

Title: **ALEX³ - Summary of Safety and Performance (SSP)**

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Product: **MDF ALEX³**

Authors: **Nikola Rogic**

Reviewers: **Bernd Nowak, Birgit Wahlmüller, Robert Maczejka**

Approvers: **Robert Maczejka**

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ALEX³ - SUMMARY OF SAFETY AND PERFORMANCE

1. Device identification and general information

Device trade name(s)	ALEX³ Allergy Xplorer
Reference Number	**ALEX³ 20 tests:** 03-2001-01 **ALEX³ 50 tests:** 03-5001-01
Basic UDI-DI	91201229203JS
European Medical Device Nomenclature (EMDN) description / text	W01020205
Risk class of device	Class C
Is it a device for near-patient testing and/or a companion diagnostic?	No
Year when the first certificate was issued under Regulation (EU) 2017/746 covering the device	2024

Manufacturer's name and address	**MacroArray Diagnostics GmbH** Lemböckgasse 59, Top 4 1230 Vienna, Austria
Manufacturer's single registration number (SRN)	AT-MF-000030541
Authorized representative if applicable; name and the SRN	N/A
NB's name (the NB that will validate the SSP) and the NB's single identification number	QMD Services GmbHZelinkagasse 10/31010 Vienna, Austria+43 (1) 533 0077office@qmdservices.com www.qmdservices.comNotified Body (NB) Number: 2962

2. Intended Use of the device

2.1. Intended Purpose

ALEX³ Allergy Xplorer is a test kit used for in-vitro examination of human serum or plasma (exception EDTA-plasma) to provide information to aid the diagnosis of patients suffering from IgE-mediated diseases in conjunction with other clinical findings or diagnostic test results.

The IVD medical device detects allergen-specific IgE (sIgE) quantitatively and total IgE (tIgE) quantitatively in the range from 2 - 1000 kU/l (semi-quantitative 1001-2500 kU/l). The product is used by trained laboratory personnel and medical professionals in a medical laboratory.

2.2. Indications and target populations

The ALEX³ test system is intended for trained laboratory personnel and medical professionals only.

Any human serum or plasma (exception EDTA-plasma) from any target population can be used for analysis as there are no restriction on the target 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.

2.3. Limitations and/or contra-indications

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 in the original food for which the patient is tested.

Negative venom results only indicate undetectable levels of venom specific IgE antibodies (e.g. due to long term non-exposure) and do not preclude the existence of clinical hypersensitivity to insect stings.

In children, especially up to 2 years of age, the normal range of tIgE is lower than in adolescents and adults (Martins TB, Bandhauer ME, Bunker AM, Roberts WL, Hill HR. New childhood and adult reference intervals for total IgE. J Allergy Clin Immunol. 2014 Feb;133(2):589-91). 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.

Anti-IgE therapy is a contra-indication for the use of IgE-based in-vitro diagnostic tests.

3. Device description

3.1. Description of the device

ALEX³ is a solid-phase immunoassay. Allergen extracts or molecular allergens, which are coupled to nano-particles, 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 the Stop Solution. The amount of precipitate is proportional to the concentration of specific IgE in the patient sample. The test procedure is followed by image acquisition and analysis. The test results are reported in allergen IgE response units (kU_A/l) for the specific allergen and in IgE response units (kU/l) for total IgE (tIgE).

The product is used in a medical laboratory by trained laboratory personnel and medical professionals only.

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Figure 1: Symbolic image of processed ALEX³ array in cartridge

