



RAPTOR

SERVER ANALYSIS SOFTWARE

INSTRUCTION FOR USE

For Research Use only!

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DISCLAIMER

MacroArray Diagnostics (MADx) has validated the provided instructions, reagents, instrument, software, and customizable features for this analyzer to optimize product performance and meet product specifications. User defined modifications are not supported by MADx as they may affect performance of the analyzer and test results. It is the responsibility of the user to validate any modifications made to these instructions, instruments, reagents, or software provided by MADx.

Please consult the relevant instructions for use before processing!

The following products are within the scope of this document and are hereinafter referred to as “tests” or “test kits”:

Product name	REF-Number
ALEX ²	02-2001-02, REF 02-5001-02
ALEX Air	06-5001-02
ALEX Food	07-5001-02
ALEX ³	03-2001-02, REF 03-5001-02
FOX	80-2001-02, REF 80-5001-02, REF 80-0001-02

LIABILITY STATEMENT

This guide was checked for correctness. The instructions and descriptions for the RAPTOR SERVER Analysis Software (syn. RAPTOR SERVER, RS), ImageXplorer and MAX Devices were valid at the time this guide was written. Subsequent guides may be changed without prior notice; however, MADx assumes no liability for harm caused directly or indirectly by errors from the guide. The ImageXplorer, MAX Devices and RAPTOR SERVER are devices that are intended to be used by trained laboratory personnel only.

This guide and the software described are protected by copyright. No part of this guide or of the software described may be duplicated, reproduced, or copied to an electronic medium or machine-readable format without prior written permission from MADx.



I. ABBREVIATIONS

DPA	Data Protection Agreement
GD	Guide dots
IFU	Instructions for use
IgE	Immunoglobulin E
IgG	Immunoglobulin G
MOD	Multiplex On Demand
QC	Quality control
RUO	Research use only
ToS	Terms of Service

II. INTENDED PURPOSE

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.

This Instruction for Use is applicable for the following product:

Basic UDI-DI	REF	Product
91201229222JW	22-0000-02	RAPTOR SERVER Analysis Software



III. SUMMARY AND EXPLANATION

RAPTOR SERVER is a cloud-based application and is operated via the browser (Google Chrome). RAPTOR SERVER is a software for the acquisition and analysis of images taken by the ImageXplorer or a MAX device (MAX 45k and / or MAX 9k) from processed test arrays. RAPTOR SERVER performs the storage of data and creation of reports based on the lab results.

The software consists of

- web-based server software that provides graphical user interface control via the user's web browser. This server software is commonly referred to as RAPTOR SERVER.
- a standalone application for data transmission between the ImageXplorer and/or a MAX device and the server software. This application is commonly referred to as "AGENT".

The software has been specifically developed for the analysis and reporting of results of test arrays.

Please refer to the MADx website for further information concerning the Instructions For Use of the tests.

III.1 OPERATION

Ideally, the operation of RAPTOR SERVER should be centralized, in the form of a cloud-based SaaS (Software as a Service) application. However, a purely local operation on a customer-owned data center (RAPTOR SERVER "on-premise") is also possible, though with much limited support and features, for more information see III.1.1.

To perform an analysis with the RAPTOR SERVER a test and a device is required:

For analysis	
ALEX ²	REF 02-2001-01, REF 02-5001-01
ALEX Air	REF 06-5001-01
ALEX Food	REF 07-5001-01
ALEX ³	REF 03-2001-01, REF 03-5001-01
FOX – not certified with notified body	REF 80-2001-01, REF 80-5001-01, REF 80-0001-01

For imaging/automation	
ImageXplorer	REF 11-0000-01
MAX 9k	REF 17-0000-01
MAX 45k	REF 16-0000-01



Please consult the IFUs of the test kit or devices for further information:
<https://www.madx.com/extras>.

IMPORTANT USER INFORMATION:

For the correct use of the ImageXplorer and/or MAX Devices with the RAPTOR SERVER software, 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.

III.1.1 OPERATION ON-PREMISE

Hardware and Software requirements:

Due to the provided application containers (Docker images), RS can be run on any Linux or Windows server. The only software prerequisite on the server in addition to the operating system (provided and maintained by the customer) is an up-to-date Docker installation. The application containers are installed there (using standard Docker commands), can start directly and include all other dependencies in their respective containers. The concrete hardware requirements depend on the number of measurements (data) being handled on the RS installation, but usually standard small business servers are more than sufficient (2 CPU cores, 16GB of memory, 100GB of disk space). After start of the application containers, RS can either be directly used via browser on the server, or of the customer so desires, he may connect the server to the local network to make RS available on other computers connected to the server (again, via browser).

As the on-premise variant uses the same application containers as the cloud-based variant, the same protections against unauthorized access to the software (username, strong password, MFA etc.) are available. Unauthorized access to the server hardware itself and the operating system is in the responsibility of the customer and the system administrators there. A main measure against unauthorized access in on-premise scenarios is the disconnect from the Internet (only access from local server or network).

Installation and update process for on-premise installations:

All application containers (Docker images) are available on a public Docker Registry provided by MADx. Both the cloud-based installation and the on-premise installations can download the latest validated release version of the application containers there using standard Docker functionality and commands. Access to the Container Registry is possible from the Internet, but protected by password. As soon as a new version (either new planned release, or hotfix version) is validated and released by MADx, it is available on this Docker Registry. It is then automatically deployed to the cloud-based installation. On-premise customers are informed either by e-mail or by their distributors about new releases.



IV. PRINCIPLE OF THE PROCEDURE

The tests are solid-phase immunoassays. Allergen / antigen extracts or molecular allergens / antigens, 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 antibodies which are present in the sample. After incubation, non-specific bindings are washed off. The procedure continues by adding an enzyme labelled antihuman detection antibody which forms a complex with the particle bound specific antibodies. 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 antibodies in the sample.

The lab test procedure is followed by image acquisition and analysis using either an ImageXplorer or a MAX device. The test results are analyzed with RAPTOR SERVER. Test results are reported in allergen specific IgE units (kU_A/l) along with the total IgE results in IgE units (kU/l), or IgG units ($\mu\text{g}/\text{ml}$) depending on the used test. Quantitative units (kU_A/l) are calculated from arbitrary intensity units by linear regression. The curve parameters for the mathematical transformation are derived from the test and provided by RAPTOR SERVER Analysis Software.



V. GLOSSARY OF SYMBOLS

	Research Use Only
	Manufacturer
	Caution
	MacroArray Diagnostics (MADx)



VI. SAFETY INSTRUCTIONS

Any serious incident that has occurred in relation to the device shall be reported to MADx and the Competent Authority of the Member State in which the user is established.

VI.1 OPERATOR QUALIFICATION

The RAPTOR SERVER Analysis Software should be operated by or under the supervision of a technician or operator who is sufficiently qualified for laboratory work. Before operating the RAPTOR SERVER Analysis Software, the operator should:

- Read these Instructions for Use carefully.
- Be aware of all relevant laboratory procedures.
- Be aware of all relevant safety rules and regulations.

VI.2 DATA BACKUP

When using RAPTOR SERVER, all data are stored according to the MADx Terms of Service Agreement in the Microsoft Azure Online Portal. Please also refer to the Online Services Terms (OST) of Microsoft, available at <https://www.microsoft.com/en-us/licensing/product-licensing/products>. For the RAPTOR SERVER on-premise version, please consult with your local IT administrator.

VI.3 WARNINGS & PRECAUTIONS

- 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.
- 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.).



VII. INSTRUCTIONS

VII.1 RAPTOR SERVER SOFTWARE SETUP

Google Chrome is recommended as a browser for using the RAPTOR SERVER. The graphical user interface of RAPTOR SERVER can be accessed on the website: <https://www.raptor-server.com>

The RAPTOR SERVER instance is designed for SaaS operation and therefore supports multiple independent tenants. Each tenant is logically differentiated from all other tenants and no exchange of data between tenants is possible in any way.

VII.1.1 LOG-IN

A Tenant is the online entity for a single laboratory within the RAPTOR SERVER. Tenants are created by MADx, and access is provided by your local distributor.

Multiple users can log in to a Tenant platform. Access to a Tenant on RAPTOR SERVER will only be available to users with a valid username and password specified by MADx or by an external directory service (Office 365/Azure Active Directory). User accounts are created by the tenant administrator (local distributor, or MADx). In case the login data was forgotten the password can be reset on the login screen as well.



Welcome to RAPTOR SERVER Analysis Software, the analysis software for the [ALEX multiplex test](#).
Please log in below to continue.

Log in with Azure AD / Office 365	Log in with Username & password
If your organization integrates the software into its Microsoft Azure/Office 365 user directory (single-sign-on) click the button below. You will be redirected to the Microsoft login screen.  Log in	Please enter your username and password. Your username Your password   Log in Forgot your password? No problem, you can request a new one.



By clicking the eye icon, the entered password can be made visible.

Log in with Username & password

Please enter your username and password.

Your username

password

Log in

After successful login, the user has to confirm reading of and agreeing to each document to gain access to the full functionality of the software for the first time. This is also the case if there are new instructions for use, terms of services or other agreements available. The user will be informed by the same new pop-up window right after logging into RAPTOR SERVER Analysis Software and has to confirm them.

Contract approval required

Please review the following documents. You are required to confirm that you have read and agree with each document in order to use RAPTOR SERVER:

☐ **Bitte lesen** (last updated 23.11.2023 18:00)

☐ **RAPTOR SERVER IFU** (last updated 04.12.2023 11:05)

☐ **Terms of Service** (last updated 22.11.2023 01:00)

Confirm

By clicking the button, I confirm that I have reviewed these documents and agree.

After confirming and gaining access to their tenant, one has a view of the dashboard. On the left side of the screen the user sees the latest new and approved measurements.



New Measurements

Last 7 days

QC	Product type / Source	QR-Code	Sample Code	Analysis Date		
❌ Failed	Research MAX 45k	99AFG0F7	NK FOX	30/03/2023 20:50	Details	Report
❌ Failed	Research MAX 45k	99AFG0F8	N.G.	30/03/2023 20:50	Details	Report
❌ Failed	Research MAX 45k	99AFG0F9	E18735	30/03/2023 20:50	Details	Report
❌ Failed	Research MAX 45k	99AFG0FA	20220325w56	30/03/2023 20:50	Details	Report
❌ Failed	Research MAX 45k	99AFG0EE	HM100038	30/03/2023 20:50	Details	Report
❌ Failed	Research MAX 45k	99AFG04D	786118	30/03/2023 20:37	Details	Report
❌ Failed	Research MAX 45k	99AFG016	HM100225	30/03/2023 20:37	Details	Report
❌ Failed	Research MAX 45k	99AFG0CA	E17685_M	30/03/2023 20:37	Details	Report
❌ Failed	Research MAX 45k	99AFG0CC	E17685_M	30/03/2023 20:37	Details	Report
❌ Failed	Research MAX 45k	99AFG015	E17685_F	30/03/2023 20:37	Details	Report

In total there are 270 new measurements in the selected time period.

View all new measurements

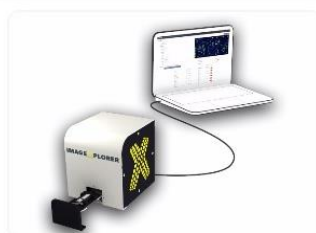
Approved Measurements

QR-Code	Product type / Source	Sample Code	Analysis Date		
02AVJ227	ALEX2	Anna LMacey	28/03/2023 21:17	Details	Report
02ARA379	ALEX2 IX	SM_28032023	28/03/2023 14:29	Details	Report
02ARA393	ALEX2 IX	RG_28032023	28/03/2023 14:26	Details	Report
02AVA31F	ALEX2 MAX 45k	PR_Mar2023_11	21/03/2023 15:05	Details	Report
02AVI3B9	ALEX2 MAX 45k	KF	17/03/2023 14:46	Details	Report
02AYT337	ALEX2 MAX 45k	2846846+CCD	14/03/2023 19:06	Details	Report
02ATL349	ALEX2 IX		22/02/2023 14:21	Details	Report
02AVE383	ALEX2 MAX 45k	AO	03/02/2023 09:41	Details	Report
02AXI29A	ALEX2 MAX 1k	OW	19/01/2023 19:12	Details	Report
02AUY3AE	ALEX2 MAX 45k	BSZ_Okt2022_8	18/10/2022 18:12	Details	Report

View all approved measurements

On the right side of the screen the connected devices and the date of their last ConfigXplorer scan and/or monthly maintenance (for MAX devices only) are shown. Furthermore, regular measurements as well as ConfigXplorer scans and monthly maintenance can be initiated via the dashboard (please refer to the MAX Devices IFU for more information). In addition, the links to the general settings of the shown devices ("Configure") and to the recordings of the QC-measurements ("QC History") can also be found on the dashboard.

Connected Devices



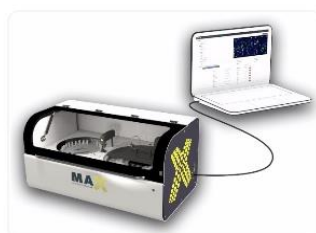
IX Test

Standby

[Start Measurement](#) Start new ConfigXplorer scan

Last ConfigXplorer scan: never

[Start QC sample scan](#) [QC History](#) [Configure](#)



9K-Test-Instrument

Not initialized

[Initialize](#) [Shutdown](#) [Monthly Maintenance](#)

Last ConfigXplorer scan: 12.04.2023 14:08

Last monthly maintenance: 01.12.2022 15:39

[QC History](#) [Configure](#)

[View all MAX devices](#)

[View all ImageXplorers](#)



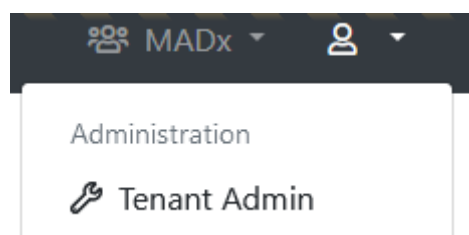
VII.1.2 PERSONAL SETTINGS

In "Personal Settings" you can select the user language, the culture (e.g., English (UK)) and the time zone. To make the RUO spots visible, the user can select "show research spots" in the drop-down menu. In addition, the display language can be selected, once the translation is available.

RAPTOR SERVER supports Multiple Factor Authentication (MFA) of users with given username and password. It can be set up in the personal settings, using an authenticator app (Google or Microsoft) installed on the smartphone of the user. Clicking on Manage MFA in the Personal Settings page, the user will be guided to set up the MFA.

VII.1.3 TENANT ADMIN

If you click on the menu icon  in the upper right corner and select Tenant Admin, you will be directed to the Tenant Admin area, where you can set the preferences for your tenant.



First, please access the Tenant Configuration page and fill out the company details accordingly. Make sure the company details represent official data. Administrators with the "Can manage basic tenant configuration" access right can enforce MFA for all users within a tenant. After MFA enforcement is activated, users will be prompted to complete MFA setup during their next login.



Configure "MADx"

General configuration		MAX device default settings	
* Name:	MADx	* Default Minimum RunId:	10
Default timezone:	(UTC+01:00) Amsterdam, Berlin, Bern, Ri	When a new MAX device is created, this value will be used for its Minimum Run Id	
Configure a timezone to see date and times in (instead of UTC). Please note that users can choose to use a different timezone.			
Default report template (ALEX2):	ALEX2		
Default report template (ALEX3, ALEX Air, ALEX Food):	check 1.21		
Default report template (FOX):	FOX (2025)		
Default report template (PAX):	PAX		
Default report language:	English (en)		
Default ALEX MOD:	< No MOD >		
Default FOX MOD:	< No MOD >		
Default PAX MOD:	< No MOD >		
Force MOD:	False		
Requires a measurement to always have an MOD assigned. If this setting is enabled, a measurement cannot be approved without an MOD assigned.			
Hide Global MOD:	False		
If this setting is enabled, only the tenant-specific MOD will be available to select, and the global system-wide MOD will be hidden.			
Display MOD Excluded Spots As Research Use Only:	False		
If this setting is enabled, spots excluded by an MOD will not be hidden from the measurement image, but displayed as a "RUO spot".			
MFA:	☐ Force MFA		
If this setting is enabled, users are forced to set up an MFA on sign-in, in case they haven't yet.			

Tenant-specific batch releases	
Restrict this tenant to only allow the following batches to be scanned or to restrict certain batches. Enter one per line.	
Use:	☒ Whitelist ☐ Blacklist
Whitelisted Batches:	Enter one batch code including product identifier per line, for example "02AAA"
Blacklisted Batches:	Enter one batch code including product identifier per line, for example "02AAA"

Company Details

* Legal Entity Name:	MacroArray Diagnostics
* Street and Number:	Street 4
* Zip Code:	1230
* City:	New York
* Country:	United States of America
* Phone:	+4318652573
* E-Mail:	office@macroarraydx.com
* Legal Representative:	Dr. Christian Harwanegg
Website:	
Vat Number:	
Company Register Number:	



VII.1.3.1 BLACKLISTING AND WHITELISTING BATCHES

Individual batches can be black or whitelisted per tenant by a user that has the tenant access right “Can manage basic tenant configuration”. To black or whitelist a batch, just toggle either “Whitelist” or “Blacklist” and enter the batch code(s) you want to black or whitelist.

