

Title:	**RAPTOR SERVER Analysis Software - Summary of Safety and Performance (SSP)**
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Valid until:	**-**

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Table of contents

1. Device Identification and General Information
2. Intended Use of the Device
3. Intended Purpose and Other Indications
4. Indications and Target Populations
5. Limitations and/or Contra-Indications
6. Device Description
7. Description of the Device
8. In case the Device is a Kit, Description of the Components
9. A Reference to Previous Generation(s) or Variants if such exists, and a Description of the Differences
10. Description of any Accessories which are intended to be used in Combination with the Device
11. Description of any Other Devices and Products which are intended to be used in Combination with the Device
12. Reference to any Harmonized Standards and CS applied
13. Risks and Warnings
14. Residual Risks and Undesirable Effects
15. Warnings and Precautions
16. Other Relevant Aspects of Safety, including a Summary of any Field Safety Corrective Action (FSCA including FSN), if applicable
17. Summary of the Performance Evaluation as referred to in Annex XIII, and Relevant Information on the PMPF
18. Summary of Scientific Validity of the Device
19. Summary of Performance Data from Conducted Studies of the Device prior to CE-Marking
20. Summary of Performance Data from Other Sources (e.g. Equivalent Devices), if applicable
21. An Overall Summary of the Performance and Safety
22. Ongoing or Planned Post-Market Performance Follow-Up
23. Metrological Traceability of Assigned Values

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24. Explanation of the Unit of Measurement, if applicable

25. Identification of Applied Reference Materials and/or Reference Measurement Procedures of Higher Order used by the Manufacturer for the Calibration of the Device

26. Suggested profile and Training for Users

27. Revision History

Version history

Approval

Signatures

1. Device Identification and General Information

Device Trade Name(s)	RAPTOR SERVER Analysis Software
Reference Number	22-0000-01
Basic UDI-DI	91201229222JW
European Medical Device Nomenclature (EMDN) Description / Text	W0201030192
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 +43 (1) 865 25 73 office@madx.com www.madx.com
Manufacturer's Single Registration Number (SRN)	SRN: AT-MF-000030541
Authorized Representative; Name and the SRN (if applicable)	N/A
NB's Name (the NB that will validate the SSP) and the NB's Single Identification Number	QMD Services GmbH Zelinkagasse 10/3 1010 Vienna, Austria +43 (1) 533 0077 office@qmdservices.com www.qmdservices.com Notified Body (NB) Number: 2962

2. Intended Use of the Device

3. Intended Purpose and Other Indications

The RAPTOR SERVER Analysis Software drives and influences MADx processing systems in combination with ALEX technology-based products.

The software analyzes the output from ALEX technology-based arrays and is used by trained laboratory personnel and medical professionals in a medical laboratory.

4. Indications and Target Populations

The target population depends on the respective test being performed (ALEX² Allergy Xplorer, ALEX Air, ALEX Food, ALEX³ Allergy Xplorer) in combination with the RAPTOR SERVER Analysis Software. Therefore, the target population of respective test is applicable: The test can be used for any population without restriction; the test is not for near-patient testing nor companion diagnostic.

5. Limitations and/or Contra-Indications

RAPTOR SERVER Analysis Software is only used in combination with MADx products and is therefore not a standalone software.

Limitations and contraindications are specific to ALEX² Allergy Xplorer, ALEX Air, ALEX Food, ALEX³ Allergy Xplorer:

There are no restrictions on the test/target population (i.e. age, sex).

The test is not intended for companion diagnostics.

No EDTA plasma is allowed to be used in the course of performing the test.

6. Device Description

7. Description of the Device

RAPTOR SERVER Analysis Software is a web application and is operated via the browser. RAPTOR SERVER Analysis Software is a software for the acquisition and analysis of images taken by the ImageXplorer or MAX Devices from processed ALEX technology-based arrays*. RAPTOR SERVER Analysis Software performs the storage of data and creation of reports based on the diagnostic lab results and only works in combination with ALEX technology-based arrays, and vice versa.

*The term '**ALEX technology-based array**' in this context refers to ALEX² Allergy Xplorer, ALEX Air, ALEX Food, ALEX³ Allergy Xplorer, which is based on the technology first used in ALEX.