3.2. Description of the kit components

Components of the ALEX³ test kit	Amount (REF 03-2001-01)	Amount (REF 03-5001-01)	Description***	Regulatory Status
ALEX³ cartridge	20	50	Polystyrol cartridge containing a solid-phase immunoassay*.	component of IVD
Washing Solution	2 x 50 ml	1 x 250 ml (4 x conc.)	TBS-Tween (0.2%) Buffer, < 0.1 % Sodium Azide	IVD****
ALEX³ Sample Diluent	1 x 9 ml	1 x 30 ml	CCD Blocker, TBS-Tween (0.2%) Buffer, < 0.1 % Sodium Azide	component of IVD
ALEX³ Detection Antibody	1 x 11 ml	1 x 30 ml	Human Anti-IgE detection antibody in Conjugate Buffer with Additives.	component of IVD
ALEX³ Substrate Solution	1 x 11 ml	1 x 30 ml	NBT/BCIP Substrate (**NBT:** 4-Nitro blue tetrazolium chloride, solution, **BCIP:** 5-bromo-4-chloro-3-indolyl-phosphate, 4-toluidine salt)	component of IVD
(ALEX³) Stop Solution**	1 x 2.4 ml	1 x 10 ml	Ethylenediaminetetraacetic acid (EDTA)-Solution	IVD****

* The cartridges comprise an array (=immunoassay) with 307 spots, as follows:

- 300 different allergens,
- 2 spots for plausibility check (QC), named “Guide Dots”,
- 2 spots for sample pipetting control
- 3 spots with anti-total IgE antibodies for the (semi-)quantitative determination of total-IgE,
- a 2-dimensional QR-Code which is used to identify the cartridge during the scanning process

** The “ALEX³ Stop Solution” corresponds to and is synonymous with the “Stop Solution"

*** Reactive ingredients of each component are underlined

**** The Washing Solution 4x conc. (Basic UDI-DI: 9120122925036H) and Stop Solution (Basic UDI-DI: 9120122925076R) are components of the kit, but can be also purchased separately, if higher volumes of solution are required for automated processing.

3.3. A reference to previous generation(s) or variants if such exists, and a description of the differences

Product variant	Description	Differences
ALEX Allergy Explorer REF: 01-2001-01	Predecessor of ALEX² Allergy Xplorer	First Allergy Explorer product by MADx
ALEX² Allergy Xplorer REF: 02-2001-01, 02-5001-01	Predecessor of ALEX³ Allergy Xplorer	ALEX² was developed based on the predecessor product ALEX - Allergy Explorer. For ALEX², the allergen panel has been reworked and several improvements were implemented. For ALEX³ a sample pipetting control was added, total IgE was optimized and the allergen panel was updated with new relevant allergens.

3.4. Description of any accessories which are intended to be used in combination with the device

Accessories	Description	Status
Accessories/Products for MANUAL processing		
ImageXplorer (REF 11-0000-01)	Imaging device specifically built to acquire images of ALEX technology based test cartridges for the manual handling	IVD

Array holder (REF 14-0000-00) (optional)	Product for an easier handling of the cartridges during manual processing. The Array holder is manufactured and supplied by **Cubicure GmbH** Gutheil-Schoder-Gasse 17 Tech Park Vienna 1230 Wien, Österreich	-
Lab Rocker (REF 13-0000-00)	Vertical rocker is necessary during manual test procedure. (WxDxH – 28x15x33 cm, inclination angle 8°, required speed 8 rpm). The Lab Rocker is manufactured and supplied by **Biosan** Rātsupītes iela 7 k-2, Rīga, LV-1067, Latvija	-
Incubation chamber (REF 15-0000-00)	Necessary during manual test procedure (WxDxH – 35x25x2 cm) The Incubation chamber is manufactured and supplied by **Linder Helmut Ing KG** Czerningasse 18 1020 Wien, Österreich	-
Accessories/Products for AUTOMATED processing		
MAX devices: MAX 45k (REF 16-0000-01) MAX 9k (REF 17-0000-01)	Instruments for the automated processing of ALEX technology based test cartridges	IVD
Washing Solution 4x conc. (REF 00-5003-01)	Reagent for the automated processing of ALEX technology based test cartridges. The Washing and Stop Solution are components of the kit, but can be also purchased separately, if higher volumes of solution are required.	IVD
Stop Solution (REF 00-5007-01)		
Other required Accessories/Products		

RAPTOR SERVER Analysis Software (REF 22-0000-01)	Software for the acquisition and analysis of images taken by the ImageXplorer or MAX devices	IVD
PC or Laptop	-	-
Pipettes & Tips	10 - 100 µl & 100 - 1000 µl	-
Demineralized Water	-	-

3.5. Description of any other devices and products which are intended to be used in combination with the device

See section 3.4.