Tenant-specific batch releases

Restrict this tenant to only allow the following batches to be scanned or to restrict certain batches. Enter one per line.

Use:

☒ **Whitelist**
☐ **Blacklist**

Whitelisted Batches:

02AAA
02ABC
02BAA

Blacklisted Batches:

Enter one batch code including product identifier per line, for example "02AAA"

Enter one batch code including product identifier per line, for example "02AAA"

If a batch is blacklisted it cannot be scanned anymore and RAPTOR SERVER will return an error.

You requested a new measurement from ImageExplorer "IX Trainingsraum". Please wait until the measurement is completed ...

Invalid batch detected! The measurement can't be processed because its batch is blocked.

If a batch is whitelisted, RAPTOR SERVER will allow only batches with this code to be scanned.

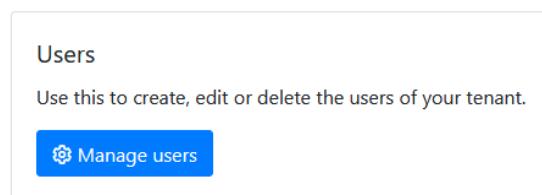


Other important pages of the Tenant Admin area are:

- ImageXplorers and MAX Devices: Use this to configure existing ImageXplorers / MAX Devices or add new ones. Every ImageXplorer / MAX Device needs to be registered as an entity to the Tenant on RAPTOR SERVER, otherwise a connection is not possible.
- Report Templates: Use this to create, edit or delete report templates for this tenant. Each template can have its specific look and configuration.
- Measurement data completion: Manage pre-defined information that can be assigned to a measurement.
- Result Sharing Portal: Use this to create, edit or delete users on the Result Sharing Portal for this tenant. Measurements can be shared with users of the Result Sharing Portal, and users can use the Result Sharing Portal to access those measurements.

VII.1.4 ADD USER TO A TENANT

In the tenant admin area, you can also create and edit users for each tenant. To do this, click on "Manage Users".



Subsequently, a list of all users of the current tenant is displayed. Via "Configure", the rights of an existing user can be adjusted. The "Add new user" button at the top of the page adds a new user to the tenant. Already existing users (from a different tenant) can be linked to the users via the option "Add user from another tenant".

Add new user

After clicking "Add new user", the name, email address and login information of the new user can be added. A user can be authenticated by username and password, or by a Microsoft account defined by the information in the "Azure AD UPN" field.



Via the predefined user groups (e.g.: laboratory staff, support, etc.), the user's rights can be assigned to a specific group. In addition, the rights can also be adjusted individually for each user.

Add New User

General Information

Name:

E-Mail address:

Status:

Login Credentials

Type:

Please select if the user should be validated against Azure AD (Office 365), or if you want to specify username and password yourself. It is recommended to use Azure AD whenever possible. This allows for increased security by supporting two-factor authentication. Also, it is more convenient for the user, because he or she does not have to remember a new username and password (single-sign-on).

Username:

It is a good idea to use the users e-mail-address as his username, because the username needs to be unique across the entire system.

Password:

Access Rights

Preconfigured groups

Use these pre-configured groups to automatically assign a set of access rights to this user. You can still add or remove specific access rights.

[Reset](#) [Lab User](#) [Super Lab User](#) [Support/Distributor User](#) [System Administrator](#)

A user can also be added to multiple tenants in one step (bulk editing) using the feature at the bottom of the page. The user needs to click the checkbox "Add User to all tenants shown below".

☐ Add user to all tenants shown below

☐ MADx

☐ MadX_Training

☐ New Tenant

You can assign the particular user only to the tenants where your user is already present. On the bottom of the page, you see the list of tenants where this user is already assigned, with the corresponding user rights, and below that a scrollable list of additional tenants where this user can be assigned to.



Tenants

This user is connected to the following tenants and has the following access rights:

☐ Tenants	Can share measurements	Can edit measurements	Can edit personal data	Can approve measurements	Can manage basic tenant configuration	Can manage API keys	Can manage ImageXplorers	Can view agent connections	Can manage users	Can manage users of Result Sharing Portal	Can manage report templates	Can manage measurement data completion	Can unapprove tenant specific batch releases	System Administration	Can unapprove measurements	Can use a custom calibration string	Can manage Run Configuration	Can skip
☐ Another MADx Tenant	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒
☐ MADx Tenant	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒

Additionally this user can be added to the following tenants by checking the tenant name and hitting save afterwards. User rights w applied from current open tenant user.

Start typing a tenant name ...

☐ Test
☐ Test Tenant

To assign the user to an additional tenant, mark the tick-boxes of the tenants (you can also use the search bar to look for one), where you want to add the user which you configure and click save. The rights on the current open tenant will be automatically applied to the user. After clicking "Save" at the end of the page, the user receives a welcome email. Via this email, the user can now log in to the RAPTOR SERVER.

Additionally this user can be added to the following tenants by checking the tenant name and hitting save afterwards. User right applied from current open tenant user.

Start typing a tenant name ...

☐ Test
☐ Test Tenant
☐ TOS Tenant
☒ Val 11,1

You can edit the user rights of the user in a bulk, corresponding to multiple tenants at once, using the tabular overview of tenants/user rights. Select the tick-boxes of the tenants for which you'd like to set this particular user rights. After selecting, a button will appear on the top to edit the rights for all the tenants selected. By clicking the button, you come to the usual edit page for user rights. The adjustments you make will affect all the tenants you selected before!



Tenants

This user is connected to the following tenants and has the following access rights:

 [Edit selected tenants rights](#)

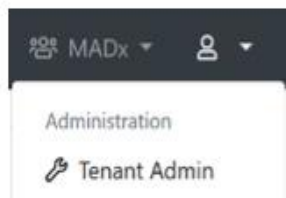
☐ Tenants		Can share measurements	Can edit measurements	Can edit personal data	Can approve measurements	Can manage basic tenant configuration	Can manage API keys	Can manage Imagey
☒	Another MADx Tenant	☒	☒	☒	☒	☒	☒	☒

After clicking "Save" at the end of the page, the user receives a welcome email. Via this email, the user can now log in to the RAPTOR SERVER.



VII.1.5 DOWNLOAD OF THE AGENT SOFTWARE

To set up a device (in this example an ImageXplorer) for your tenant, go to the Tenant Admin area and click "Manage ImageXplorers". To add a new ImageXplorer, please select "Add new ImageXplorer" and assign a name to it. An ImageXplorer key will be generated automatically.



ImageXplorers

Use this to configure ImageXplorers, or add new ones. Every ImageXplorer needs to be known to ~~Raptor Server~~, otherwise it won't be able to connect.

[Manage ImageXplorers](#)

Add new ImageXplorer

General information

Name:	
Key:	Cxltclg8okSwQ6CqJ4EZLWgnw2PdJ3
	This key is required when installing an Agent.
ImageXplorer Serialnumber:	
	Serialnumber of connected ImageXplorer.
Notes:	
Internal Notes:	
	For internal use only.
Disabled:	Not disabled

QR-Code image configuration

QR-Code Exposure:	3000
-------------------	-----------------------------------

Calibration configuration

Mode:	Use automatic exposure
-------	---

Array image configuration

Array Offset X:	400
Array Offset Y:	350
Array Width:	600
Array Height:	280
Array Exposure:	1600

[Save](#) [← Cancel](#) [⚙ Debug information](#)

After clicking on "Save" you will return to the overview page of the respective ImageXplorer. Here you shall download the ImageXplorer Agent software.



ImageXplorers for "MADx"

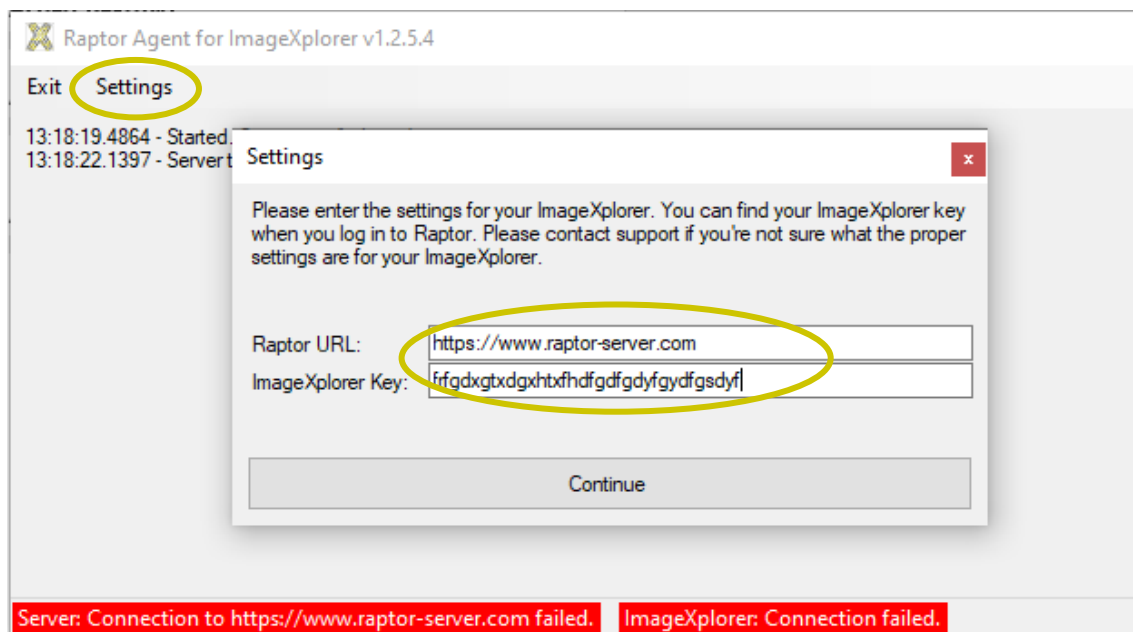
Add new ImageXplorer

Download ImageXplorer Agent Software

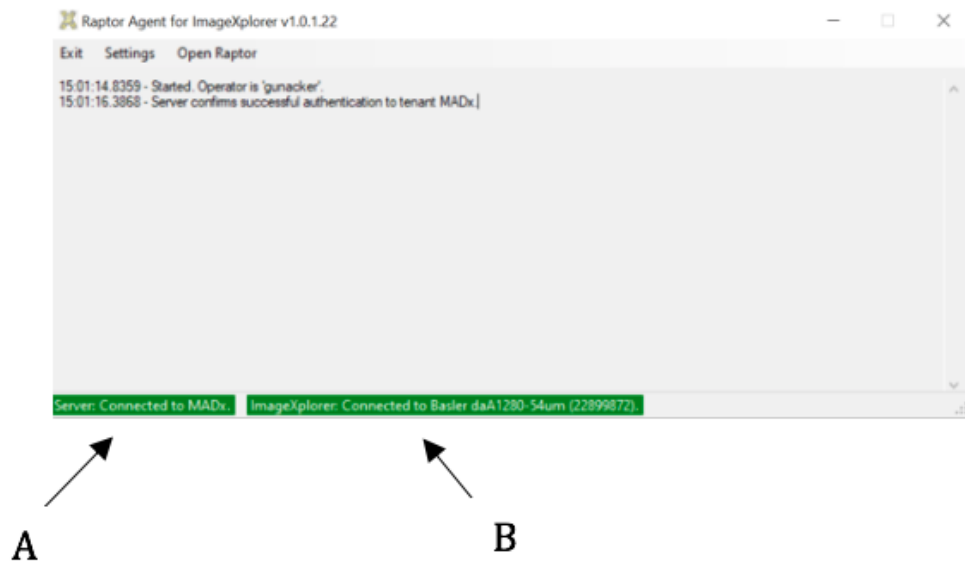
Carry out the installation of the ImageXplorer agent, as a regular installation process.

NOTE: The use of the ImageXplorer requires the presence of the software "Pylon Runtime 6.1.1", by Basler. If you install the "full" version of the ImageXplorer Agent, the software is included. If you already have this software, it is enough to install the "slim" version of the Software.

NOTE: It is suggested to remove any other Pylon software from the PC before installing the ImageXplorer Agent, such as previous versions of the Pylon Runtime.



To activate the Agent and connect it to ImageXplorer and RAPTOR SERVER, please go to Settings and type in the RAPTOR SERVER URL: <https://www.raptor-server.com> and your ImageXplorer Key and click "Continue".



A: Connection to RAPTOR SERVER

B: Connection to ImageXplorer

If a connection to both the RAPTOR SERVER and the ImageXplorer is established, both fields are highlighted in green. If one connection fails, refer to the troubleshooting section for further instructions.

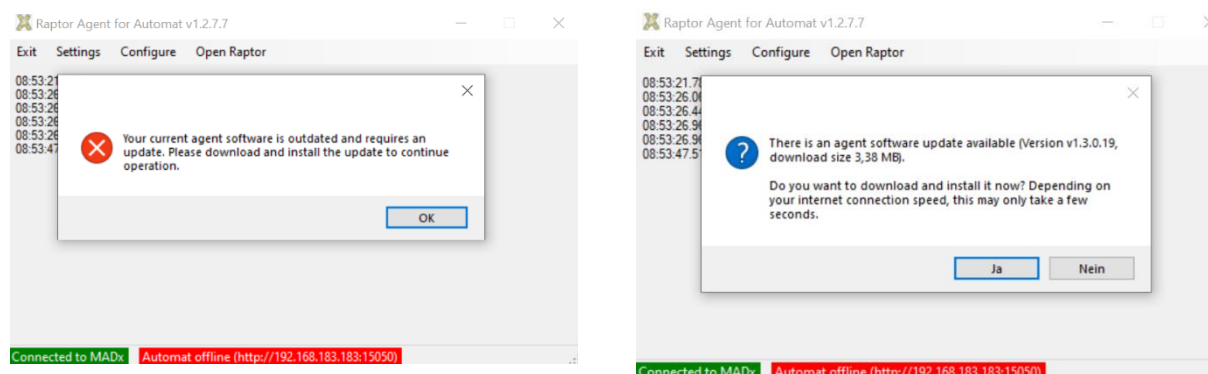
Further information on how to adjust the settings of a device please refer to the ImageXplorer or MAX Device Instructions for use respectively.



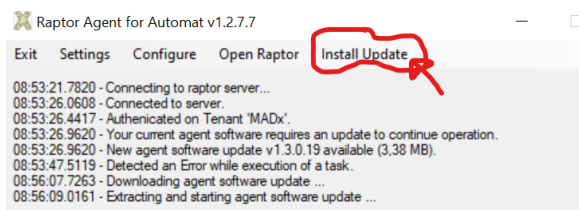
VII.1.6 UPDATING THE AGENT SOFTWARE

Once an update is released, the User receives a pop-up warning in their Agent software window. Click OK, and then say “Ja” to carry out the update.

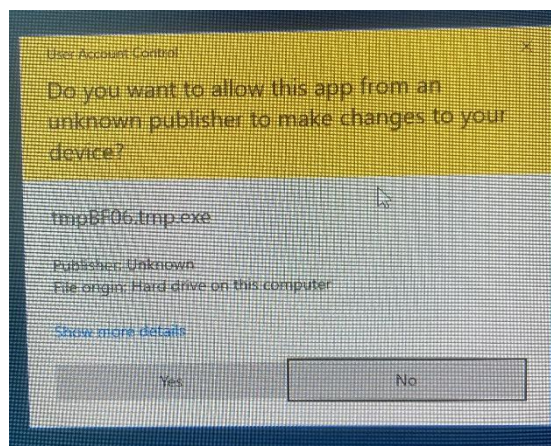
NOTE - you might need administrator rights on the PC to install software - Contact your local IT!



If you skipped the pop-up, you can still start the update anytime by clicking „Install Update“.



Windows might interrupt and ask whether “you would like to allow the software to make changes“.

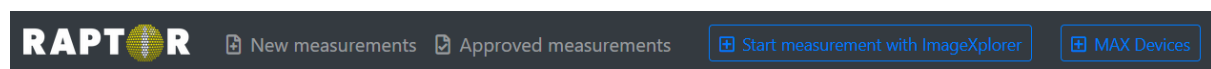


Say “Yes” to proceed. You will then proceed with a software installation similar to other common software (windows setup wizard). Once the update is completed the agent restarts.



VII.1.7 IMAGE ACQUISITION, QR-CODE READING AND GRID FINDING

On the overview page you will find a tab "New measurements", a tab "Approved measurements", a button for "Start measurement with ImageXplorer" and a button for MAX devices. The tab "New measurements" contains all new and unapproved measurements, the tab "approved measurements" contains all hitherto approved measurements.