8. In case the Device is a Kit, Description of the Components

N/A (RAPTOR SERVER Analysis Software is not a kit)

9. A Reference to Previous Generation(s) or Variants if such exists, and a Description of the Differences

Raptor Analysis Software, called Raptor (REF 12-0000-01) was available on the market as IVD under IVDD (self-declared, Classification: Other device). The support was discontinued by the end of 2021. The RAPTOR SERVER Analysis Software was developed based on the Raptor Analysis Software that therefore represents the previous generation.

The main difference is that RAPTOR SERVER Analysis Software is web-based in contrast to Raptor Analysis Software.

10. Description of any Accessories which are intended to be used in Combination with the Device

Product	Description
IVD: **ALEX² Allergy Xplorer** (REF Number for 20 Test Kits 02-2001-01, REF Number for 50 Test Kits 02-5001-01)	Immunoassay for Measurement of Specific Immunoglobulin E (IgE) against 295 Allergens.
IVD: **ALEX Air** (REF Number 06-5001-01)	Immunoassay for Measurement of Specific Immunoglobulin E (IgE) against 58 Allergens.
IVD: **ALEX Food** (REF Number 07-5001-01)	Immunoassay for Measurement of Specific Immunoglobulin E (IgE) against 58 Allergens.
IVD: **ALEX³ Allergy Xplorer** (REF Number for 20 Test Kits 03-2001-01, REF Number for 50 Test Kits 03-5001-01)	Immunoassay for Measurement of Specific Immunoglobulin E (IgE) against 300 Allergens.
IVD: **ImageXplorer** (REF Number 11-0000-01)	Imaging Device built to acquire Omages of ALEX Technology-Based Arrays.
IVD: **MAX 9k** (REF Number 17-0000-01)	Automated Batch Analyzer intended to be used to perform ALEX Technology-Based Immunoassays.
IVD: **MAX 45k** (REF Number 16-0000-01)	Automated Batch Analyzer intended to be used to perform ALEX Technology-Based Immunoassay.

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11. Description of any Other Devices and Products which are intended to be used in Combination with the Device

Product	Description
IVD: **Lyphochek Allergen sIgE Control, Panel A** (REF 12000142, REF 12000144)	Assayed, Lyophilized Human Serum based Control for Monitoring Precision of In-Vitro Allergen specific IgE Test Procedures.
PC or **Laptop**	RAPTOR SERVER Analysis Software is a Cloud-Based Software and can be accessed via the Internet.

12. Reference to any Harmonized Standards and CS applied

EN ISO 13485:2016, **EN ISO 13485:2016/A11:2021**	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (ISO 13485:2016)
EN ISO 13485:2016, **EN ISO 13485:2016/A11:2021,** **EN ISO 13485:2016/AC:2018**	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes (ISO 13485:2016)
EN ISO 14971:2019, **EN ISO 14971:2019/A11:2021**	Medical Devices - Application of Risk Management to Medical Devices (ISO 14971:2019)
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 20916:2024	In-Vitro Diagnostic Medical Devices - Clinical Performance Studies using Specimens from Human Subjects - Good Study Practice (ISO 20916:2024)

Reference to Applicable Standard

EN 62304:2006 **EN 62304:2006/AC:2008**	Medical Device Software - Software Life-cycle Processes (IEC 62304:2006)

13. Risks and Warnings

14. Residual Risks and Undesirable Effects

The risks were evaluated based on recognized potential hazards during the developmental phase of the software, on the feedback of employees or customers and on post-market surveillance activities. For each software update, an evaluation takes place whether new risks appeared or existing risks were changed. The same evaluation takes place during CAPAs, change requests and deviations.

For all risks, appropriate mitigation strategies have been implemented. These risks and relevant precautions implemented are addressed in detail in the Risk Management File. Hence, all Residual Risks were thoroughly evaluated and found to be acceptable. The Benefit- Risk Assessment reveals that all known and foreseeable risks, and any undesirable effects have been minimized and can be acceptable when weighed against the evaluated potential benefits to the patients and/or the user arising from the intended performance of the software during normal conditions of use.

There are no specific restrictions associated with the use. It can be safely used in all age groups as long as appropriate samples are collected.