4. Reference to any harmonized standards and CS applied

EN ISO 13485:2016 **EN ISO 13485:2016/A11:2021** **EN ISO 13485:2016/AC:2018**	Quality management systems – Requirements for regulatory purposes (ISO 13485: 2016) • Amendment A11:2021 • Corrigendum AC:2018
EN ISO 14971:2019 **EN ISO 14971:2019/A11:2021**	Medical Devices – Application of risk management to medical devices (ISO 14971: 2019) • Amendment A11:2021
ISO 24971:2020	Medical Devices - Guidance on the application of ISO 14971
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1: 2021)
EN ISO 17511:2021	In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)
EN ISO 20916:2019	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2024)
EN ISO 23640:2015 **ISO 23640:2024**	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

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EN ISO 18113-1 **EN ISO 18113-2** **EN ISO 18113-3**	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements Part 2: In vitro diagnostic reagents for professional use Part 3: In vitro diagnostic instruments for professional use

5. Risks and warnings

5.1. Residual risks and undesirable effects

One residual risk involves the utilization of samples containing EDTA, which may have a detrimental effect on the test results. Although the complete exclusion of EDTA-containing samples cannot be assured, the Instructions for Use (IFU) provide appropriate guidelines for the samples used, thus leading to the assessment of this risk as acceptable.

Another residual risk pertains to the inhomogeneous distribution of the Stop Solution on the array. Nevertheless, the IFU offers clear procedural instructions to address this concern, resulting in the evaluation of the risk as acceptable.

5.2. 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.
- ALEX³ Sample Diluent and Washing Solution contain sodium azide (<0.1%) as a preservative and must be handled with care.
- The (ALEX³) Stop Solution contains Ethylenediaminetetraacetic acid (EDTA)-Solution and must be handled with care.
- 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.
- ALEX³ cartridges are intended for single use only and must not be reused. Reagents may be opened and reused within a period of up to 6 months from the date of first opening or until the kit contents are fully consumed, whichever occurs first.
- The following P and H statements are applicable to the Stop Solution: H319 - Causes serious eye irritation; P264 - Wash skin intensively after use; P305 + P351 + P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing; P337 + P313 - In case of persisting eye irritation: get medical advice.
- Any serious incident that occurs in relation to the use of this device shall be reported to the manufacturer at support@madx.com and to the competent authority of the Member State in which the user and/or the patient is established.

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- Malfunction or degradation of one or more test kit components may not be visually detectable (e.g. absence of visible degradation products). If this occurs, the built-in test control (guide dots) will fail or not be visible, and the RAPTOR SERVER Analysis Software will indicate a QC failure. Contact your local distributor or MADx support for guidance.

5.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN), if applicable

No FSCAs were initiated since launching ALEX³.

6. Summary of the performance evaluation as referred to in Annex XIII, and relevant information on the PMPF

6.1. Summary of scientific validity of the device

Using ELISA for the detection of sIgE and tIgE in serum is state of the art, moreover multiplex in vitro assays have several advantages against the widely used skin prick test:

Serum IgE testing entails no risk to the patient other than a blood draw and is preferable if the patient:

- has an unstable or uncontrolled medical condition
- is at high risk of anaphylaxis
- is taking essential medication that interferes with testing
- is very young such that the procedure would be unduly stressful, or
- has a skin condition that limits available skin for testing

The development of screening tests with multiple allergens or multiplex tests that identify multiple specific IgEs with a small blood volume is especially beneficial for testing very young children.