The QR-Code on each cartridge contains the following information:

- type of test array
- corresponding allergen layout
- QC information
- Lot number of cartridge

After imaging and analysis, a detailed overview of the measurement is displayed with sample information fields on the left, an analytic image of the array on the right and a detailed result view of allergens below.

A: Sample information fields

Barcode: 02AE3488

Sample Code:

Requisition Code:

Sampling Date: TT.MM.JJJJ

Assay Date: 04.10.2021

Patient Code:

Patient Name:

Date of Birth: TT.MM.JJJJ

Info:

Doctor Info:

Choose a doctor... Insert doctor info

Tags:

MOD: < No MOD >

Report Template: Version 2 (ALEX2 only) - Deutsch (de)

B: Analytic image

Received: 04.10.2021 16:23
ImageXplorer: 22124137

Analysis: 04.10.2021 16:23
Automatic QC: ☒ OK

C: Result view

Name	Code	Biochemical	Tissue & Exposure	E/M	Feature	kUA/L
Kiwi	f501	Kiwellin	Plant Food	M	Act d 5	4.84
Actinidia deliciosa			Food			
Alternaria alternata	m229	Alt a 1-Family	Microorganisms & Spores	M	Alt a 1	2.65
Alternaria alternata			Inhalation			
Ragweed	w1		Pollen	E	Amb a	4.04
Ambrosia artemisiifolia			Inhalation			
Ragweed	w230	Pectate Lyase	Pollen	M	Amb a 1	11.66
Ambrosia artemisiifolia			Inhalation			
Cashew	f443	2S Albumin	Plant Food	M	Ana o 3	6.78
Anacardium occidentale			Food			
Herring worm	p10	Kunitz Serin Protease Inhibitor	Animal Food	M	Ani s 1	8.22
Anisakis simplex			Food			
Herring worm	p11	Tropomyosin	Animal Food	M	Ani s 3	22.58
Anisakis simplex			Food			

A: Sample information fields

B: Analytic image

C: Result view



In addition, date of analysis, serial number of the ImageXplorer, QC and possibly also an error log are displayed below the analytical image.

Additional sample information can be added manually:

- sample code
- requisition code
- sampling date
- assay date
- patient code
- name of the patient
- date of birth
- additional information (Info)
- name of the referring physician (Doctor Info)
- tags
- MOD panel

The entries in “Info” and “Doctor Info” can be formatted to appear bold, cursive and/or underlined. This is done as follows:

- _Info_ will appear underlined
- *Info* will appear *cursive*
- **Info** will appear **bold**



Details

QR-Code: 02APH008

Sample Code:

Requisition Code:

Sampling Date:

Assay Date:

Patient Code:

Patient Name:

Date of Birth:

Info:

Doctor Info:

Tags:

MOD:

Report Template: Version 2 (ALEX2 only) - Deutsch (de)

If you click on "Save" the entered information will be saved.

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. For more information on the Guide Dots please refer to the product specific IFUs.

After processing, the Guide Dots have to be easily visible with the naked eye. Please also verify their correct orientation. 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 analyzed.

During the image acquisition of a 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.



VII.1.8 IMAGE PROCESSING MODE

To enter the image processing mode, click on the image.

Details

Barcode: 02AE3408

Sample Code: 12

Requisition Code:

Sampling Date: 01.10.2021

Assay Date: 04.10.2021

Patient Code: TE

Patient Name: Test

Date of Birth: 17.05.2010

Info: Info

Doctor Info: Dr. A

Choose a doctor... Insert doctor info

Tag: Tag Info

MOD: < No MOD >

Report Template: Version 2 (ALEX2 only) - Deutsch (de)

Report

Save

Save and approve

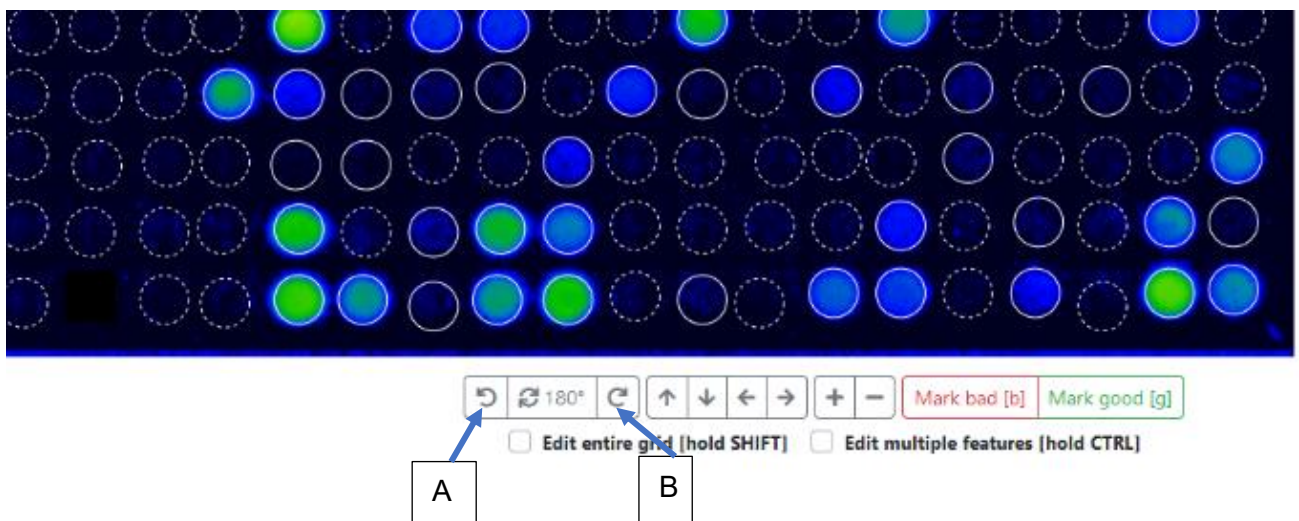
Previous Next

Received: 04.10.2021 16:23

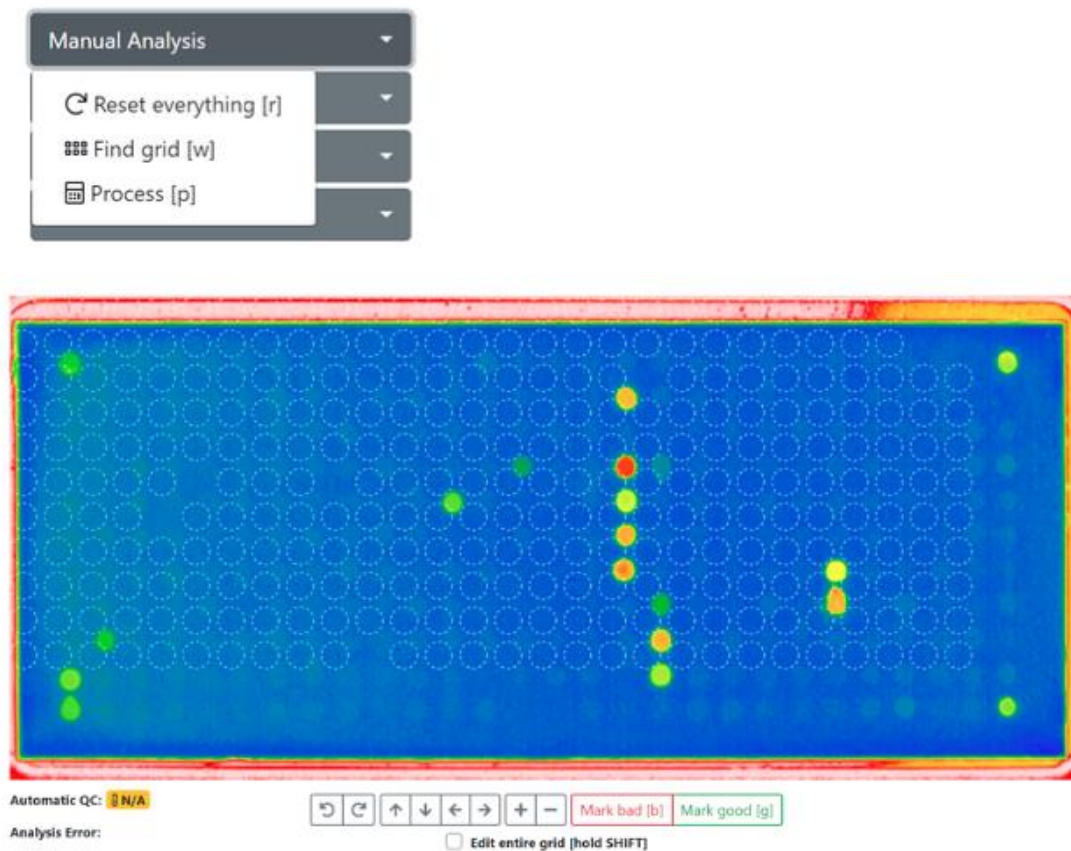
Analysis: 04.10.2021 16:23

ImageExplorer: 22124137

Automatic QC: OK



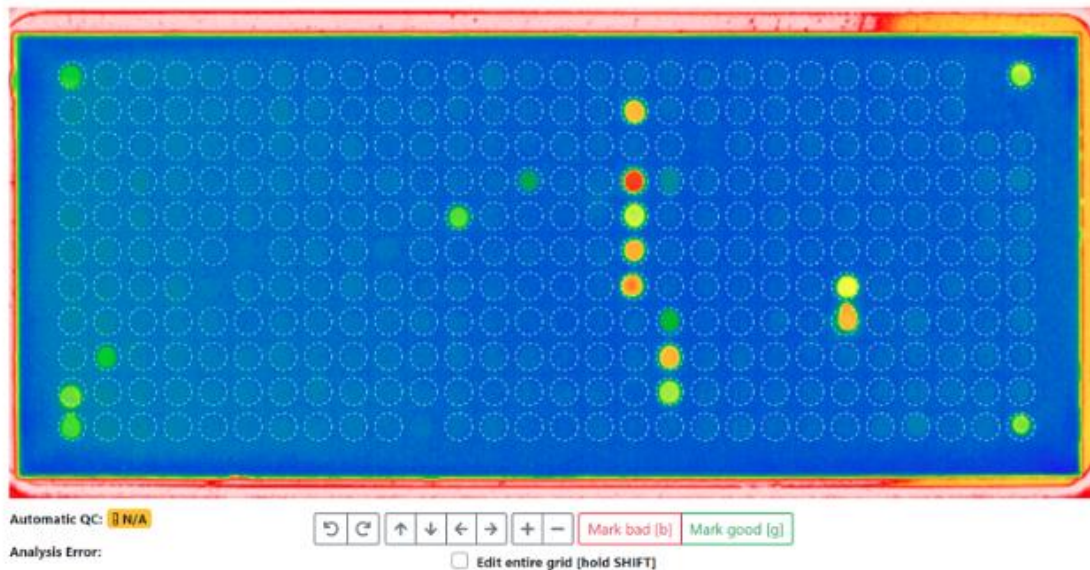
If the automatic position finding fails, the user will be alerted, and the measurement quality control (QC) will be set to FAIL. In this case, the user can try to manually position the array by resetting the grid by pressing "R" or go to "Manual Analysis --> Reset Grid". After resetting, you can move the whole grid with the mouse by additionally pressing "Shift", or by setting a check mark at "edit entire grid". Note that you are only able to move the grid within certain limits.



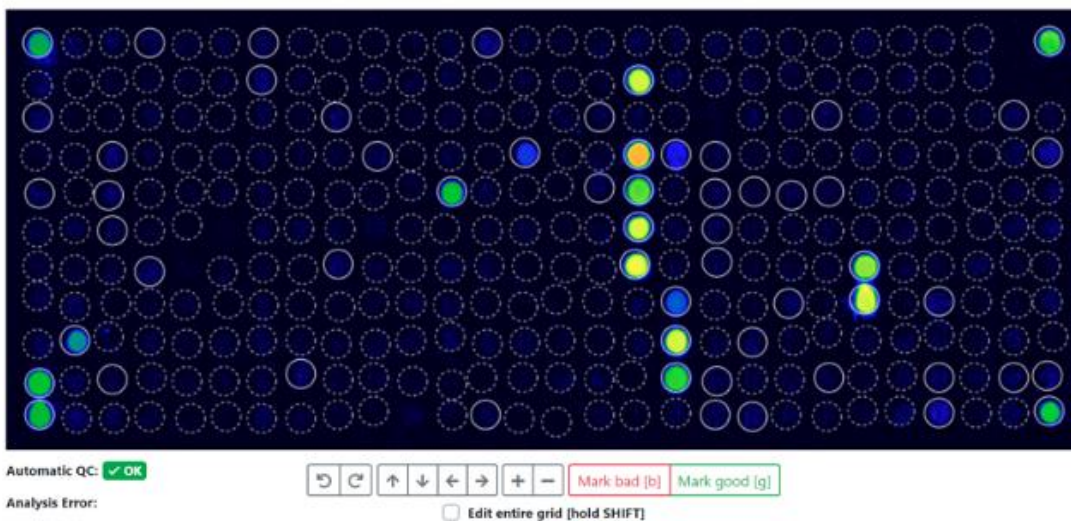
Press "R" or "Manual Analysis --> Reset Grid", then move the entire grid.

After aligning approximately towards the correct position (use two of the corner dots as alignment "targets"), press "Manual Analysis --> Find grid" or press "W", to automatically drive the grid further to the correct position.

If the grid is still not aligned to the spots, repeatedly move the grid manually, and use "find grid" to turn the grid clockwise or counter-clockwise, click the buttons "A" or "B" according to the picture above.

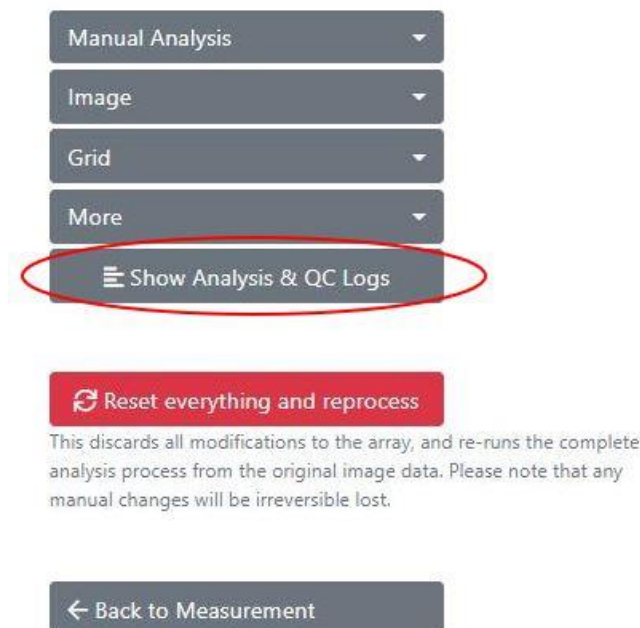


Finalize the grid-finding and analysis by pressing "P" or Manual Analysis -> Process.



Press "P" or "Manual Analysis --> Process"

All processed measurements have information about the image analysis under "Show analysis & QC logs".



Click on this button to get information about the background, QC dot values and the applied reference values. This is especially useful if you need to find out why a measurement failed QC. For the QC to be OK, the background must be within a certain range and all guide dots must reach a certain threshold value. If these QC criteria are still not fulfilled after manually adjusting the spots on the image, please contact your local distributor or MADx Support.

Analysis Log

```
'PreProcessedPixels' took 128ms.
Using definition '92_ALEXIL_IVD_v1.6.0'.
'ApplyArrayDefinition' took 74ms.
Parsing calibration string ...
'ApplyDefinitions' took 75ms.
'FindGrid' took 1ms.
'AlignFeatures' took 862ms.
'CropImage' took 1ms.
'QuantifyFeatures' took 231ms.
'SubtractBackground' took 669ms.
Parsing calibration string ...
Using calibrators from QR-Code.
Total IgG (tIgG) normalized by calculating 8,330999755859375E-07x*+0,05697999954223633x+-30,69269921875
(x=8515), which results in 515.
'ReQuantify' took 57ms.
```

QC Log

These are the values used for QC (ALEX v2): Curve Correction=0,9997370867894242, tIgG=8515, GD1=28985 (598=185.38), GD2=29369 (598=185.28), GD3=28569 (598=147.53), GD4=28305 (598=128.1). Reference values are as follows: Guide Dots must have a value above 5000; each Guide Dot spot must exist and be unique; Guide Dot spot must not be set to bad. Average background must be between 4000 and 16000. QC (ALEX v2) succeeded.