15. Warnings and Precautions

Warnings and precautions of RAPTOR SERVER Analysis Software:

- Results and data must be manually approved by a qualified person. RAPTOR SERVER Analysis Software suggests optimal settings (e.g., grid settings), which require manual review and optimization if necessary.
- The approval of this report does not automatically constitute a diagnosis. This report must be considered alongside other clinical findings and interpreted by an allergologist or physician. Always consult a qualified healthcare professional for accurate diagnosis and treatment recommendations.
- The RAPTOR SERVER Analysis Software including the API has been fully validated by MADx. The interaction between any external software and the API, as well as the external software itself, are not covered by the validation conducted by MADx.
- Standard data protection, data integrity and data security measures must be followed. These include, but are not limited to: Using strong, unique passwords, using multi-factor authentication, restricting access to the software and data to authorized personnel only, not sharing sensitive information (e.g. API key, passwords, etc.)

16. 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 RAPTOR SERVER Analysis Software.

17. Summary of the Performance Evaluation as referred to in Annex XIII, and Relevant Information on the PMPF

RAPTOR SERVER Analysis Software analyzes the output from ALEX technology-based tests. The scientific validity, analytical and clinical performance can only be evaluated in conjunction with an ALEX technology-based test.

The scientific validity, analytical and clinical performance of the test system, consisting of RAPTOR SERVER Analysis Software and ALEX technology-based test, are described in the performance evaluation report of the respective test.

18. Summary of Scientific Validity of the Device

State of the Art

RAPTOR SERVER Analysis Software is built upon the Microsoft .NET platform and related state-of-the-industry technologies and frameworks. Special care is taken to use up-to-date versions of the platform and frameworks to ensure a state-of-the-art software product.

RAPTOR SERVER Analysis Software was developed following EN 62304:2006, which reflects the current state of the art.

Association of Analyte with Clinical Condition

The analyte is dependent on ALEX² Allergy Xplorer, ALEX Air, ALEX Food, ALEX³ Allergy Xplorer. Further information on the association of analyte with clinical condition can be found in the Summary of Safety and Performance of the respective test.

Summary and Conclusion

The scientific validity of RAPTOR SERVER Analysis Software is demonstrated by developing the software according to the state of the art and by the scientific validity of the respective test.

19. Summary of Performance Data from Conducted Studies of the Device prior to CE-Marking

RAPTOR SERVER Analysis Software shows no clinical or analytical performance on its own. The evaluation is therefore carried out in combination with ALEX² Allergy Xplorer. Performance data of RAPTOR SERVER Analysis Software are based on ALEX² Allergy Xplorer:

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 allergen 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). [1]

	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

PRECISION WITH MAX DEVICES

The variation between different MAX Devices in the ALEX² Allergy Xplorer assay was determined on three MAX 45k and MAX 9k devices in three separate runs (same ALEX² Allergy Xplorer 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 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

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 kU_A/l, 1-10 kU_A/l and 0.3 - 1 kU_A/l). [2]

	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

HOMOGENEITY FOR MAX DEVICES

The homogeneity of the ALEX² Allergy Xplorer 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

ANALYTICAL SENSITIVITY

The Limit Of Detection (LOD) was determined in accordance with CLSI guideline EP17-A [3] for representative allergen components and was below 0.3 kU_A/l for all allergen components and all allergen extracts.

ANALYTICAL SPECIFICITY

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

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.

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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_A/l to 2500 kU_A/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 Allergy Xplorer) - 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 Allergy Xplorer 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.

INFORMATION ON STABILITY

Stability testing in accelerated and real-time stability of ALEX² Allergy Xplorer showed high robustness, 2 years post production 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.

20. Summary of Performance Data from Other Sources (e.g. Equivalent Devices), if applicable

There are various software systems available for both singleplex and multiplex devices, each tailored to meet specific usage requirements.

RAPTOR SERVER Analysis Software was programmed and developed for multiplex analysis, without any reference device. High performance and constant improvement is ensured by regular validation and updates, in-house testings, strict compliance to regulations and constant enhancements due to thorough post-market surveillance i.e. through customer feedback evaluations. The analysis process (quantification from an image) is well established in computer science and an industry standard (refer to section 2.5. Multiplex ELISA Analysis with MultiSero Software of Byrum et al. MultiSero: An Open-Source Multiplex-ELISA Platform for Measuring Antibody Responses to Infection. Pathogens. 2023 May 2;12(5):671. doi: 10.3390/pathogens12050671.