IgE allergy diagnostics and other relevant tests in allergy, a World Allergy Organization position paper

Ansotegui et al. World Allergy Organization Journal (2020) 13:100080
http://doi.org/10.1016/j.waojou.2019.100080

6.2. Summary of performance data from conducted studies of the device prior to CE-marking

6.2.1. Precision

The precision of the ALEX³ test was evaluated according to the “single-site study” design outlined in guideline EP05-A3. Here, multiple samples are assayed on 20 days, with one run per day, and three replicates per run ("20 x 1 x 3 design"). The statistical analysis treats the sources of variation associated with “days” and “runs” as factors. This method yields estimates for two precision types: repeatability (= within-run precision) and within-laboratory precision (= within-device precision = total precision). [1]

Repeatability	Results
CV [0.3 - 1.0 kU_A/l]	13.7 %

CV [1.0 - 10.0 kU_A/l]	7.0 %
CV [>10.0 kU_A/l]	5.7 %
CV [>1.0 kU_A/l]	6.6 %
Total Precision	**Results**
CV [0.3 - 1.0 kU_A/l]	25.7 %
CV [1.0 - 10.0 kU_A/l]	14.4 %
CV [>10.0 kU_A/l]	12.6 %
CV [>1.0 kU_A/l]	13.8 %

6.2.2. Trueness of measurement (sIgE)

63 different samples were tested with all 3 ALEX³ methods and ALEX² (MAX 45k only). Selected samples were also tested with the ImmunoCAP method for the priority allergens. The observed coefficient of determination, R^2, between the different methods are shown for all priority allergens:

Ara h 2

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,940	0,922	0,939	0,960
ALEX3 MAX 45K			0,993	0,990	0,998
ALEX3 MAX 9K				0,985	0,989
ALEX3 IX Manual					0,988
ALEX2 MAX 45k					

Pla l 1

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,949	0,993	0,987	0,978
ALEX3 MAX 45K			0,950	0,967	0,984
ALEX3 MAX 9K				0,976	0,969
ALEX3 IX Manual					0,996
ALEX2 MAX 45k					

Phl p 1

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,934	0,984	0,910	0,952
ALEX3 MAX 45K			0,976	0,769	0,964
ALEX3 MAX 9K				0,853	0,967
ALEX3 IX Manual					0,868
ALEX2 MAX 45k					

Der p 2

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,959	0,956	0,943	0,962
ALEX3 MAX 45K			0,991	0,983	0,993
ALEX3 MAX 9K				0,992	0,998
ALEX3 IX Manual					0,985
ALEX2 MAX 45k					

Gal d 1

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,986	0,983	0,980	0,979
ALEX3 MAX 45K			1,000	0,997	0,998
ALEX3 MAX 9K				0,999	0,998
ALEX3 IX Manual					1,000
ALEX2 MAX 45k					

Gal d 2

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,984	0,993	0,988	0,991
ALEX3 MAX 45K			0,997	0,999	0,999
ALEX3 MAX 9K				0,998	1,000
ALEX3 IX Manual					1,000
ALEX2 MAX 45k					

Pru p 3

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,954	0,991	0,972	0,975
ALEX3 MAX 45K			0,962	0,935	0,998
ALEX3 MAX 9K				0,991	0,994
ALEX3 IX Manual					0,995
ALEX2 MAX 45k					

Gly m 4

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,927	0,966	0,932	0,966
ALEX3 MAX 45K			0,992	1,000	0,992
ALEX3 MAX 9K				0,994	1,000
ALEX3 IX Manual					0,994
ALEX2 MAX 45k					

Art v 1

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,949	0,952	0,940	0,951
ALEX3 MAX 45K			0,998	0,995	0,999
ALEX3 MAX 9K				0,992	0,998
ALEX3 IX Manual					0,995
ALEX2 MAX 45k					

Car i

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,899	0,942	0,935	0,947
ALEX3 MAX 45K			0,989	0,996	0,979
ALEX3 MAX 9K				0,997	0,998
ALEX3 IX Manual					0,990
ALEX2 MAX 45k					

Fel d 1

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,911	0,954	0,844	0,871
ALEX3 MAX 45K			0,982	0,976	0,988
ALEX3 MAX 9K				0,961	0,975
ALEX3 IX Manual					0,997
ALEX2 MAX 45k					

Art v

R^2	ImmunoCAP	ALEX3 MAX 45K	ALEX3 MAX 9K	ALEX3 IX Manual	ALEX2 MAX 45k
ImmunoCAP		0,992	0,998	0,994	0,991
ALEX3 MAX 45K			0,994	0,999	0,978
ALEX3 MAX 9K				0,996	0,995
ALEX3 IX Manual					0,984
ALEX2 MAX 45k					