Background Log

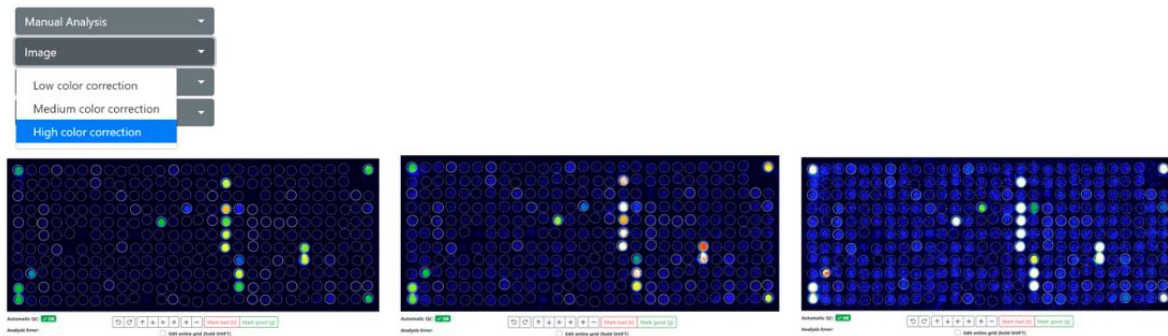
Calculated background statistics for 164 pixels (from a total of 182, skipped smallest 9, and highest 9 pixels). The average is 9.419, the minimum 7973 and the maximum 11792 (minimum and maximum is calculated including skipped pixels). This results in an average difference of 628, which is an SD of 49,17 and a CV of 0,52%.

For comparison, there is an overall total of 282944 pixels. The overall average is 14.871, the minimum 6.012 and the maximum 64.965.

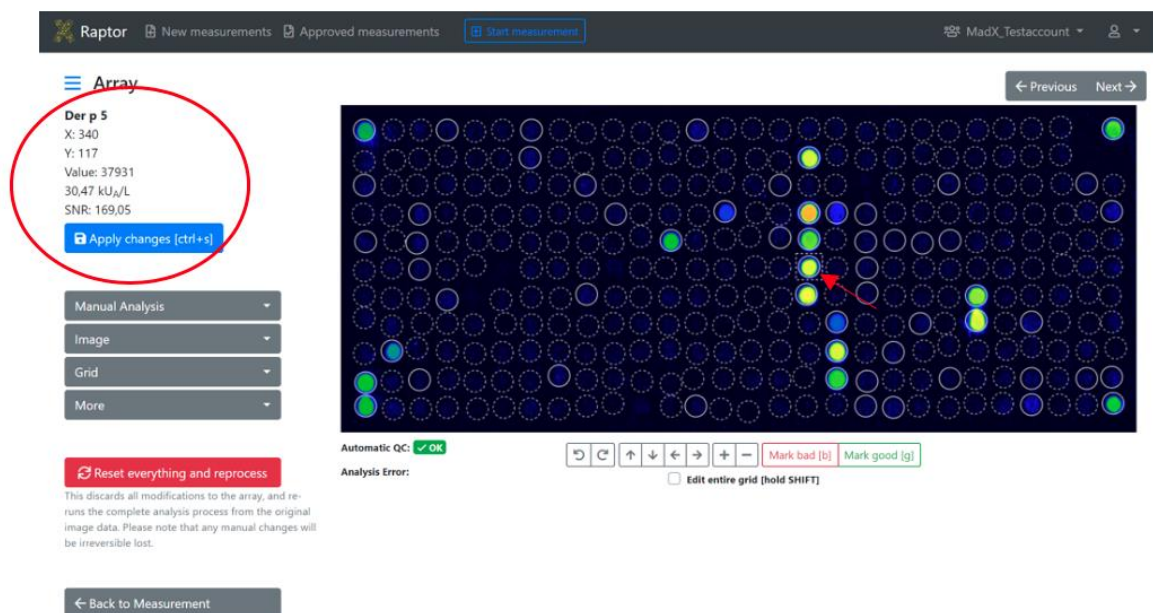


VII.1.8.1 IMAGE ANALYSIS

The analytic image of the selected array is displayed in a false color code to allow a clear visualization. The false color intensity can be adjusted in three steps. Go to “Image” and select one of the three levels (low color correction, medium color correction or high color correction).



Pictures above from left to right: High color correction (default) - Medium color correction - Low color correction. By clicking inside one spot, name, x and y coordinates of the image, raw and result value of the spot and the signal-to-noise ratio (SNR) are displayed.

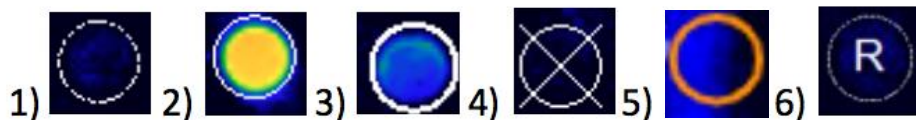


Each allergen is surrounded by a circle. The graphic depiction of the circle represents the automatic interpretation by the software or the modification by the user:

1. Circle with dotted line: not yet analyzed or below cut-off
2. Circle with a solid thin line: positive spot automatically found
3. Circle with solid thick line: spot set to good by user
4. Circle with a solid thin line and an X in the center: spot set to bad by the user



5. Circle with a thick orange line: Spots to be inspected by the user with poor signal-to-noise ratio but a quantitative result above the system cut-off. Those spots should be set to “good” or “bad” by the user.
6. Research Use Only Spots (RUO) are marked with a “R” inside of the circle and will not be displayed in the PDF report, but are exported in the CSV, EXCEL, or ASTM file. The RUO spots can be displayed by changes in the personal settings.



Spots are editable by the user:

- A single spot is selected by clicking on a spot.
- If you simultaneously press "SHIFT" or select "edit entire grid", all spots will be selected.
- Multiple single spots can be selected by pressing and holding "CTRL", or selecting "edit multiple features".
- Selected spots can be moved with the arrow keys (left, right, up, down) or with the mouse.
- Selected spots can be set to Good by pressing "G"
- Selected spots can be set to Bad by pressing "B"
- By pressing "H", the grid can be hidden and displayed again.
- By pressing "N", all spots are annotated, and the abbreviated name of each allergen is displayed. This can be undone by pressing "N" again.

The last two features can also be used by selecting “Grid” --> “show or hide grid” and “show or hide names”.





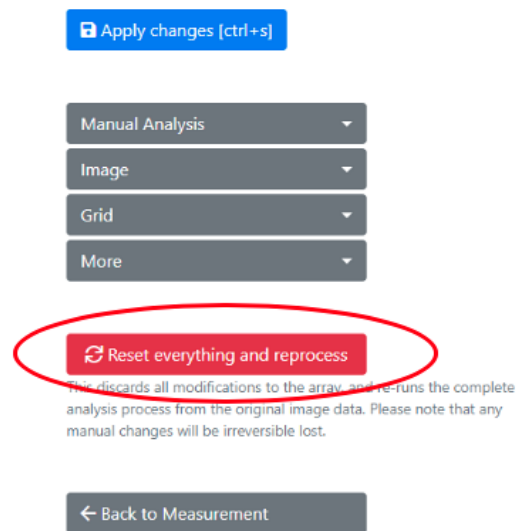
VII.1.8.2 SHORTCUT SUMMARY

Short Cut	Execution
R	Reset analysis
W	Find grid
P	Process
G	Set feature to good
B	Set feature to bad
N	Annotate allergen features
H	Hide/unhide grid
SHIFT	Select all measurements

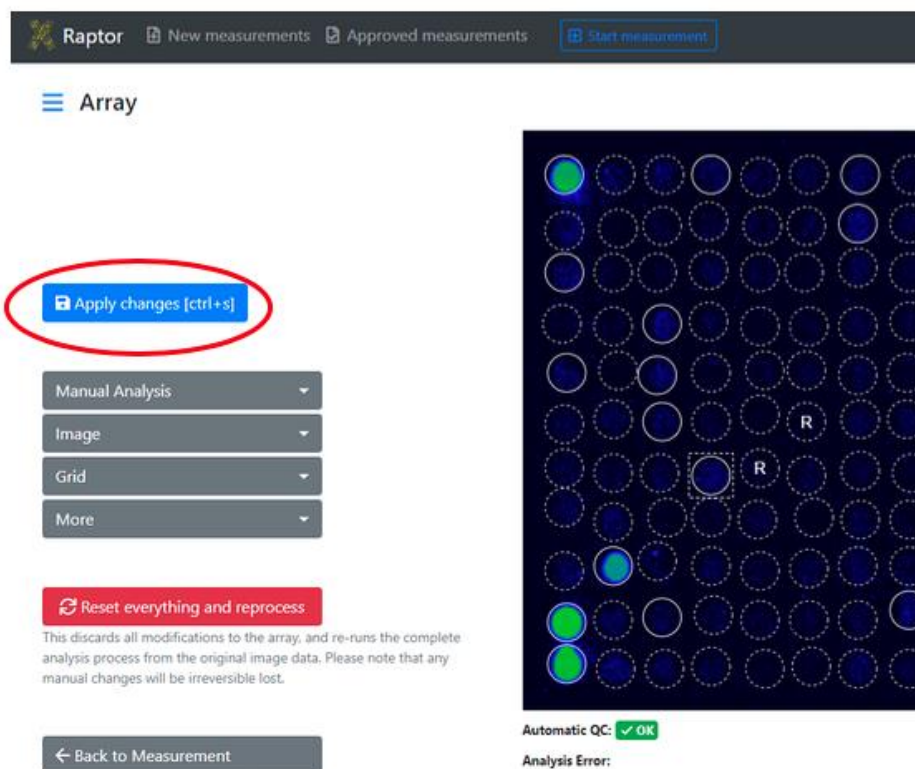
Orange marked spots need to be inspected and set to Good or Bad by the user. Otherwise, they will be marked by an orange triangle with an exclamation mark in the report. If the spot was set to “good” or “bad”, this will not be displayed.

Milk				
Cow, milk	Bos d 4	M	α -Lactalbumin	0,38
Cow, milk	Bos d 5	M	β -Lactoglobulin	0,90
Cow, milk	Bos d 8	M	Casein	6,04
Cow, milk	Bos d_milk	E		3,40

It is also possible to open an image of the QR-Code, an image of the unprocessed or the processed array. To do this, go to "More" and select the desired image. A complete reset is also possible by pressing the "Reset everything and reprocess" button.



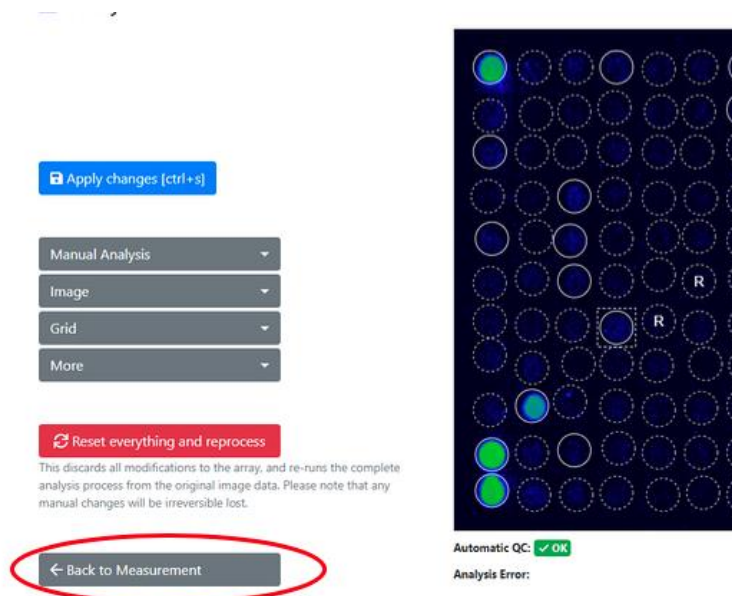
If the user changes the position or the interpretation of the spot or the whole grid, the analytic data will be erased, and the QC set to NA. After the analysis, press "Apply Changes" to save the modifications.



To return to the detail page of the measurement from the image processing mode, press "Back to measurement". You can also click "Next/Previous" to go to the editing page of the following image. If a filter on the overview page for, for example a specific product was set, navigation



through Measurements using the buttons will only show the ones according to the filtering criteria already applied in the list.



VII.1.8.3 ANALYTICAL RESULTS

In the detailed results list, below the sample information and the analytic image, the results of the selected measurement will be displayed. The analytic result will display a list containing the following information:

- Allergen name & species
- Allergen code
- Biochemical function
- Source & exposure route
- Allergen extract or molecular allergen
- Feature name
- IgE value expressed as kU_A/l (color coded)
- IgG value expressed as µg/ml (color coded)



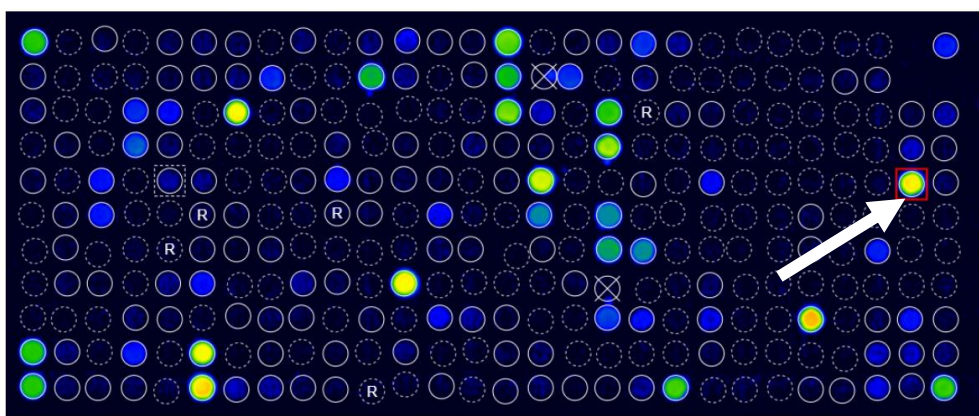
⌵ All allergens

1½ Name	Code	Biochemical	Source & Exposure	E/M	Feature	kUA/L
Acacia <i>Acacia mimosa</i>	t19		Pollen Inhalation	E	Aca m	< 0.10
Acarus siro <i>Acarus siro</i>	d70		Mites Inhalation	E	Aca s	0.39
Alder <i>Alnus glutinosa</i>	t100	PR-10	Pollen Inhalation	M	Aln g 1	< 0.10
Alder <i>Alnus glutinosa</i>	t101	Polcalcin	Pollen Inhalation	M	Aln g 4	6.75
Almond <i>Prunus dulcis</i>	f20		Plant Food Food	E	Pru du	< 0.10
Alternaria alternata <i>Alternaria alternata</i>	m229	Alt a 1-Family	Microorganisms & Spores Inhalation	M	Alt a 1	9.21
Alternaria alternata <i>Alternaria alternata</i>	m230	Enolase	Microorganisms & Spores Inhalation	M	Alt a 6	< 0.10

By clicking on the drop-down menu “All allergens/Only positive allergens”, the information to be displayed in the analytic results window can be selected. This is independent of those results that are displayed in the PDF report.

	All allergens	⌵ All allergens
	Only positive allergens	
Tissue &	ire	kUA/L
Pollen Inhalation	E Aca m	≤ 0.10
Mites	E Aca s	7.11

By clicking on the name of one or more allergens in the list of allergen results, the corresponding spots on the array image are highlighted by a red rectangular box.





VII.1.9 OVERVIEW OF MEASUREMENTS

New and unapproved measurements are displayed in the “New Measurements” overview. With a dropdown at the bottom of the page, you can set the number of displayed measurements to 25, 50, 100 or 250.



The “New Measurement” page also displays the following information for each measurement:

- Source of measurement
- QC status
- Tags
- Product Type
- QR-Code
- Sample Code
- Patient Code
- Patient Name
- Analysis Date

New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...

	Source	QC	Tags	Product type	QR Code	Sample Code	Patient Code	Patient Name	Analysis Date
☐	IX	✓ OK		ALEX2	02AGT957				29.04.2021 10:51
☐	IX	✓ OK		ALEX2	02AGT956				29.04.2021 10:55
☐	IX	✓ OK		ALEX2	02AGT955				29.04.2021 10:50
☐	IX	✓ OK		ALEX2	02AGT954				29.04.2021 10:51
☐	IX	✓ OK		ALEX2	02AGT953				29.04.2021 10:51
☐	IX	✓ OK		ALEX2	02AGT952				29.04.2021 10:50
☐	IX	✓ OK		ALEX2	02AGT951				29.04.2021 10:53
☐	IX	✓ OK		ALEX2	02AGT950				29.04.2021 10:56
☐	IX	✓ OK		ALEX2	02AGT949				29.04.2021 10:56

Clicking on the QR-Code or the analysis date takes you to the detail area of the measurement. Sample information, sample code and tags can also be entered in the overview page. To do this, simply click in the corresponding field of the measurement and insert it. Press the “Tab” button to automatically enter the next field and your entry will be saved.