It has to be noted that the performance of the RAPTOR SERVER Analysis Software is evaluated with respect to the used test, namely ALEX² Allergy Xplorer. Performance data of ALEX² Allergy Xplorer are summarised in section 19. Summary of Performance Data from Conducted Studies of the Device prior to CE-Marking.

21. An Overall Summary of the Performance and Safety

The RAPTOR SERVER Analysis Software is used in combination with ALEX² Allergy Xplorer, ALEX Air, ALEX Food, ALEX³ Allergy Xplorer which are innovative products that improve allergy diagnosis through the ability to detect specific IgE against a wide range of molecular allergens and allergen extracts, as well as total IgE.

The RAPTOR SERVER Analysis Software analyzes, processes and interprets results of ALEX technology-based tests with high specificity, positive/negative predictive values 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 RAPTOR SERVER Analysis Software and ALEX technology-based tests have been determined to be acceptable given the significant benefits it provides to patients. Overall, RAPTOR SERVER Analysis Software is a robust, reliable and safe tool for supporting the diagnosis of a wide range of allergies.

22. Ongoing or Planned Post-Market Performance Follow-Up

The ongoing or planned post-market performance follow-up (PMPF) of the RAPTOR SERVER Analysis Software and its combination with ALEX² Allergy Xplorer, ALEX Air, ALEX Food, ALEX³ Allergy Xplorer is essential to ensure their continuous safety and performance. The structured approach taken to monitor and improve these products post-launch is outlined in the following.

The Post-Market Surveillance and PMPF initiatives focus on continuously assessing the safety and performance of the RAPTOR SERVER Analysis Software and its compatibility with ALEX² Allergy Xplorer, ALEX Air, ALEX Food, ALEX³ Allergy Xplorer. These efforts are integral to maintaining product integrity and meeting regulatory requirements.

A comprehensive Post-Market Surveillance Plan, which includes PMPF activities, has been established. Key measures include:

- **Vigilance and Incident Handling:** Prompt identification and management of incidents related to the software's performance or safety.
- **Complaint Handling and Analysis:** Systematic evaluation of feedback and complaints from distributors, customers, and users to address issues promptly.
- **Literature and Scientific Data Surveillance:** Ongoing monitoring of published literature and scientific findings relevant to the software's safety and performance.
- **Performance Metrics Monitoring:** Tracking metrics such as software releases, hotfixes, bug occurrences, and validation failures to gauge performance and reliability.

Data collected from distributors, customers, users, healthcare professionals, and regulatory authorities undergoes rigorous analysis. Insights gained from this analysis drive continuous improvement efforts aimed at enhancing product performance and ensuring safety. Any update of the respective PMPF evaluation report and the periodic safety update report (PSUR) will also be evaluated if it will lead to an update of the summary of safety and performance.

The ongoing post-market performance follow-up of the RAPTOR SERVER Analysis Software and ALEX technology-based tests underscores our commitment to delivering high-quality, safe, and effective software solutions. Through diligent surveillance and proactive measures, we strive to meet user expectations and regulatory standards while advancing product excellence. This structured approach ensures that our software remains robust and responsive to evolving market needs and regulatory requirements.

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23. Metrological Traceability of Assigned Values

24. 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.

25. 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.

26. Suggested profile and Training for Users

The RAPTOR SERVER Analysis Software is for trained laboratory personnel and medical professionals only. It is essential that RAPTOR SERVER Analysis Software 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 RAPTOR SERVER Analysis Software, 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 software. All users of the RAPTOR SERVER Analysis Software must acknowledge and confirm

that they have read and understood the IFU before accessing the software. 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.

27. Revision History

SSP Revision Number	Date Issued	Change Description	Revision Validated by the Notified Body
1.0	09-2024	First Compilation of the Document.	☑ 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	ALEX Air, ALEX Food and ALEX³ Allergy Xplorer were added to the scope. Added Reference to EN ISO 20916:2024.	☐ 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	11-2026	No content updates in the document. The document was transferred from Qualio to Confideck, where it will be updated from now on. Editorial changes within the document; Update of references; Addition of reusable content snippets and blocks.	☐ Yes Validation Language: English ☑ No







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