Results	The mean R^2 between all methods is **0.972** The mean R^2 between ImmunoCAP and ALEX³_MAX 45k is **0.949** The mean R^2 between ImmunoCAP and ALEX³_MAX 9k is **0.969** The mean R^2 between ImmunoCAP and ALEX³_ImageXplorer is **0.947** (for details see figure above)

6.2.3. Trueness of measurement (tIgE)

28 samples were tested with all 3 ALEX³ methods and ImmunoCAP as a reference method for tIgE. Additionally, a negative sample was spiked with the WHO standard 11/234 and tested in duplicates at 9 different dilutions.

Results	tIgE method comparison "real samples": R^2 tIgE ImmunoCAP and ALEX³_MAX 45k is **0.963** R^2 tIgE ImmunoCAP and ALEX³_MAX 9k is **0.919** R^2 tIgE ImmunoCAP and ALEX³_MAX ImageXplorer is **0.963** tIgE method comparison "spiked samples": R^2 MAX 45k is **0.996** & interdilutional CV: **5.62 %** R^2 MAX 9k is **0.981** & interdilutional CV: **5.67 %** R^2 ImageXplorer is **0.966** & interdilutional CV: **7.19 %**

6.2.4. Analytical sensitivity

The Limit Of Detection (LoD) for sIgE was determined for representative allergen components (priority allergens) and was below 0.3 kU_A/l for all tested allergen components. The Limit Of Detection (LoD) for tIgE is 1.27 kU/l. The Limit of Quantification (LoQ) is not applicable for this test.

6.2.5. Analytical specificity

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

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.

6.3. Summary of performance data from other sources

No relevant performance data from other external sources that are applicable to ALEX³ are available. Therefore this section is considered not applicable. All performance and safety data are derived from the

manufacturer's own performance evaluation and post-market activities.

6.3.1. Usability

To analyze the quantitative usability of the MAX system, we calculated the System Usability Scale (SUS). The SUS is a standardized questionnaire designed to assess perceived usability (Brooke, 1996, 2013; Sauro, 2011). We performed a standard questionnaire of 10 items. It is a mixed-tone questionnaire in which the odd-numbered items have a positive tone, and the even-numbered items have a negative tone.

A SUS value of 97.5% was achieved, which represents an excellent usability.

6.4. An overall summary of the performance and safety

ALEX³ is an innovative product that improves allergy diagnosis through the ability to detect specific IgE against a wide range of molecular allergens and allergen extracts, as well as total IgE. ALEX³ demonstrates a high specificity and sensitivity. Safety measures have been implemented to protect patients, users and all persons involved. Through risk assessment, all known and foreseeable potential risks associated with the use of ALEX³ have been determined to be acceptable given the significant benefits it provides to patients.

Overall, ALEX³ is considered a reliable, safe and sensitive tool for supporting the diagnosis of a wide range of allergies.

6.5. Ongoing or planned post-market performance follow-up

Performance and relevant scientific data from the use of the device is proactively collected with the aim of:

- confirming the safety and performance of the device throughout its expected lifetime,
- identifying previously unknown risks or limits to performance and contra-indications,
- identifying and analyzing emergent risks on the basis of factual evidence,
- ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio, and
- identifying possible systematic misuse.

Feedback from users (e.g. survey, direct feedback,...), screening of scientific literature, customer inquiries and complaints are systematically evaluated. Performance data of ALEX³ is collected and analyzed to catch potential trends early on. New scientific and clinical data are gained by getting new cooperation partners, where ALEX³ is used for the analysis.

7. Metrological traceability of assigned values

7.1. Explanation of the unit of measurement, if applicable

Total IgE results are reported in IgE response units (kU/l). The sIgE (specific IgE) results are reported in kU_A/l, whereas 1 kU/l correlates to 2.42 ng/ml.

During development a master calibration curve was established. The master calibration curve is stored in the RAPTOR SERVER Analysis Software. The customer performs a measurement and the RAPTOR SERVER Analysis Software takes the Signal-to-Noise data and calculates, based on the master calibration curve, the calibrated data in kU_A/l and kU/l, respectively.

