ALEX FOOD
INSTRUCTIONS FOR USE

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I. LANGUAGE DISCLAIMER

These Instructions for Use (IFU) are 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.

II. LIABILITY STATEMENT

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

The ALEX Food kit is an in-vitro diagnostic device intended for use by trained laboratory personnel only. The ALEX Food 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 Food kit, you are obliged to obtain information from MacroArray Diagnostics (MADx) before using it. MADx assumes no liability for improper use of the ALEX Food 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.

III. DESCRIPTION

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

These Instructions for Use are applicable for the following product:

Basic UDI-DI	REF	Product
91201229207K2	07-5001-01	ALEX Food for 50 Analyses

IV. INTENDED PURPOSE

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

It is to be used by clinical chemistry laboratories, trained laboratory personnel and medical professionals for the purpose of supporting the clinical diagnosis of IgE mediated diseases, in conjunction with other clinical findings or diagnostic test results. The test is intended for MAX 45k and MAX 9k only.

	The test is intended for automatic analysis only.

V. 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 food allergen sources are covered by ALEX Food. A complete list of ALEX Food allergen extracts and molecular allergens can be found at the bottom of these instructions.

Important information for the user!

For the correct use of ALEX Food, 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 Food kit variant 07-5001-01 (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.

VI. PRINCIPLE OF THE PROCEDURE

ALEX Food 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, 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 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 (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.

VII. SHIPMENT AND STORAGE

The shipment of ALEX Food takes place at ambient temperature conditions. Nevertheless, the kit must be stored immediately upon delivery at 2-8°C. Stored correctly, ALEX Food 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).

VIII. WASTE DISPOSAL

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

IX. 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
	In-vitro diagnostic medical device
	CE mark (Notified Body 2962: QMD Services GmbH, Zelinkagasse 10/3, 1010 Vienna, Austria)
	Lot code
	Consult instructions for use
	Manufacturer
	Date of manufacture
	Do not re-use
	Cartridge
	Use-by date
	Temperature limit
	Caution

UDI	Unique device identifier
	ALEX Food Icon
MADx MACRO ARRAY DIAGNOSTICS	MacroArray Diagnostics (MADx)

X. 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 Food kits with lot number 07DAA01 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 Food array, please contact pm@macroarraydx.com.

Kit Components REF 07-5001-01	Content	Properties
ALEX Food Cartridge	5 Blisters à 10 ALEX Food 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 Food 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. + 750ml demineralized water). Allow reagent to reach room temperature before use. Opened reagent is stable for 6 months at 2-8°C.
ALEX Food 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 Food 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 Food) 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.

XI. REQUIRED EQUIPMENT FOR PROCESSING AND ANALYSING

- MAX device (MAX9k 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.

XII. 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 Food images before array is completely dry (dry at room temperature).

XIII. 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 Food 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 Food) 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 lots.

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

Depending on the sample volume, **two operation modes are available for using ALEX Food:** 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 Food 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 Food 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 Food 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

XV. 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.

XVI. DATA ANALYSIS

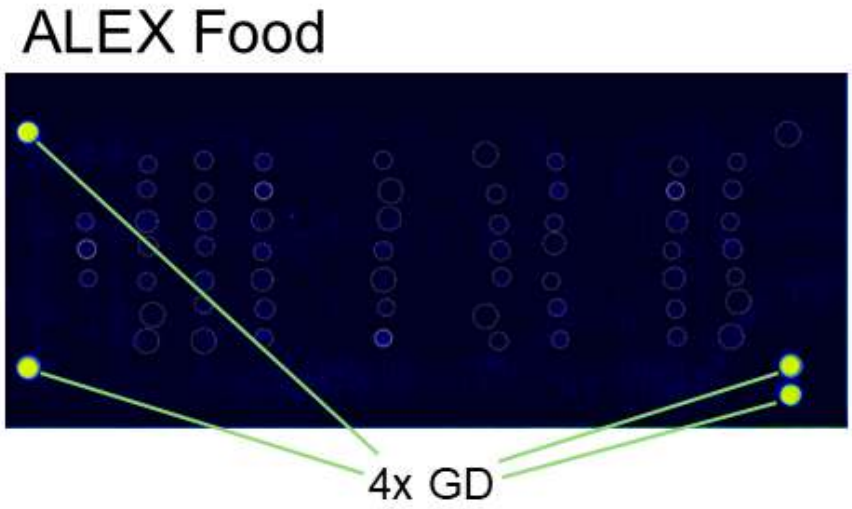
For the image analysis of processed arrays, the MAX device is to be used. ALEX Food images are automatically analyzed using RAPTOR SERVER Analysis Software and a report is generated summarizing the results for the user.

