usability as well as the processing duration (incl. hands-on time) were assessed. In total, 111 birch pollen allergic patients, 113 grass pollen allergic patients and 107 cat allergic patients were included in the study conducted from July 2020 to April 2022, leading to a total number of 839 patients. All set outcomes of this study were successfully achieved.

9. **Information on stability**

   Stability testing in accelerated and real-time stability of ALEX Air showed high robustness, 2 years postproduction stored at 2-8°C. Thus, the determined shelf life is 2 years. Additionally, as part of the accelerated stability study and real time stability study,

   transport stability studies were performed. For the transport simulation study, the kits were subjected to a transport simulation (TS) protocol before they were tested. Additionally, the packaging and labeling was tested for their convenience.

WARRANTY

The herein presented performance data were obtained using the procedure outlined in this 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.

ABBREVIATIONS

ALEX	Allergy Xplorer
CCD	Cross-reactive carbohydrate determinants
EDTA	Ethylenediaminetetraacetic acid
ELISA	Enzyme-Linked Immunosorbent Assay
IgE	Immunoglobulin E
IVD	In-vitro diagnostic
kU/l	Kilo units per Liter
kUA/l	Kilo units of allergen-specific IgE per liter
MADx	MacroArray Diagnostics
REF	Reference number
sIgE	Allergen-specific IgE
tIgE	Total IgE
µl	Microliter

ALLERGEN LIST ALEX AIR

Allergen extracts: Aca s, Par j, Can f ♂ urine

Purified natural components: nCup a1, nOle e 7, nPla a 2

Recombinant components: rAlt a 1, rAlt a 6, rAmb a 1, rAmb a 4, rArt v 1, rArt v 3, rAsp f 1, rAsp f 3, rAsp f 4, rAsp f 6, rBet v 1, rBla g 1, rBla g 2, rBla g 4, rBla g 5, rBlo t 21, rBlo t 5, rCan f 1, rCan f 2, rCav p 1, rChe a 1, rCla h 8, rCyn d 1, rDer p 1, rDer p 10, rDer p 2, rDer p 20, rDer p 23, rEqu c 1, rEqu c 4, rFel d 1, rFel d 2, rFel d 4, rFra e 1, rHom s LF, rLep d 2, rMus m 1, rOle e 1, rOle e 9, rOry c 1, rOry c 2, rOry c 3, rPar j 2, rPer a 7, rPhl p 1, rPhl p 12, rPhl p 2, rPhl p 5, rPhl p 7, rPla a 1, rPla a 3, rPla l 1, rSal k 1

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CHANGE HISTORY

Version	Description	Replaces
03	Table of Contents added; Language Disclaimer and Liability Statement added as chapter I and II; New label icons added to chapter IX; Information on sample dilution added to chapter XIV; Information on image analysis added to chapter XVI; Details on Performance Characteristics added to chapter XX; Typos corrected; Specific wording improved without changing the content.	02

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Documents / Resources

	MADx Macro Array Diagnostics Alex Air Kit [pdf] Instruction Manual Macro Array Diagnostics Alex Air Kit, Array Diagnostics Alex Air Kit, Diagnostics Alex Air Kit, Alex Air Kit

References

- User Manual

Alex Air Kit, Array Diagnostics Alex Air Kit, Diagnostics Alex Air Kit, Macro Array Diagnostics Alex Air Kit,

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