New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...									
☐	Source	QC	Tags	Product type	QR-Code	Sample Code	Patient Code	Patient Name	Analysis Date
☐	IX	✓ OK		ALEX2	02AGT957				29.04.2021 10:51
☐	IX	✓ OK		ALEX2	02AGT956				29.04.2021 10:55
☐	IX	✓ OK		ALEX2	02AGT955				29.04.2021 10:50
☐	IX	✓ OK		ALEX2	02AGT954				29.04.2021 10:51
☐	IX	✓ OK		ALEX2	02AGT953				29.04.2021 10:51
☐	IX	✓ OK		ALEX2	02AGT952				29.04.2021 10:50
☐	IX	✓ OK		ALEX2	02AGT951				29.04.2021 10:53
☐	IX	✓ OK		ALEX2	02AGT950				29.04.2021 10:56

Tags can be added to or removed from multiple measurements at once using the dropdown menu.

New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...				
Selected measurements				
☐	Source	QC	Tags	Product type
☐	IX	✓ OK		ALEX2
☒	IX	✓ OK		ALEX2
☒	IX	✓ OK		ALEX2
☒	IX	✓ OK		ALEX2

Selected measurements

- Download CSV format
- Download Excel format
- Approve
- Update interpretation
- Choose Reporttemplate
- Modify Tags**
- » Move
- Delete

To re-process multiple measurements together, select the measurements you want to re-process and open the dropdown menu on top and choose "Re-Process".

New Measurements

Search by QR-Code, patient	
Selected measurements	
☐	IX
☒	IX
☒	IX
☒	IX

Re-process measurements

You are about to re-process the following measurements. undone, the existing analysis result will be irreversibly over

QR-Code	Sample Code
02APK3C8	Dummy8
02APK258	Dummy1
02APK07F	Dummy13

Re-process these measurements

Cancel



In the search field, measurements can be searched for by their tag, product type, QR-Code, sample code, patient code and patient name as well as analysis date.

New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...

	Source	QC	Tags	Product type	QR-Code	Sample Code
☐	IX	✓ OK		ALEX2	02AGT957	
☐	IV	✓ OK				

It is possible to duplicate the QR-Code and the measurement data in the data repository if cartridge is acquired several times. However, this is indicated by a triangle with an exclamation mark during measurement.

New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...

	Source	QC	Tags	Product type
☐	Recaptured	✓ OK	recaptured	ALEX1
☐	⚠ Recaptured	✓ OK	recaptured	ALEX1
☐	QR-Code was scanned more than once.		recaptured	ALEX1

VII.1.10 APPROVING AND EXPORTING MEASUREMENTS

After analysis and careful revision of the results, the measurements can be approved by two ways. However, make sure to take care of uncertain spots before approving a measurement, see also **Fehler! Verweisquelle konnte nicht gefunden werden.:**

1. One or more measurements can be selected by ticking and then approved in the drop-down menu in a bundle:

RAPTOR New measurements Approved measurements

New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...

Selected measurements

	Source	QC	Tags	Product type	QR-Code
☒	IX	✓ OK		ALEX2	02AMC180
☒	IX	✓ OK		ALEX2	02AMC078
☒	IX	✓ OK		ALEX2	02AKV2D9

Unapproved measurements can also be downloaded as CSV or EXCEL.



2. A measurement can also be approved on the detail page of a measurement. Simply click on "Save and approve".

Details

QR-Code: 02APH008

Sample Code:

Requisition Code:

Sampling Date:

Assay Date:

Patient Code:

Patient Name:

Date of Birth:

Info:

Doctor Info:

Choose a doctor...

Tags:

MOD:

Report Template: Version 2 (ALEX2 only) - Deutsch (de)

Re
ImageX
Analysis

If the QC of a measurement is "OK", the measurement simply moves to the "Approved Measurements" tab upon approval. If the QC of a measurement is "Failed", the user will get a notification that the "Measurement QC is not OK". In addition, it will also be stated on the report that the internal QC (plausibility check for GD and background signal) was not successful.

Approve measurements

You are about to approve the following measurements.

There are measurements with one or more warnings. Please make sure to double-check these measurements before approval.

QR-Code	Sample Code	Analysis Date
02AKV035		28.04.2022 11:14

Approved measurements are stored in the section "Approved measurements". With a dropdown at the bottom of the page, you can set the number of displayed measurements to 25, 50, 100 or 250. No information can be changed or added to approved measurements. The details/result of a measurement can be displayed by clicking on a measurement. The features of the image can also be displayed but cannot be adjusted anymore.



Approved Measurements

Search by QR-Code, patient, sample, tag, analysis date ...										
☐	Source	Tags	Product type	QR-Code	Sample Code	Patient Code	Patient Name	Date of Birth	Analysis Date	Approval Date
☐	IX		FOX	88AAHB48	Ton1	Stark	Avengers	11.10.1988	01.07.2021 15:10	01.07.2021 15:12
☐	IX		ALEX2	02A1S310	Wanda	Vision	Avengers	07.05.1983	01.07.2021 15:06	01.07.2021 15:12
☐	IX		FOX	88AAHB48	Ton1	Stark	Avengers	11.10.1988	01.07.2021 15:01	01.07.2021 15:12

The results of selected measurements in the approved measurements section can be downloaded as PDF report, as EXCEL, CSV, or ASTM file. Values under 0.1 kU_A/l will be displayed as < 0.1, and values over 50 kU_A/l as >50 instead of the absolute value.

[New measurements](#)
[Approved measurements](#)
[Start measurement](#)

Approved Measurements

Search by QR-Code, patient, sample, tag, analysis date ...

Download selected measurements

☐	Source	Tags	Product type	QR-Code	Sample Code
☒	IX		ALEX2	02AKV39D	
☒	IX		ALEX2	02AKV39D	
☒	IX		ALEX2	02AKV39D	

Download selected measurements

- Report (PDF format)
- CSV format
- Excel format
- ASTM format
- Update interpretation
- Choose Reporttemplate
- Share
- Move
- Unapprove

If a larger amount of data is requested for export, for example multiple .pdf reports, an export download link will be generated in a separate window. The export process then runs in the background and can be viewed by clicking on the menu in the upper right corner. A finished export can be downloaded by clicking on “download”.

[New measurements](#)
[Approved measurements](#)
[Start measurement](#)
[Automats](#)

MADx Testtenant

Exports

Certain types of data exports (for example, the export of many PDF reports at once) take a few minutes to prepare for download. Here you can download your requested exports. Please note that you can keep working, all exports are done in the background and you can download them when they are completed.

Export requested	# of measurements included	Export completed
8/16/2021 11:07 AM	4	0 / 4
8/16/2021 11:06 AM	4	8/16/2021 11:06 AM
8/16/2021 11:04 AM	3	8/16/2021 11:04 AM

- Administration
- Tenant Admin
- Exports
- Personal Settings
- Log out
- Support
- Imprint
- Download



To initiate an export of multiple measurements “Exports” and then “Export Multiple Measurements” can be clicked.

Exports

Certain types of data exports (for example, the export of many PDF reports at a time) are possible. Please note that you can keep working, all exports are done in the background.

Export requested	# of measurements included
06.07.2022 08:52	3

After selecting the appropriate filters and clicking “Search Measurements”, the number of found measurements are displayed. After clicking on “Start export” the user will be directed back to the Exports page and will see the Export requested ready to Download. If the user wants to change filters, they can click on the back button, RAPTOR SERVER remembers the filter previously set.

Export multiple measurements

Please note that **Report** and **ASTM** export is only available for certain product types.

Product Type

Analysis Date From

Tag

use , to separate tags

QR Code

Analysis Date

Approved or not

☐ **Export CSV**
☐ **Export Excel**



Export multiple measurements

Please note that **Report** and **ASTM** export is only available for certain product types.

Product Type

ALEX2

QR Code

Analysis Date From

TT . MM . JJJJ

Analysis Date To

TT . MM . JJJJ

Tag

Approved by

Approved by

use , to separate tags

☐ Export CSV

☐ Export Report

 Start export ...

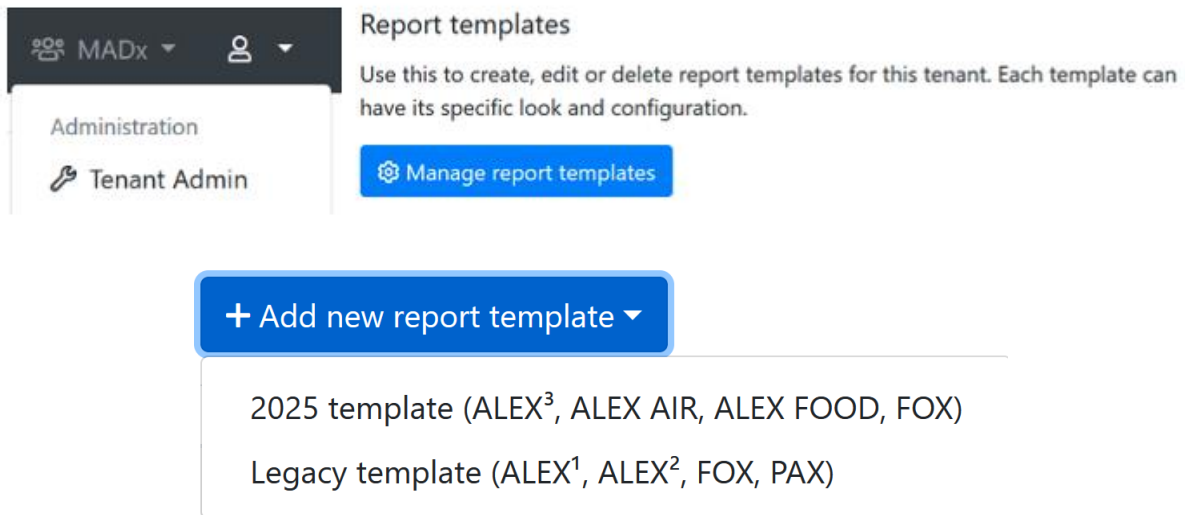
← Back

122 Measurements found that match your criteria



VII.2 REPORT

Reports can be customized by clicking on “Tenant Admin” → “Manage report templates” and “Add new report template”.



There are two kinds of templates available: the legacy template for products such as ALEX, ALEX² and FOX, and the 2025 template for the newer products such as ALEX³, ALEX Air, ALEX Food but also FOX.

VII.2.1 CREATING A CUSTOM REPORT TEMPLATE (2025 TEMPLATE)

The Report Template Configurator consists of six cards, which can be used to customize a report template: General configuration, header layout, content, PDF file name, branding and signatures.

VII.2.1.1 GENERAL CONFIGURATION FOR CUSTOM REPORT TEMPLATE (2025 TEMPLATE)

In the card “General configuration” the following settings can be selected:

- Name of the report template
- Default language (you can still change the language for every report separately)
- Supported products
- PDF size



VII.2.1.2 HEADER LAYOUT FOR CUSTOM REPORT TEMPLATE (2025 TEMPLATE)

In the card “Header layout” the content and order of the header can be configured. The following information can be added via dropdowns:

- Sample Date
- Assay Date
- Analysis Date
- Approval Date
- Print Date
- Patient Code
- Sample Code
- Patient Name
- Date of Birth
- QR-Code
- Allergens/Antigens
- Test method
- Doctor information
- Additional Info Text
- Requisition Code
- Approved By
- Tested By

If the dropdown is left at “None”, no text will be displayed at that position.

VII.2.1.3 CONTENT FOR CUSTOM REPORT TEMPLATE (2025 TEMPLATE)

In the card “Content” the following settings can be selected:

- Results filter: the allergens displayed in the report can be specified (all allergens, only positive allergens, only negative allergens)
- Allergen sort order: The allergen details in the report (in one allergen group) can be sorted in three different ways:
 - Alphabetical order by allergen codes
 - Descending from the highest to the lowest value
 - Alphabetically order by allergen name (common name)
- Include QR-Code for patient portal: to access the patient portal a QR-Code can be printed on the report:
 - None
 - Top and Bottom
 - Top
 - Bottom
- Include total IgE with three options:
 - Do not include
 - Top



- Bottom
- Include interpretation (RAVEN)
See corresponding chapter. Here can be selected whether an interpretation shall be included automatically in the report, or only by request.
- Cross-reactive information: By selecting “include cross-reactive information”, explanatory sentences will be added to the end of the report describing those allergen families that are positive on the first page. (see “cross-reactive allergens”). It is possible to include the information as text only or the information and a table of all positive allergens).

VII.2.1.4 PDF FILE NAME FOR CUSTOM REPORT TEMPLATE (2025 TEMPLATE)

In the card “PDF file name” the following settings can be selected for the file name:

- Include measurement QR-Code
- Include Patient Code
- Include Patient Name
- Include Sample Code
- Include Date and Time

A manual pattern can be defined as well, in that case any other settings will be ignored.

VII.2.1.5 BRANDING FOR CUSTOM REPORT TEMPLATE (2025 TEMPLATE)

In the card “Branding” the following settings can be selected:

- Custom color: the colors of the header can be customized across the entire color palette
- Logos: Additional to the Logos on both sides of the front-page header, a miniature logo can be added to the headnote of all pages. By default, this is a miniature of the left-side header logo.

VII.2.1.6 SIGNATURES FOR CUSTOM REPORT TEMPLATE (2025 TEMPLATE)

In the card “Signatures” up to 3 images can be added to the end of the report in the form of signatures.

After the change, the report template can be saved by clicking the “Save” Button.

A report template can be duplicated using the button “Duplicate” at the bottom of the page. The current report template will be duplicated and the duplicate will be automatically loaded, which can be seen by the name of the report template:



Edit report template

Your changes have been saved successfully.

General configuration

Name:

FOX new - Duplicate

Supported products:

FOX (2025)

Default language:

English (en)

PDF size:

A4



VII.2.2 CREATING A CUSTOM REPORT TEMPLATE (LEGACY TEMPLATE)

The Report Template Configurator consists of four tabs, which can be used to customize a report template: General, Design, Header and Content.

Add a new report template



VII.2.2.1 GENERAL SETTINGS FOR CUSTOM REPORT TEMPLATE (LEGACY TEMPLATE)

In the tab "General" the following settings can be selected:

- Name of the report template
- Base template
- Preferred language (you can still change the language for every report separately)

Configure report template "New report template"

Setting	Value	Description
Name:	New report template	This is the name of the template which shows up in the dropdown list while generating a report.
Base Template:	Version 2 (ALEX2 only)	A base template which specifies basic functionality must be chosen.
Preferred language:	English (United States) (en-us)	A default language can be specified which will be used if there isn't yet a language stored to a measurement's report.

- PDF naming:
 - Setting Type: Automatic --> choose from the following options:
 - Patient ID
 - Patient Name
 - Sample ID
 - Measurement QR-Code
 - Date & Time
 - Setting Type: Manual --> select options the way you prefer
Example: Report_{PatientID}_{DateAndTime}



- Footer: Text can be added to the footnote of all pages

PDF naming

Setting Type:

Manual

The filename of the report PDF can be customized. Either built automatically based on your selection below or manually adjusted in the order of your needs.

Name Pattern:

Report_{PatientId}_{MeasurementQrCode}

Available Elements: {PatientId} ; {PatientName} ; {SampleId} ; {MeasurementQrCode} ; {DateAndTime}

PDF naming

Setting Type:

Automatic

The filename of the report PDF can be customized. Either built automatically based on your selection below or manually adjusted in the order of your needs.

Include Patient ID:

☒

Include Patient Name:

☒

Include Sample ID:

☐

Include Measurement QR-Code:

☐

Include Date & Time:

☒

Footer

Footer text:

Will be printed in the footer if provided and rendered as HTML.

Save

← Cancel



VII.2.2.2 DESIGN SETTINGS FOR CUSTOM REPORT TEMPLATE (LEGACY TEMPLATE)

In the tab "Design" the following settings can be selected:

- PDF Format
- Font
- Background image: it is possible to add a watermark background to all pages.

Configure report template "New report template"

The screenshot shows the 'Design' tab of a configuration interface. It includes the following elements:

- Tabs:** General, Design (selected), Header, Content.
- PDF format:** Radio buttons for A4 (selected) and Letter. A description states: "Specifies the paper size of the output PDF."
- Font:** A dropdown menu showing 'Arial'. A description states: "The font family of the whole report texts can be adjusted."
- Background image:** A text input field followed by a 'Browse' button. A description states: "If set, this image is used as background on the first page of the PDF." Below the input field, it says "Maximum file size 1 MB".

- Color palette: The base colors of the template and the result classes can be customized across the entire color palette
- Logos: Additional to the Logos on both sides of the front-page header, a miniature logo can be added to the headnote of all pages. By default, this is a miniature of the left-side header logo.
- Signature: In addition, a picture of a signature can be uploaded to be added at the end of the report.
- Custom intensity indicator (a custom SVG for displaying allergen intensity can be added)



Color settings

Color palette: Palette 1

Color 1:

Color 2:

Color 3:

Color 4:

First level headline color:

Second level headline color:

Third level headline color:

Logos

Logo (left): Browse

Maximum file size 1 MB

This logo will appear on the **top left corner** of the first page of the report.