7.2. Identification of applied reference materials and/or reference measurement procedures of higher order used by the manufacturer for the calibration of the device

There is no reference material for sIgE available. For tIgE a WHO reference preparation 11/234 is available.

MADx uses sera which are tested with ImmunoCAP (Thermo Fisher), which at the moment is perceived as “reference method” for in vitro IgE testing (WAO position paper).

The validity of the master calibration curve is controlled with control sera with known sIgE levels, e.g. Lyphochek Allergen sIgE, Panel A by Bio-Rad Laboratories or the recently launched QualityXplorer by MADx.

8. Suggested profile and training for users

The ALEX³ test system is for trained laboratory personnel and medical professionals only. It is essential that ALEX³ is handled and used by qualified clinical laboratory personnel who have undergone the appropriate training. The following profile and training guidelines are recommended:

Professional Qualifications: Users should hold relevant qualifications in clinical laboratory science or a related discipline.

Specific Training: MADx provides comprehensive training programs specifically designed for ALEX³, the related products and in vitro diagnostic procedures.
During the distributor onboarding process, extensive training is provided across various modules covering specific topics such as instrument operation, sample preparation, assay setup, assay processing, hardware installation, software application, data interpretation, quality control measures and more. This training is conducted through live sessions either at MADx or remotely via web-based training. For end customers, a "train-the-trainer" model is employed, where trained distributors are responsible for educating the final users.

In Vitro Diagnostic Expertise: MADx offers extensive knowledge and expertise in the field of in vitro allergy diagnostics. Users can depend on MADx's guidance regarding regulatory requirements, quality assurance, and best practices for using IVD products for allergy diagnostics. This expertise ensures both compliance and the reliability of test results.

Compliance with IFU: Users are required to strictly follow the instructions provided in the Instructions for Use (IFU) accompanying the product. The IFU contains essential information on the proper handling, and usage of the test system. All users of ALEX³ must acknowledge and confirm that they have read and understood the IFU before accessing the RAPTOR SERVER Analysis Software in order to be able to process and analyse the test. This acknowledgment must be renewed with each release of a new version of the IFU.
MADx is available to provide clarification and support to ensure users adhere to the recommended procedures and protocols.

Ongoing Education and Proficiency: MADx encourages users to engage in continuous education and professional development. MADx offers access to a variety of educational resources, workshops, conferences, and training programs designed to enhance users' skills and knowledge of allergy-specific in vitro diagnostics.

9. Revision history

SSP Revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	09-2025	First compilation	☐ Yes Validation language: English ☑ No (only applicable for Class C (IVDR, Article 48 (7)) for which the SSP is not yet validated by the NB)
2.0	10-2025	Added reference to EN ISO 20916:2024; Update of REF for ALEX² Allergy Xplorer	☐ Yes Validation language: English ☑ No
3.0	02-2026	The release date of the approved SSPs was not reflected in the last update; the date has been updated to indicate the month and year.	☐ Yes Validation language: English ☑ No
4.0	05-2026	The reference numbers (REFs) and corresponding supplier information for accessories have been included (section 3.4) to ensure completeness and traceability. In alignment with the feedback received from the notified body: A statement was included in order to clarify that no relevant external performance data have been identified and section 6.3. is therefore considered not applicable; and an additional statement addressing the limit of quantification (LOQ) has been incorporated in section 6.2.4. Analytical sensitivity, in alignment with the feedback received from the notified body.	☑ Yes Validation language: English ☐ No

5.0	11-2026	V5.0 is identical to V4.0. An updated is being performed so that we can state that V4.0 was validated by the Notified Body as part of the positive TD Review during surveillance and post-certification monitoring. There are no changes in the content between V4.0 and V5.0.	☑ Yes (*V5.0 is identical to V4.0 content-wise*) Validation language: English ☐ No







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MacroArray Diagnostics (MADx)

Lemböckgasse 59, Top 4

1230 Vienna, Austria

+43 (0)1 865 2573

www.madx.com

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