ALEX AIR
INSTRUCTION FOR USE

For Research Use only!

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I. 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 adevice 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.

II. DESCRIPTION

The ALEX Air is an Enzyme-Linked Immunosorbent Assay (ELISA) – based test for the quantitative measurement of allergen-specific IgE (sIgE) and is intended for research use only.

This Instruction for Use is applicable for the following product:

Basic UDI-DI	REF	Product
91201229206JY	06-5001-02	ALEX Air for 50 Analyses

III. INTENDED PURPOSE

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

This test is for research use only. The processing of ALEX Air should always be carried out by qualified researchers in a laboratory environment. The test is intended for MAX 45k and MAX 9k only.

	The test is intended for automatic analysis only.

IV. SUMMARY AND EXPLANATION OF THE TEST

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.

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.

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. This test is for research use only and not intended for the diagnosis or treatment of diseases.

Attention: The ALEX Air kit variant 06-5001-02 (50 arrays) is to be used for automated processing with MAX 9k (REF 17-0000-02) as well as MAX 45k (REF 16-0000-02) only, under no circumstance with the ImageXplorer device (REF 11-0000-02).

If needed, the Washing Solution (REF 00-5003-02) and Stop Solution (REF 00-5007-02) can be ordered separately. All further product information can be found in the corresponding instructions for use: https://www.madx.com/extras.

V. 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 sample. After incubation, non-specific 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 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 (kU_A/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.raptor-server.com/imprint.

VI. 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.

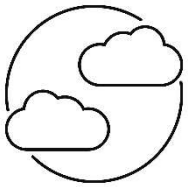
	Kit reagents are stable for 6 months after opening (at the indicated storage conditions).

VII. 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.

VIII. 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
	For Research Use only
	Batch code
	Consult instructions for use

	Manufacturer
	Date of manufacture
	Do not re-use
	Cartridge
	Use-by date
	Temperature limit
	Caution
	Unique device identifier
	ALEX Air Icon
	MacroArray Diagnostics (MADx)

IX. KIT COMPONENTS

New Nomenclature for Reagent Lots

Attention: We are introducing a new lot nomenclature for all MADx reagents (the nomenclature for the cartridges is not affected).

ALEX Air kits with lot number 06DAA01 and subsequently produced lots will be affected by this change.

Key Details:

- **No change for cartridge labels**
- The specific reagents of one reagent lot will show the same label nomenclature and can be combined with different cartridge lots.
  We will only vary **position 1 and 2** of our **three-letter code** for the reagents. For instance:
  - Reagents with labels **DAA** can be combined with the cartridge lots **DAA, DAB, DAC, DAD,… up to DAT**.
  - Reagents with labels **DBA** can be combined with the cartridge lots **DBA, DBB, DBC, DBD,… up to DBT.**
- The RAPTOR SERVER Analysis Software has already been updated to reflect these changes. **No action is required from customers.**
  The RAPTOR SERVER will recognize and combine the correct cartridges with the corresponding reagents.

Each component (reagent) is stable until the date stated on each individual component's label. Do not combine or mix reagents from different reagent lots (different first two letters). For a list of allergen extracts and molecular allergens immobilized on the ALEX Air array, please contact pm@macroarraydx.com.

Kit Components REF 06-5001-02	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).

Kit Components REF 06-5001-02	Content	Properties
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. + 750ml 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 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.

X. 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.

XI. 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).

XII. WARNINGS AND PRECAUTIONS

- This test is FOR RESEARCH USE ONLY and not for the diagnosis or treatment of diseases in humans or animals.
- 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.
- 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.

XIII. ASSAY 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/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 kU_A/l. Total IgE results are semi-quantitative 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 lot-specific measurement deviations.

Measuring Range

Specific IgE: 0.3-50 kU_A/l quantitative

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

XIV. 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.

XV. DATA ANALYSIS

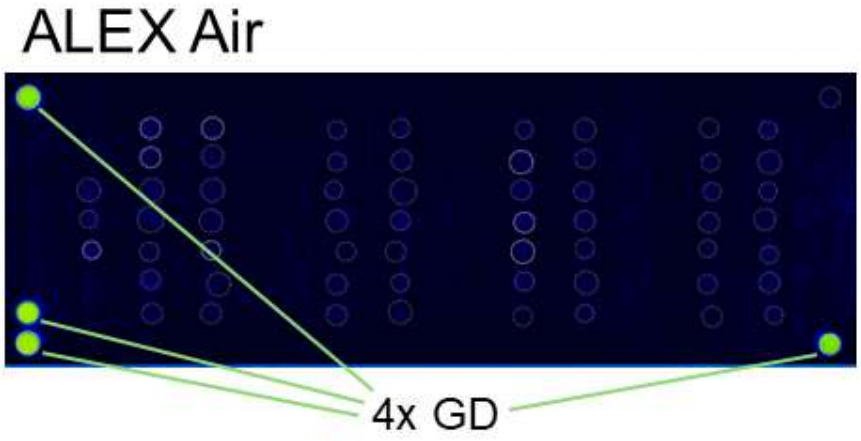
For the image analysis of processed arrays, the MAX device is to be used. ALEX Air images are automatically analyzed using RAPTOR SERVER Analysis Software and a report is generated summarizing the results for the user.

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.



XVI. 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 (kU_A/l), total IgE results as kU/l. RAPTOR SERVER Analysis Software automatically calculates and reports sIgE results (quantitatively) and tIgE results (semi- quantitatively).

XVII. LIMITATIONS OF THE PROCEDURE

In children, especially up to 2 years of age, the normal range of tIgE is lower than in adolescents and adults. 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.

XVIII. EXPECTED VALUES

Good laboratory practice recommends that each laboratory establishes its own range of expected values.

XIX. WARRANTY

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.

XX. ABBREVIATIONS

ALEX	Allergy Xplorer
CCD	Cross-reactive carbohydrate determinants
EDTA	Ethylenediaminetetraacetic acid
ELISA	Enzyme-Linked Immunosorbent Assay
IgE	Immunoglobulin E
RUO	Research Use Only
kU/l	Kilo units per Liter
kU_A/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

CHANGE HISTORY

Version	Description	Replaces
02	Adaptation to English IFU Version 04	01

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