Text (center):

This text will appear either on the left, right, or center of the top of the first page (depending on your configured logos). Supports the placeholders `{{ PATIENT_PORTAL_QRCODE }}` and `{{ PATIENT_PORTAL_URL }}` to dynamically insert measurement information.

Logo (right): Browse

Maximum file size 1 MB

This logo will appear on the **top right corner** of the first page of the report.

Small logo: Browse

This logo is used on all detail pages. If not set, the default logo is used.

Signatures

Left: Browse

Maximum file size 1 MB

This signature or image will appear on the last page, left aligned.

Center: Browse

Maximum file size 1 MB

This signature or image will appear on the last page, center aligned.

Right: Browse

Maximum file size 1 MB

This signature or image will appear on the last page, right aligned.

Indicators

Custom intensity indicator:

A custom SVG for displaying allergen intensity can be pasted here. Will be styled according to specified colors.

The SVG element must contain the attributes **width** and **height** with a minimum dimension of 16 for correct display in PDF.

SVGs paths which should be colored must require the **colorize** class as well as a fill defined in the **defs** segment of the SVG.



VII.2.2.3 HEADER SETTINGS FOR CUSTOM REPORT TEMPLATE (LEGACY TEMPLATE)

The content and layout of the header can be configured to appear on the left or right side via an 8x2 table. The following information can be added via dropdowns to each position of the 8x2 table:

- Sample Date
- Assay Date
- Analysis Date
- Approval Date
- Print Date
- Patient ID
- Sample Code
- Patient Name
- Date of Birth
- QR-Code
- Amount of tested allergens
- Test method
- Doctor information
- Quality Control text
- Additional Info Text
- Requisition Code
- Approved by
- Tested by

If the dropdown is left at “None”, no text will be displayed at that position. This is the same if no information for a specific position is filled in the measurement details.

Furthermore, a custom headline can be added if desired by ticking the checkbox next to the textbox that should be customized.

Configure report template "New report template"

Header content:		Left half	Right half
		Custom headline	Custom headline
	Patient Name	☐	Doctor Information
	Patient Name	☒	None
	Custom headline		
	Date of Birth	☐	None
	Sample ID	☐	None
	QR-Code	☐	Additional Info text
	Analysis Date	☐	None
	Amount of tested allergens	☐	None
	Test method	☐	Quality Control text



VII.2.2.4 CONTENT SETTINGS FOR CUSTOM REPORT TEMPLATES (LEGACY TEMPLATE)

In the tab “Content” the following settings can be selected:

- Allergens to include
- Allergen sort order: The allergen details in the report (in one allergen group) can be sorted in three different ways:
 - Alphabetical order by allergen codes
 - Descending from the highest to the lowest value
 - Alphabetically order by allergen name (common name)
- Include allergens overview
- Include product type
- Include total IgE with three options:
 - Do not include
 - After specific allergen results
 - On the front page
- Cross-reactive information: By selecting “include cross-reactive information”, explanatory sentences will be added to the end of the report describing those allergen families that are positive on the first page. (see “cross-reactive allergens”). It is possible to include the information as text only or the information and a table of all positive allergens).
- Include interpretation (RAVEN)
- See corresponding Chapter. Here can be selected whether an interpretation shall be included automatically in the report, or only by request.
- Additional information printed on the report under the list of results:
 - Approval date
 - Assay date
 - Doctor Info
 - Print date
 - Report info
 - Sample date



General	Design	Header	Content
Allergens to include:	All allergens	Specifies which kind of allergens should be included in the report.	
Allergens sort order:	Alphabetically by allergen	Specifies the sort order of the allergens.	
Include Overview:	☒	Whether the allergen overview should be printed or not.	
Include product type in overview:	☒	Whether the product type should be printed in the header of allergen overview.	
Include Total IgE:	On the front page	Whether the information of total IgE should be included in the report and where.	
Cross-reactive information:	Include text	This section will be displayed underneath the allergen list itself.	
Include Interpretation:	Include manually	It can be specified if the Raven report interpretation information should be included in the report or not. This section is printed underneath the allergens overview.	

Additional information (below the list of results)		Those informations are integrated into the report in an extra section underneath the allergen list.
Approval date:	☐	
Assay date:	☐	
Doctor info:	☐	The information about the doctor which accompanied the measurement/patient.
Print date:	☒	When the report was generated.
Report info:	☐	The „additional info“ field belonging to the measurement.
Sample date:	☒	

After the change, the report template can be saved by clicking the “Save” Button.

A report template can be duplicated using the button “Duplicate” at the bottom of the page. The current report template will be duplicated and duplicate will be automatically loaded, which can be seen by the name of the report template:

Configure report template "New report template - Duplicate"

General	Design	Header	Content
Name:	New report template - Duplicate		
Support products:	ALEX ²		
Preferred language:	Deutsch (de)		



The following languages are available:

- Azerbaijani
- Albanian
- Arabic
- Arabic (Saudi Arabia)
- Bulgarian
- Chinese
- Chinese (Hong Kong)
- Croatian
- Czech
- Dutch
- English
- English (India)
- English (United Kingdom)
- English (United States)
- Estonian
- Farsi
- Farsi (Iran)
- French
- Georgian
- German
- Greek
- Hindi
- Hungarian
- Italian
- Kazakh
- Korean
- Latvian
- Lithuanian
- Macedonian
- Norwegian
- Persian
- Polish
- Portuguese
- Portuguese (Brasil)
- Romanian
- Russian
- Serbian
- Slovak
- Slovenian
- Spanish
- Spanish (Latin American)



- Spanish (Mexico)
- Swedish
- Thai
- Turkish
- Ukrainian

To define your “default” template, which is used as standard template, you need to have the corresponding user rights. Then, if you go to "Configure Tenant" in the Tenant Admin area, you can select your default language and templates for each type of test.

Tenant configuration
The general configuration settings for your tenant.

[Configure Tenant](#)

General configuration

*** Name:** MADx

Default timezone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna
Configure a timezone to see date and times in (instead of UTC). Please note that users can choose to use a different timezone.

Default report template (ALEX 1): Version 1 (ALEX1 & ALEX2)

Default report template (ALEX 2): Version 2 (ALEX2 only)

Default report language: English (United Kingdom) (en-gb)

Default MOD: < No MOD >

Require ImageXplorer testarray scan: Warn after 60 days, enforce after 90 days.

A report of an unapproved measurement can be viewed by clicking on the measurement QR-Code under in the “New measurements” tab; Select the desired report template and click “Report”.



Details

QR-Code: 02APH008

Sample Code:

Requisition Code:

Sampling Date:

Assay Date:

Patient Code:

Patient Name:

Date of Birth:

Info:

Doctor Info:

Choose a doctor...

Tags:

MOD:

Report Template: Version 2 (ALEX2 only) - Deutsch (de)



Re
ImageX
Analysi

Then you see a preview of the report, where you can select a report template (default or customized) and set the default language. However, it is not possible to download this PDF report. For this purpose, it is necessary to approve the measurement first.

Raptor

Report

Template:

Language:

Usually this tenant's default template and language will be used when sharing or exporting measurements. You may change the template and language associated with this measurement by saving your current configuration.

You can download this report in PDF format once the measurement has been approved.

You have access to manage the report templates and settings via the tenant administration. Please note that any changes will affect all users.

MAD X

MAD X

PATIENT ID
PATIENT NAME
DATE OF BIRTH
SAMPLE ID
LAB CODE
LAB ADDRESS CH
11-9-2020
TESTED ALLERGENS
205
TEST METHOD CODE
ALEX2

REFERRING PHYSICIAN

NOTE
The internal QC (Feasibility check for QC) was within acceptance range.

Lab report: Summary on detectable sensitisations

POLLEN
Grass Pollen

MICROORGANISMS
Fungal Spores & Yeast

Approved measurements can either be downloaded together or individually. To download measurements together, first go to the "Approved measurements" tab and select the measurements you want to download. Then select PDF Report from the drop-down menu and a zip folder containing the PDF Reports will be saved locally on your computer.



RAPTOR New measurements Approved measurements Start m

Approved Measurements

Search by QR-Code, patient, sample, tag, analysis date ...

Download selected measurements ▼

	Source	Tags	Product type	QR-Code	Sample C
☒	IX		ALEX2	02AKV39D	
☒	IX		ALEX2	02AKV39D	
☒	IX		ALEX2	02AKV39D	

Download selected measurements ▼

- Report (PDF format)
- CSV format
- Excel format
- ASTM format
- Update interpretation
- Choose Reporttemplate
- Share
- Move
- Unapprove

If you click on a measurement, you get to the detail area of this measurement. From there, you can also display a preview of the report and change the settings for the header and language of this report. You can then download the report directly from there.

Details

QR-Code: 02AKV39D

Sample Code:

Requisition Code:

Sampling Date:

Assay Date: 27.09.2021

Patient Code:

Patient Name:

Date of Birth:

Info:

Doctor Info:

Analysis: 27.09.2021 15:39

Approved: 27.09.2021 15:39

ImageXplorer: 23167844

Tags:

MOD:

Report Template: Version 2 (ALEX2 only) - Deutsch (de)

Download ▼ **Report** Save >> Move to other tenant



[New measurements](#)
[Approved measurements](#)
[Start measurement](#)
[Automats](#)

Report

Template: Default

Language: English

Save

Use defaults

Usually this tenants default template and language will be used when sharing or exporting measurements. You may change the template and language associated with this measurement by saving your current configuration.

Download PDF

Manage report template and settings

You have access to manage the report templates and settings via the tenant administration. Please note that any changes will affect all users.

Patient ID:	
Patient Name:	
Date of Birth:	
Sample ID:	
Barcode:	02AAE
Sampled on:	
Tested on:	12/18/
Printed on:	12/19/
Note:	The internal QC (Plausibility)

Lab report: Summary on de

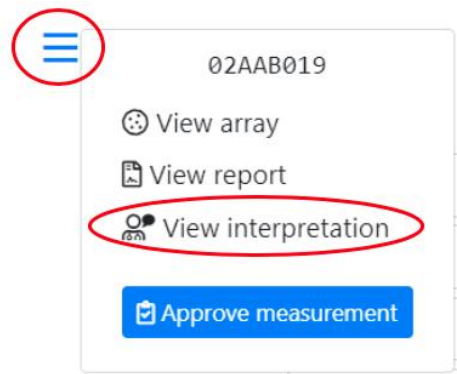
Pollen	Grass Pollen
	Tree Pollen
	Weed Pollen
Mites	House Dust M
Microorganisms	Fungal Spores
	Legumes
	Grain
Plant-Based Food	Spices
	Fruits
	Vegetables
	Nuts & Seeds
	Milk

VII.2.3 REQUESTING INTERPRETATION GUIDANCE

A special software module has been implemented to support the interpretation of test results: RAVEN interpretation guidance.

An interpretation query with RAVEN is possible for both - approved and unapproved - measurements. The report can only be downloaded for approved measurements. The interpretation is added automatically to the report, if a report template is chosen for which the option "Automatically include interpretation" was specified.

In case for your report template the Interpretation option "Include manually triggered interpretation" was selected, you must trigger the interpretation manually for a measurement by getting to the detail page of a measurement, then clicking on the menu icon and selecting "View interpretation".



This opens a window in which the settings, such as language, specific information (age, gender, environment) and symptoms can be entered.

Rule set

RAVEN Ruleset A for ALEX

A rule set defines the RAVEN or RAVEN² engine that is used to interpret results.

 Continue

For “RAVEN Ruleset A and B for ALEX” a page in which the settings, such as language, specific patient information (age, gender, environment) and patient symptoms can be entered, opens.



Patient symptoms

Asthma	None	⌵
Rhinitis	None	⌵
Conjunctivitis	None	⌵
Urticaria	None	⌵
Angioedema	None	⌵
Oral Allergy Syndrome	None	⌵
Eczema	None	⌵
Anaphylaxis	None	⌵
GastroentericSymptoms	None	⌵

≡ Interpretation

Settings

Language: English ⌵

Patient information

Gender: Female ⌵

Age: 30 years

Environment: Continental ⌵

 Request interpretation

For “RAVEN² for ALEX” the language and region can be selected before continuing to the anamnesis, provided as a questionnaire.



Interpretation settings

Language:

English (en)

Region:

No specific region



Continue with Anamnesis

RAVEN[®]

INTERPRETATION SOFTWARE

Overview

Spring

Summer

Perennial

Food

Insects

AIT

Medication

MADx data declaration for smartRaven

☒ I accept to enter clinical data for using the full interpretation function of smartRAVEN

Patient has reported any symptoms

☐ Yes ☐ No

Additional information about the patient

☐ Atopic Dermatitis

☐ Allergen-specific immunotherapy (AIT) - ongoing, completed or discontinued

☐ Medication

Submit

By clicking “Request interpretation” in case of “RAVEN Rulesets A and B for ALEX” or “Submit” in case of “RAVEN² for ALEX” the interpretation will be generated.



Interpretation

Patient information

Gender: Female
 Age: 30 years
 Environment: Continental
 Asthma: None
 Rhinitis: None
 Conjunctivitis: None
 Urticaria: None
 Angioedema: None
 Oral Allergy Syndrome: None
 Eczema: None
 Anaphylaxis: None
 GastroentericSymptoms: None

[Request new interpretation](#)

This measurement already has an interpretation stored. Usually, it should not be necessary to request those again, but it could be necessary when the patients information has changed.

Interpretation

Raven Interpretation Summary

Sample Information

The sample was tested on ALEX² Barcode 02AAB019, interpretation date 12/19/2019.

Of the tested 295 allergens, 25 were above the detection limit of 0.3 kU_L/L. A sensitization can be an indicator of an allergy. For selected allergens, comments for interpretation are listed below.

Total IgE: 512 kU/L

The measured total IgE was 512 kU/L. Above a total IgE of 100 kU/L, allergy is likely.

Cross-Reactive Allergen Sensitization detected

Sensitization against allergen molecules which are markers of (broad) cross-reactivity between different allergen sources.

Detected cross-reactive allergen sensitizations:

- PR-10s: Aln g 1, Bet v 1, Cor a 1.0103, Fag s 1
- Polcalcins: Aln g 4, Phi p 7

PR-10 Proteins (PR10)

PR-10 inhalative: The major birch pollen allergen, Bet v 1, represents the prototype of all PR-10 allergens and is the primary sensitizer in regions with birch pollen exposure. The presence of PR-10 allergens in Fagales tree pollen explains IgE cross-reactivity between pollen from hazel, alder, beech, oak and hornbeam. PR-10 nutritive: PR-10 allergens in raw fruits, nuts, vegetable and legumes can induce oral allergy syndrome and sometimes severe allergic reactions in sensitized individuals. PR-10 allergens are not stable to heat and digestion.

Polcalcins (Ca++ binding proteins, PC)

Members of the PC family can cause inhalative symptoms. PC allergens can be found in pollen from grasses, trees and weeds. Inhalative symptoms manifest as allergic rhino-conjunctivitis and/or allergic asthma.

The interpretation will be then inserted at the end of the report and is also displayed in a preview window. Measurements which have already received an interpretation are indicated



by the following symbol: . After clicking on the symbol, the interpretation can be reviewed as above, with the possibility to update (request new) or delete the existing interpretation.

In addition, several interpretation queries can also be triggered in a batch. If you select several measurements on the overview page (of both unapproved and approved measurements) and click with the mouse on the 3 lines in the upper left corner, you can select "Update Interpretation" to perform the query in batch.

✓ Selected measurements ▾

Download CSV format

Download Excel format

Approve

Update interpretation

Choose Reporttemplate

Modify Tags

Re-Process

» Move

Modify QC Result

Delete



VII.2.4 MULTIPLEX ON DEMAND

The user has the option to choose a defined group of allergens to be considered for the result. In the detail window of a measurement, a predefined panel can be selected. If a panel is selected, the software will only display the allergen spots and results of the selected panel. To reset the selection and display all allergens, select "no MOD".