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 Food.

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 Food 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 Food 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.



XVII. RESULTS

ALEX Food 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).

XVIII. 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 certain areas of application (e.g. food allergy), circulating IgE antibodies may remain undetectable although a clinical manifestation of food allergy against a certain allergen may be present, because these antibodies may be specific to allergens that are modified during industrial processing, cooking or digestion and hence do not exist on the original food for which the patient is tested.

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.

XIX. 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 Food. The IgE response with samples from healthy non-allergic individuals will be below 0.3 kU_A/l for single molecular allergens and for allergen extracts when tested with ALEX Food.

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.

XX. 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 Food is a derivative of ALEX², consisting of allergen subsets, these performance characteristics also apply to ALEX Food.

1. Precision (lot-to-lot variation) with ImageXplorer

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

	0.3 - 1 kU_A/l	1 - 10 kU_A/l	>1 kU_A/l	>10 kU_A/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 multi-sensitized samples were tested covering the majority of priority components at 3 different levels (> 10 kU_A/l, 1-10 kU_A/l and 0.3-1 kU_A/l). For the selected allergen components, the CV (in %) was calculated between runs and between instruments (= total CV).

	0.3 - 1 kU_A/l	1 - 10 kU_A/l	> 1 kU_A/l	> 10 kU_A/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 allergens per sample combinations covering 165 individual allergens at 3 different levels (>10 kU_A/l, 1-10 kU_A/l and 0.3 - 1 kU_A/l). [9]

	0.3 - 1 kU_A/l	1 - 10 kU_A/l	>1 kU_A/l	>10 kU_A/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 kU_A/l	1 - 10 kU_A/l	> 1 kU_A/l	> 10 kU_A/l
Total CV% MAX 45k	33.6	12.3	11.5	9.2
Total CV% 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 kU_A/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, among others, 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 Food 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.

XXI. 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.

XXII. 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
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 FOOD

Allergen extracts: Pru du, Ber e, Car i, Lol spp, Pan b, Rud spp, Tri s

Purified natural components: nAct d 1, nAna o 3, nAra h 1, nAra h 3, nBos d 4, nBos d 5, nBos d 6, nBos d 8, nCor a 11, nCor a 9, nFag e 2, nGal d 2, nGal d 3, nGal d 5, nGly m 5, nGly m 6, nPis v 2, nTri a aA_TI

Recombinant components: rAct d 10, rApi g 2, rApi g 6, rAra h 2, rAra h 6, rAra h 9, rCor a 1.0401, rCor a 14, rCor a 8, rCra c 6, rCuc m 2, rGad m 1, rGal d 1, rGly m 4, rHom s LF, rJug r 1, rJug r 2, rJug r 3, rMal d 1, rPen m 1, rPen m 2, rPen m 3, rPen m 4, rPis v 1, rPru p 3, rRaj c Parvalbumin, rSal s 1, rSco s 1, rSes i 1, rSola l 6, rThu a 1, rTri a 14, rTri a 19, rZea m 14

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CHANGE HISTORY

Version	Description	Replaces
04	New label icon added to chapter IX; Explanation on lot-specific reagents added to chapter X; 'ELISA procedure' was changed to 'Assay Procedure' in Chapter XIV; Allergen nGad m 1 was changed to rGad m 1.	03

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