Details

QR-Code: 02BJU3C0

Sample Code:

Requisition Code:

Sampling Date:

Assay Date:

Recapture Date: 14.03.2024 09:47

Patient Code:

Patient Name:

Date of Birth:

Info:

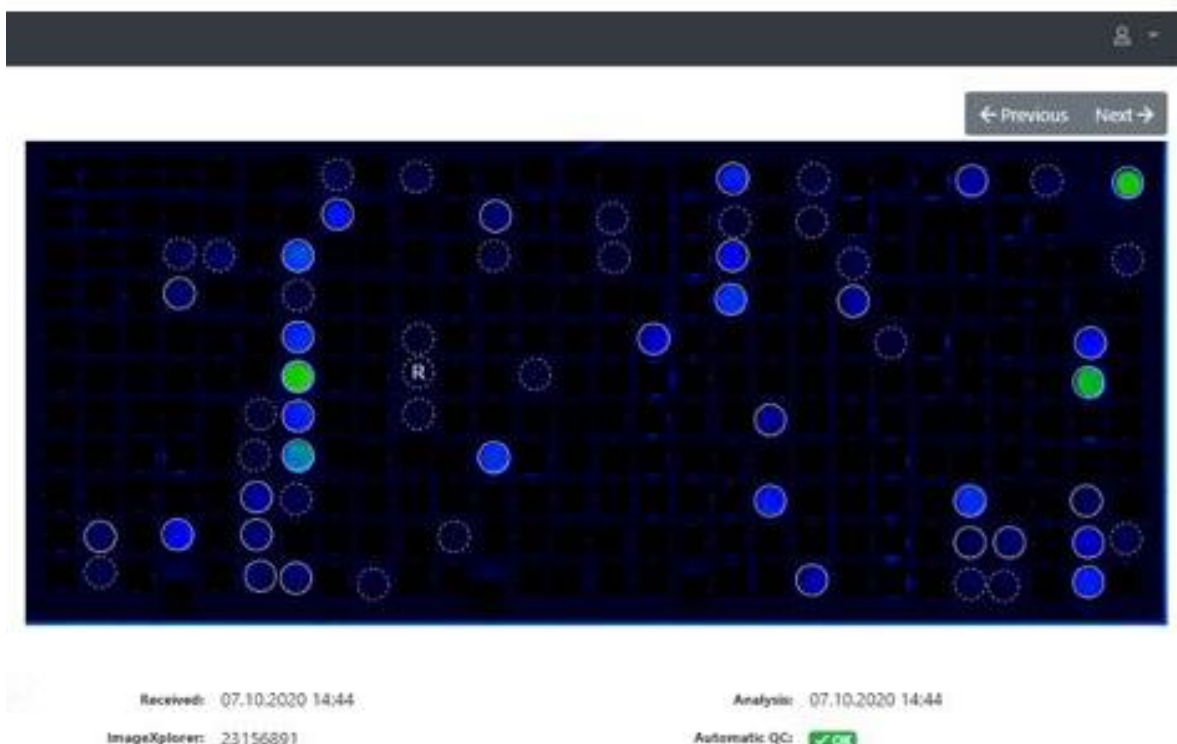
Doctor Info:

Choose a doctor...

Tags:

MOD:

Report Template: Version 2 (ALEX2 only) - English (United States) (en-us)



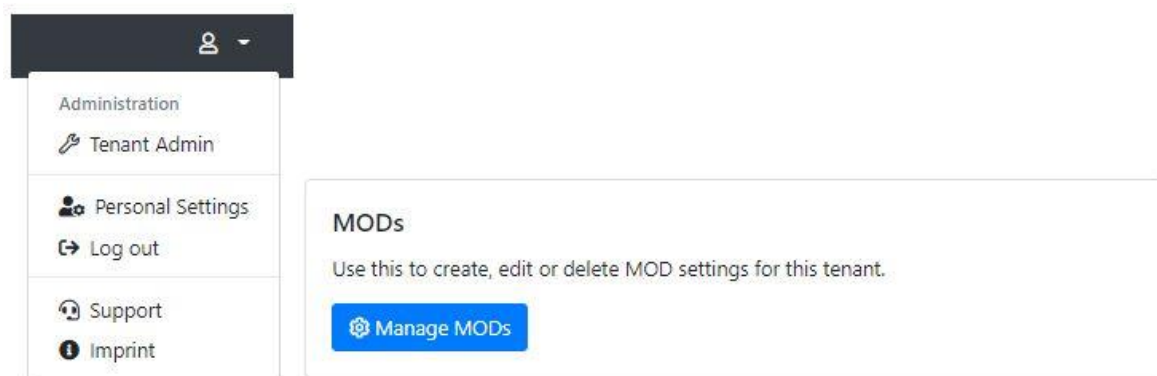


CAUTION! After approval of the measurement, the allergen results, which were not included in the MOD, will be deleted from both image and data. The unselected allergens are then listed in the report as “-“.

The following allergen panels can be selected as the predefined MODs:

- AIT relevant
- ALEX² without venoms
- Animal based food
- Cockroaches, mites & insects
- Contact allergens
- Egg & milk
- Food allergens
- Fruit allergens
- Furry animals
- Inhalative allergens
- Legumes, nuts & seeds
- Molecular allergens
- Plant based food
- Pollen allergens
- Venom allergens

Each tenant can define their own MOD panels. To do this, go to "Tenant Admin" --> click on "Manage MODs" and create a tenant-specific MOD panel by clicking on "Add new MOD". For each product type a MOD can be defined.



Enter the name of the panel, the product type, the MOD type (only specified allergens, or all allergens except the specified ones), and the allergens (by their code) you would like to include in the panel.



Raptor New measurements Approved measurements Start measurement Automats

Create new MOD

Name:

Type:

Deactivated:

You cannot delete an MOD once it is in use. But you can deactivate it, so that it's not available for new measurements anymore.

Allergens:

Enter one allergen (2"

Furthermore, in the tenant configuration (Tenant Admin → Configure Tenant) there are three MOD settings available.

General configuration

* Name:

Default timezone:

Configure a timezone to see date and times in (instead of UTC). Please note that users can choose to use a different timezone.

Default report template (ALEX 1):

Default report template (ALEX 2):

Default report template (FOX):

Default report template (PAX):

Default report language:

Default ALEX2 MOD:

Default FOX MOD:

Default PAX MOD:

Force MOD:

Requires a measurement to always have an MOD assigned. If this setting is enabled, a measurement cannot be approved without an MOD assigned.

Hide Global MOD:

If this setting is enabled, only the tenant-specific MOD will be available to select, and the global system-wide MOD will be hidden.

Display MOD Excluded Spots As Research Use Only:

If this setting is enabled, spots excluded by an MOD will not be hidden from the measurement image, but displayed as a "RUO spot".

Require ImageXplorer ConfigXplorer scan: Warn after 60 days, enforce after 90 days.



- **Force MOD:** If this setting is true, a MOD must be selected when saving or approving a measurement.

Doctor Info:

Choose a doctor...

Tags:

MOD:

MOD is required!

Report Template: ALEX2_v1.17 - Español (es)

- **Hide Global MOD:** When this setting is true, global MODs are not displayed in the MOD drop-down list when editing a measurement.

MOD:

Report Template:

Force MOD:
Requires a measurement to always have an MOD assigned. If this setting is enabled, a measurement cannot be approved without an MOD assigned.

Hide Global MOD:
If this setting is enabled, only the tenant-specific MOD will be available to select, and the global system-wide MOD will be hidden.

Display MOD Excluded Spots As Research Use Only:
If this setting is enabled, spots excluded by an MOD will not be hidden from the measurement image, but displayed as a "RUO spot".

MOD:

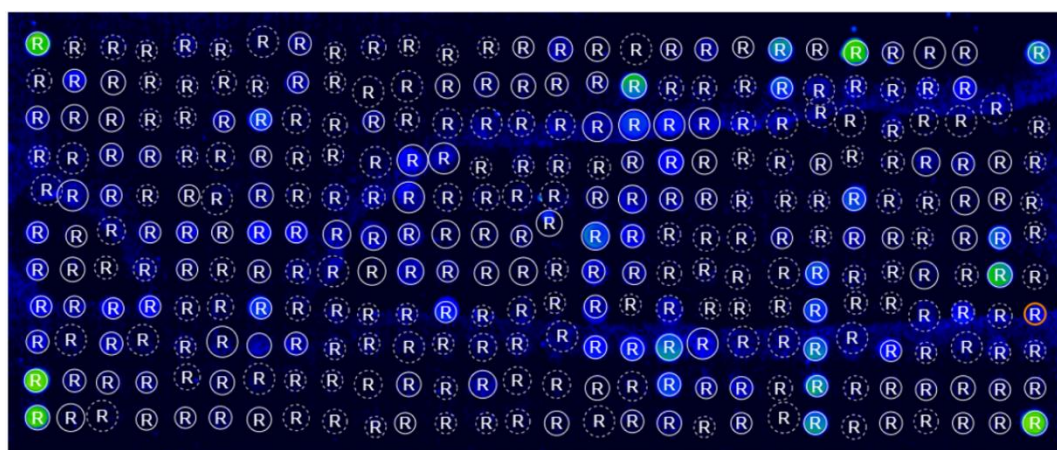
Report Template:



- **Display MOD Excluded Spots As Research Use Only:** If this setting is true, the spots hidden by the MOD will be displayed as RUO in the Details and Array views of the measurement. (In the personal settings page, Research Spots must be set to Show).

Force MOD:	False	Requires a measurement to always have an MOD assigned. If this setting is enabled, a measurement cannot be approved without an MOD assigned.
Hide Global MOD:	False	If this setting is enabled, only the tenant-specific MOD will be available to select, and the global system-wide MOD will be hidden.
Display MOD Excluded Spots As Research Use Only:	True	If this setting is enabled, spots excluded by an MOD will not be hidden from the measurement image, but displayed as a "RUO spot".

Configuration	
Calibration string:	Allows to override the calibration information from the cartridge's QR-Code. Leave empty to use the calibration information from the QR-Code on the cartridge (the usual behaviour).
Research spots:	Show research spots If enabled, "research use only" spots will be displayed on measurement details and arrays. This does not affect the export behaviour or the reports of measurements.

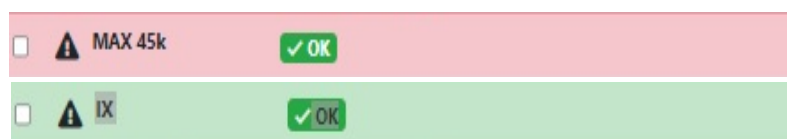




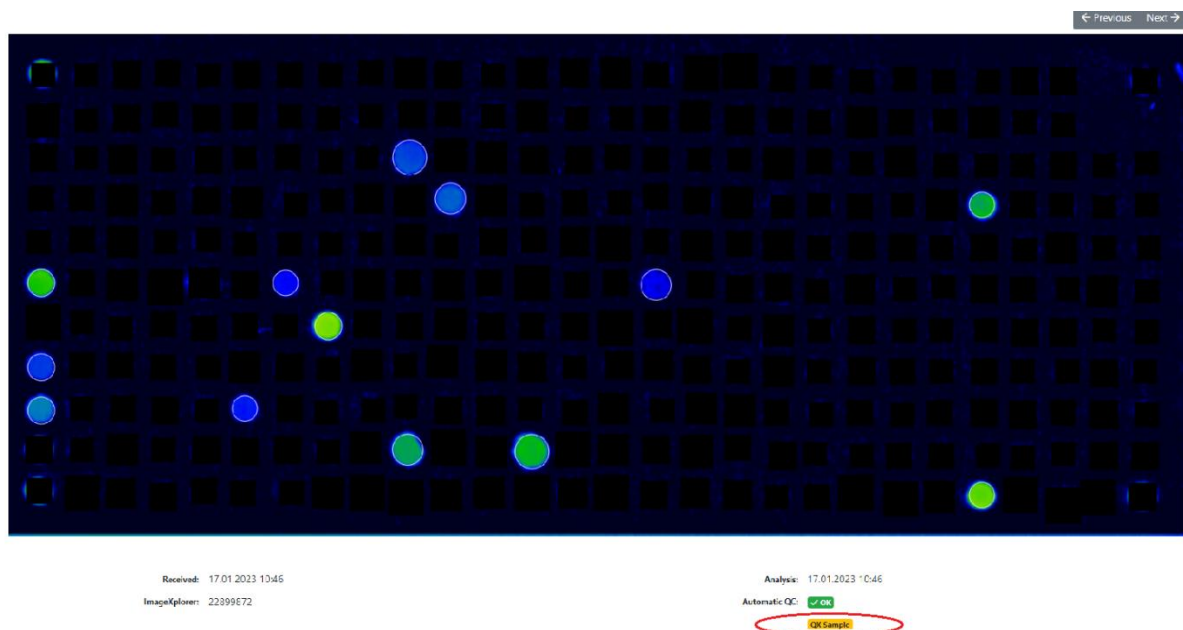
VII.3 MEASUREMENTS OF QUALITY SAMPLES

“Lyphochek Allergen IgE, Panel A” from Bio-Rad Laboratories (REF 12000142, REF 12000144) can be used as a quality sample. Acceptance criteria for selected allergens of the respective Lyphochek lot (lot 22670, lot 22660, lot 22650, lot 22640) are stored in the RAPTOR SERVER.

New measurements of quality samples are displayed in the “New Measurements” overview. If the measurement is highlighted in red, the measured values of individual antibodies are outside the defined acceptance intervals. If the measurement is marked as green, all acceptance criteria have been met.



The detailed view of a measurement shows the analysis picture with all allergens. Only these allergens are shown in this image and this specific MOD cannot be modified. In addition, the analysis image is also marked as a QC sample.



The detailed results of the measurements can be found in tabular or graphic form in the QC module of the device (Tenant Admin > Manage ImageXplorers or Manage MAX Devices). If the device is connected to the RAPTOR-SERVER, the QC module can also be controlled directly via the link on the dashboard (see page 8).

A report of a quality sample measurement can be loaded via the option “List View” and “View Results”.



MAX devices for "MADx Tenant"

[Add new MAX device](#)
[Download MAX Agent Software](#)

Name	Type	Key	Serialnumber	Last connection	Last activity	
9k-TR03-PROD	Max9k	9Dgg8JMH64E03gag5hdjknB16KVRB	22069993	vor 7 Monaten	vor 7 Monaten	QC Configure
AutomatWithKeyThatDidNotWorkBefore	Max45k	1q4DGWbYq1IOcPudmNlyMMwvrX2B6G	19090008	vor einem Jahr	nie	List View
MAX 002	Max45k	d0bknHfKbJEa6eMMbLnN71JGTG101V	19120002	vor einem Jahr	vor einem Jahr	Chart Trend View

The option "Chart Trend View" shows all acceptance criteria for the in graphic form, with the acceptance interval also being marked in color (with at least two measurements). To provide more information for the evaluation, the CV, Standard Deviation and the Mean Value are available for each allergen by default. It is also possible to remove them from the chart by clicking their name in the description below the chart.



CV: 114,08 %

SD: 0,768 kUA/L

After a min. number of measurements (e.g.: 20 measurements), device-specific intervals (2 and 3 standard deviations) can be monitored. In this way, the laboratory-specific intervals for each Lyphocheck allergen can be determined precisely.



VII.4 DELETING MEASUREMENTS

Non-approved (new) measurements can be deleted by selecting the desired measurements and choosing “delete” in the drop-down menu. Before a measurement is permanently deleted, a warning appears that is to be approved. Deleted measurements will be permanently erased and cannot be restored.

New Measurements

Search by barcode, patient, sample, tag, analysis date, a

Selected measurements ▾

- Download CSV format
- Download Excel format
- Approve
- Update interpretation
- Re-Process
- » Move
- Delete**

Tags	Product type
	FOX
	FOX
	ALEX2
	FOX
	ALEX2
	ALEX1

Delete measurements

You are about to delete the following measurements. Please note that this action is irreversible and cannot be undone.

Barcode	Analysis Date
02AAB160	16.12.2019 13:41

It is also important to know, that the deletion of new measurements is linked to the specific user right “edit measurement”. Tenant admin users with this right or system admin users can delete new measurements. Tenant admin users without this right don’t have this option. But any user can request the deletion of measurements on the RAPTOR SERVER GUI (opened measurement, at the bottom right). This request can also be withdrawn.

Plant Food Food	M	Jug r 3	0.40
Plant Food Food	M	Jug r 1	0.38



Plant Food	M	Jug r 3	0.40
Food			
Plant Food	M	Jug r 1	0.38
Food			

Delete request scheduled now. [Cancel delete request](#)

System admin users will receive this request (special feature in the system admin rights: “Measurement delete/unapproval log & requests”) and they can accept or reject it.

Sign in. Can be

Background jobs
View details about running background jobs and manually schedule runs.
[View dashboard](#)

Measurement delete / unapproval log & requests
Show logging and pending requests for measurement delete and unapproval.
[Show log & requests](#)

Measurement unapproval / delete requests

Open requests Log & Finished requests				
Requested UTC	Requesting User (Email)	QR-Code	Request Type	Action
11.10.2023 13:05:28	Test Test (Test@test.com)	02AYQ145	Unapprove	Accept Reject
11.10.2023 12:59:27	Test Test (Test@test.com)	02AYQ14C	Delete	Accept Reject

For an unapproval request, users can follow the same functionality (“request unapprove”; opened measurement, at the bottom right). Again, system admin users are receiving such requests, and they can accept or reject this request.

Any deletion or unapproval will be logged in the database which stays in line with regulatory requirements.

Measurement unapproval / delete requests

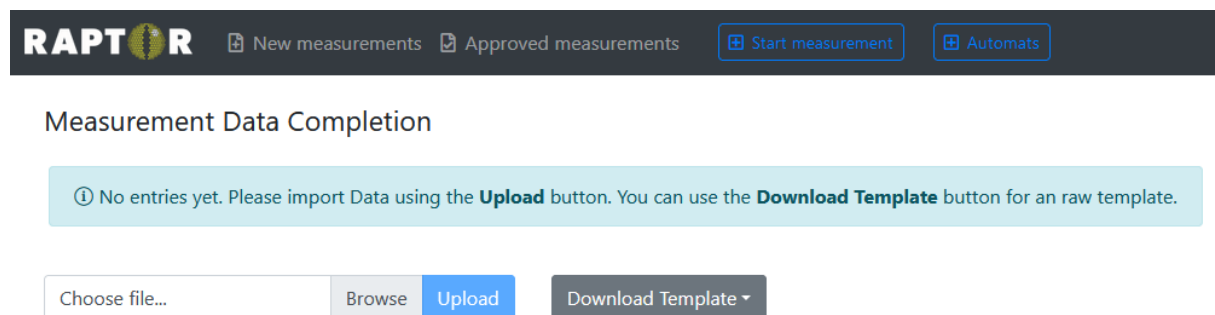
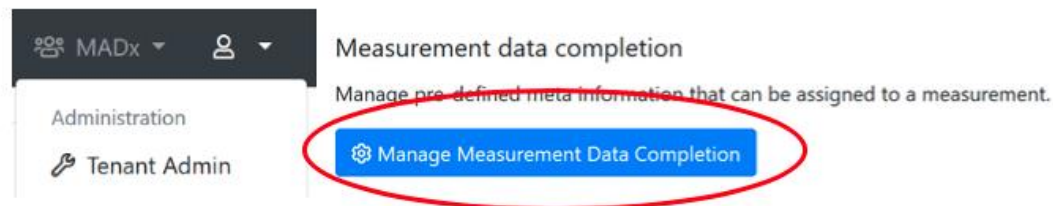
Open requests Log & Finished requests						
Requested UTC	Completed UTC	Requesting User (Email)	Processing User (Email)	QR-Code	Request Type	Decision
11.10.2023 08:49:38	11.10.2023 08:49:38		Sigi Schnabl (schnabl.s@macroarraydx.com)	02AYQ145	Unapprove	
11.10.2023 08:40:31	11.10.2023 08:40:31		Sigi Schnabl (schnabl.s@macroarraydx.com)	02AYQ14C	Unapprove	
11.10.2023 08:15:49	11.10.2023 12:54:53	Siegfried Schnabl (s.schnabl@gmx.at)	Sigi Schnabl (schnabl.s@macroarraydx.com)	02AYQ146	Delete request	Accepted
10.10.2023 15:30:27	10.10.2023 15:30:27		Sigi Schnabl (schnabl.s@macroarraydx.com)	91AAED13	Delete	
10.10.2023 14:58:04	11.10.2023 12:54:55	Siegfried Schnabl (s.schnabl@gmx.at)	Sigi Schnabl (schnabl.s@macroarraydx.com)	02BFE3D5	Delete request	Rejected

If users are submitting a request for the unapproval or deletion of a measurement, they will receive an e-mail notification as soon as the request has either been accepted or rejected by a system administrator.



VII.5 IMPORTING INFORMATION FROM A FILE

Information corresponding to a certain test QR-Code can be added in an Import-Template .csv or .xls file. To download this file, go to the Tenant Admin area and click on "Manage Measurement Data Completion" under "Measurement data completion". There you can choose between the .csv and .xls formats (xls is suggested).



After downloading the template file, you can type in specific details for the corresponding QR- or Sample Code, save it on your computer, upload the document again and click "Apply Changes". In case of MAX measurements, the matching will take place based on the Sample Code. For ImageXplorer measurements, the QR-code shall be provided and added in the first column of the template file. For MAX devices, add the Sample Code in the first column and do not add a QR code.

A	B	C	D	E	F	G	H	I	J
Identifier	Sample Code	Patient ID	Patient Name	Date Of Birth	Sampling Date	Assay Date	Referring Physician	Additional Info	Requisition Code
QR-Code/SampleCode	SampleCode	PatientId	PatientName	31.12.2000	01.01.2015	15.03.2015	ReferringPhysician	AdditionalInfo	RequisitionCode

After uploading this file, the entered information will be displayed. This information can be further edited, and changes can be applied.

Verify Changes

+	QR-Code	CreatedAtUtc	SampleId	PatientId	PatientName	DateOfBirth	SamplingDate	AssayDate	ReferringPhysician	AdditionalInfo
+	02AAB159	-	12	Te	Test	31.12.2000	01.01.2015	15.03.2015	Dr.A	Info

Apply Changes ← Cancel



Measurement Data Completion

QR-Code	CreatedAtUtc	SampleId	PatientId	PatientName	DateOfBirth	SamplingDate	AssayDate	ReferringPhysician	AdditionalInfo	Actions
02AAB159	01.07.2022 10:44:36	12	Te	Test	31.12.2000	01.01.2015	15.03.2015	Dr.A	Info	 

If an image is acquired and the information for the corresponding test QR-Code was uploaded before, the information is automatically imported into the software.

VII.6 ADDING A USER TO THE RESULT SHARING PORTAL AND SHARING A MEASUREMENT

Measurements can be shared with a doctor or a user who is not registered to any Tenant on RAPTOR Server. To do this, you must first create a user account on the Result Sharing Portal for the doctor. To create the account, go to "Tenant Admin --> Result Sharing Portal", click on "Manage Users" and add a new doctor.

Enter the user information and send an E-mail for password creation. Alternatively, you can predefine the password for the user. Make sure you change the status of the user to "enabled".

Only already approved measurements can be shared. For this purpose, please go to the tab "Approved measurements", click on the detail page of a measurement, click on the menu icon, and select "View Shares".

Add new user on Result Sharing Portal

General configuration

First name:

Last name:

E-Mail address:

Username:

It is a good idea to use the users e-mail-address as username as well.

Status:

Locked (user cannot log in)

Enabled (user can log in)

Locked (user cannot log in)

Password:

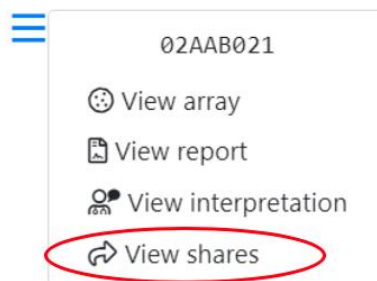
Send an invitation e-mail to user automatically

Doctor Info Text:

This information will be printed on a patients report.

Save

Cancel



Then select the user with whom you want to share the measurement and click "Share". After that you can send a link by E-mail, with which the user can access this measurement.



≡ Share

You are about to share a measurement with a user of the User Portal. Please note that the doctor will have access to the results of the measurement. Once you share a measurement you'll be provided with a link to access the shared information via the encrypted User F

Barcode: 02AAB021

Share with: X Dr. (testuser2@macroarraydx.com)

If you can't find a specific user of the User Portal, go to the [tenant administration](#) to configure the list of available users of the User Portal.

Share

Cancel

Measurements that have been shared are marked with the following symbol in the list of



approved measurements:

Shared measurements can also be withdrawn by a tenant user, by clicking on Revoke:

User	Link	Shared
RP Bak	https://resultshare.raptor-server.com/s/07PXEpC7ZNytm4PdRfmct4NR5pUtWq5FJcqOY7Ry6oEx08U5j	7 months ago Revoke

VII.7 LOG-OUT

To log out of RAPTOR SERVER, click on the personal menu symbol in the upper right corner, choose "Log out" and close the window.

- Administration
 - Tenant Admin
 - System Admin
- Personal Settings
 - Log out**
- Support
- Imprint



VII.8 RESULT SHARING PORTAL

The Result Sharing Portal can be accessed via <https://resultshare.raptor-server.com>.

The screenshot shows the login interface of the Result Sharing Portal. At the top, there is a dark header bar with the MADX logo and the text 'Result Sharing Portal' on the left, and a language dropdown menu set to 'English (en)' on the right. Below the header, the page title 'Welcome to the Result Sharing Portal' is displayed. A paragraph explains that users need a username and password to log in and view shared measurements. The login form consists of two input fields: 'Your username' and 'Your password'. The password field has an eye icon to toggle visibility. A blue 'Log in' button is positioned below the fields. At the bottom, a link for 'request a new one' is provided for users who forgot their password.

Please enter your username and your password:

Your username

Your password

Log in

Did you forget your password? No problem, you can [request a new one](#).

The language can be changed at the top of the screen. By clicking the eye icon the entered password can be made visible. A new password can be requested by clicking “request a new one”.

This screenshot is identical to the previous one, but the password field now displays the text 'password' instead of being masked, and the eye icon is crossed out, indicating that the password is visible.

Please enter your username and your password:

Your username

password

Log in

After logging in, the user can view the details of the measurements which have been shared with them. On the top of the page the password can be changed by clicking “Change password”.




Result Sharing Portal

English (en) ▼
Change password
Log out

Measurements

These are the measurements that are available for you. You may view the details of each measurement, or download the report PDF file.



Measurement	Product	Patient	Sample	Date
01AAK239	ALEX1		11852162	7/12/2019
01AAK281	ALEX1		04824821	12/18/2019
01AAK891	ALEX1		66560260	1/28/2020
02AAA015	ALEX2			2/21/2020

The list of shared measurements can be sorted by QR-Code, Product type, Product name, Patient name, Sample ID or date.

By clicking on the QR-Code of a measurement a new page opens. On this page the report language can be chosen for each measurement individually.

After choosing the language either an interpretation can be requested or the report can be downloaded directly by clicking on “Download Report”. Clicking on “download report” will open a new window displaying the report in pdf format.

Measurement 02AYQ143

Product: ALEX2
Patient:
Date of Birth:
Sample:
Info:
Doctor Info:
Sampling Date:
Assay Date: 10/12/2023
Processed Date: 10/12/2023
Approval Date: 10/12/2023

Report Language:
English (United Kingdom) ▼

You can request a new RAVEN interpretation that will be included in the report.

[Request new RAVEN interpretation](#)

You can download a PDF report that includes all information and results of this measurement.

[Download Report](#)

[Back](#)

Log out of the Result Sharing Portal by clicking the “Log Out” Button at the top of the screen.

English (en) ▼
Change password
Log out



VII.9 TECHNICAL SUPPORT

If you have any questions, experiences or difficulties concerning the RAPTOR SERVER Analysis Software, please contact your local distributor.

VII.10 TECHNICAL DATA

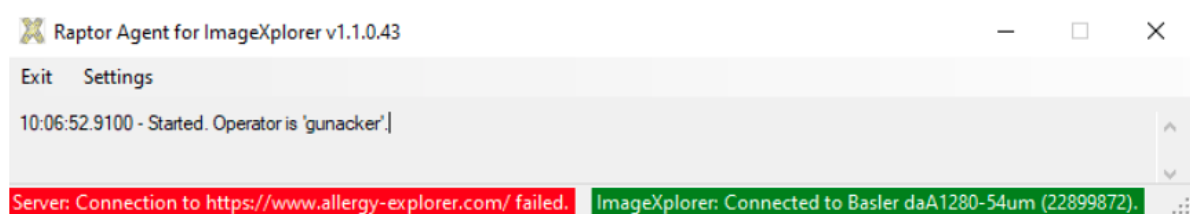
The GUI of RAPTOR SERVER can be accessed in a single web-browser. The application is optimized for Google Chrome on Windows 10 and 11. Following access rights must be enabled for the use, at least on the outgoing port 443:

- www.raptor-server.com
- <https://api.raptor-server.com/swagger>
- <https://resultshare.raptor-server.com>
- www.madx.com

VII.11 TROUBLESHOOTING

The following errors are the most common ones and therefore explained here in more detail.

Server Connection to www.raptor-server.com failed (Agent flags connection in red color)



Possible Solutions:

- Check internet connection
- Click settings and check if RAPTOR SERVER URL (www.raptor-server.com) is correct
- Click settings and check if ImageXplorer key is correct and corresponds to the one specified for the Tenant on RAPTOR SERVER



Settings ✕

Please enter the settings for your ImageXplorer. You can find your ImageXplorer key when you log in to Raptor. Please contact support if you're not sure what the proper settings are for your ImageXplorer.

Raptor URL:

ImageXplorer Key:

ImageXplorer Connection failed (Agent flags connection in red color):

Raptor Agent for ImageXplorer v1.1.0.43

Exit Settings Open Raptor

10:06:52.9100 - Started. Operator is 'gunacker'.
10:11:33.9399 - Disconnecting from server ...
10:11:35.0321 - Server confirms successful authentication to tenant MADx.]

Server: Connected to MADx. ImageXplorer: Connection failed.

Possible Solutions:

- Check if ImageXplorer is connected to the computer
- Reconnect ImageXplorer to the computer (pull out and plug in the USB cable again).
- Click settings and check if the ImageXplorer key is correct and the same as on RAPTOR SERVER

Settings ✕

Please enter the settings for your ImageXplorer. You can find your ImageXplorer key when you log in to Raptor. Please contact support if you're not sure what the proper settings are for your ImageXplorer.

Raptor URL:

ImageXplorer Key:



Start Measurement is not possible:

RAPTOR  [New measurements](#) [Approved measurements](#) [Start measurement with ImageXplorer](#)

The ImageXplorer IX training cannot be used, because it requires a ConfigXplorer scan.

[Go to ImageXplorer configuration](#)

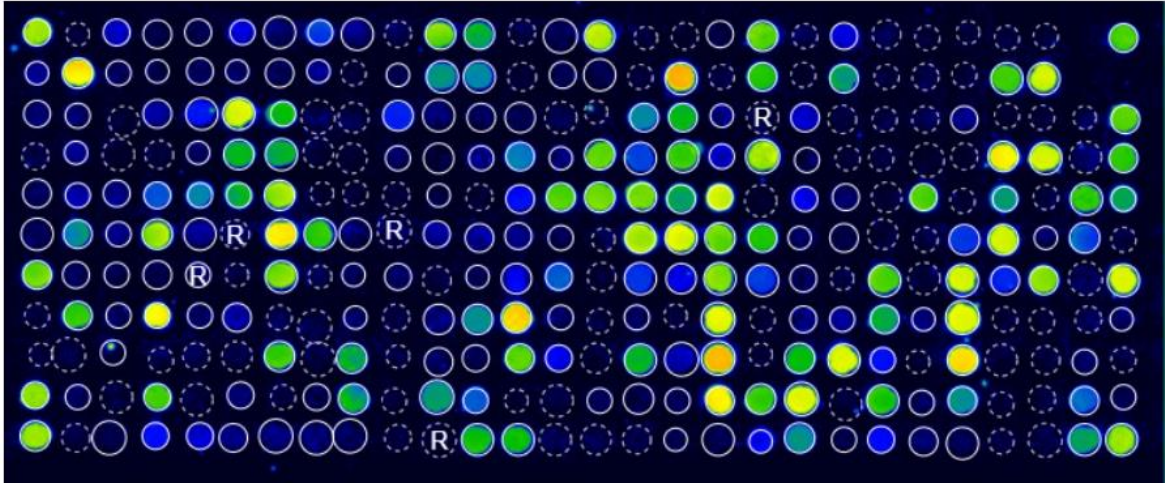
Possible Solutions:

- Check if ImageXplorer is connected
- Check if the last required ConfigXplorer Scan has been performed

Failed transmission of the measurements to the RAPTOR-SERVER:

Each measurement consists of 257 individual images (256 images of the ROI and 1 image of the QR-code). If the number of transferred images is lower (due to unstable transfer) the error message ("Analysis Error: Insufficient data transfer – check connection" appears with the image in the RAPTOR SERVER. In this case, the measurement has to be repeated.

Next →



Received: 06.04.2023 13:37

Analysis: 06.04.2023 13:37

ImageXplorer: 40287249

Automatic QC: ✗ Failed

Analysis Error: Insufficient data transfer - check connection.



Possible solutions:

- Please, use the original USB cable, which was sent along with the device.
- Use a different USB port on the computer to which the ImageXplorer is connected.
- The ImageXplorer has to be connected via a USB 3.0/3.1 port. Notebooks or laptops have a so-called “always-on” USB port (usually the port next to the charging port). If possible, use this port.
- Reconnect ImageXplorer to the computer (pull out and plug in the USB cable again).

If you still experience problems or have any other questions to the products and services of MADx, please contact your local distributor.

VII.12 CHANGE HISTORY

Version	Description	Replaces
02	Created on basis of English IFU Version 24. III.1 Table with required products for analysis and imaging split, VII.2.1.2 Device Information added as possible header content, VII.2.1.6 and VII.2.2.4 possibility to duplicate report template added. VII.1.3 Possibility to enforce MFA added, VII.3 Lyphochek lot 22670 added, Korean, Kazakh and Chinese (Hong Kong) added as available languages.	01

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