



INSTRUCTION FOR USE

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DISCLAIMER

MacroArray Diagnostics 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 MacroArray Diagnostics 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 MacroArray Diagnostics.

Please consult the relevant instructions for use of ALEX² and FOX tests before processing!

LIABILITY STATEMENT

This guide was checked for correctness. The instructions and descriptions for the RAPTOR SERVER Analysis Software and ImageXplorer were correct at the time this guide was written. Subsequent guides may be changed without prior notice; however, MacroArray Diagnostics assumes no liability for harm caused directly or indirectly by errors from the guide. The ImageXplorer and RAPTOR SERVER are *in-vitro* diagnostic devices that is 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 MacroArray Diagnostics.



I. ABBREVIATIONS

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

II. INTENDED PURPOSE

The RAPTOR SERVER Analysis Software is an accessory to ALEX technology-based products. The IVD medical product analyses pictures of ALEX technology-based arrays and is used by trained laboratory personnel and medical professionals in a medical laboratory.

Currently available test kits for use with RAPTOR SERVER:

- ALEX² - REF 02-2001-01, REF 02-5001-01
- FOX - REF 80-5001-01

This Instruction for Use is applicable for the following product:

Basic UDI-DI	REF	Product
91201229222JW	22-0000-01	RAPTOR SERVER Analysis Software



III. SUMMARY AND EXPLANATION

RAPTOR SERVER Analysis Software is a web-based alternative to Raptor Analysis Software. RAPTOR SERVER is a cloud-based application and is operated via the browser. RAPTOR SERVER is a software for the acquisition and analysis of medical device images taken by the ImageXplorer device from processed ALEX² or FOX test arrays. RAPTOR SERVER is developed as a standalone solution which also performs the storage of data and creation of reports based on the diagnostic 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 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 ALEX² and FOX 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 centre (RAPTOR SERVER "on-premise") is also possible, though with much limited support and features.

IMPORTANT USER INFORMATION:

For the correct use of the ImageXplorer and 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.








IV. PRINCIPLE OF THE PROCEDURE

ALEX² and FOX tests are solid-phase immunoassays. Allergen extracts or molecular allergens, which are coupled to nanoparticles, are deposited in a systematic fashion onto a solid phase forming a macroscopic array.

First, the particle bound allergens react with specific IgE (ALEX²) or IgG (FOX) antibodies which are present in the patient sample. After incubation, non-specific IgE/IgG is washed off. The procedure continues by adding an enzyme labelled antihuman detection antibody which forms a complex with the particle bound specific IgE/IgG. 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 patient 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 MADx's RAPTOR SERVER. ALEX² test results are reported in allergen specific IgE units (kUA/l), along with the total IgE results in IgE units (kU/l). FOX test results are reported in specific IgG units (µg/ml).

V. GLOSSARY OF SYMBOLS

	In vitro diagnostic medical device
	CE mark
	Manufacturer
	Caution
	MacroArray Diagnostics (MADx)



VI. SAFETY INSTRUCTIONS

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 analytical and patient related 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.

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.




RAPTOR

SERVER ANALYSIS SOFTWARE

Welcome to RAPTOR-SERVER, the analysis software for the **ALEX** and **FOX** multiplex test. Please log in below to continue.

Log in with Azure AD / Office 365

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**

Log in with Username & password

Please enter your username and password.

Your username

Your password

 **Log in**



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

After successful login, the user has access to their tenant and 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	99AFGDF7	NK FOX	30/03/2023 20:50	Details Report
❌ Failed	Research MAX 45k	99AFGDF8	N.G.	30/03/2023 20:50	Details Report
❌ Failed	Research MAX 45k	99AFGDF9	E18735	30/03/2023 20:50	Details Report
❌ Failed	Research MAX 45k	99AFGDFA	20220325w56	30/03/2023 20:50	Details Report
❌ Failed	Research MAX 45k	99AFGDEE	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](#)

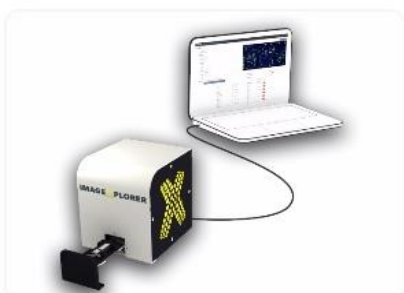
Approved Measurements				
QR-Code	Product type / Source	Sample Code	Analysis Date	
02AVJ227	ALEX2	Anna LMaciey	28/03/2023 21:17	Details Report
02ARA379	ALEX2 IX	SM_28032023	28/03/2023 14:29	Details Report
02ARA393	ALEX2 IX	RG_28032023	28/03/2023 14:26	Details Report
02AVA31F	ALEX2 MAX 45k	PR_Mar2023_11	21/03/2023 15:05	Details Report
02AVI3B9	ALEX2 MAX 45k	KF	17/03/2023 14:46	Details Report
02AVT337	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
02AXE29A	ALEX2 MAX 9k	OW	19/01/2023 19:12	Details Report
 02ALY3AE	ALEX2 MAX 45k	BS7_Oh2022_B	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 and QualityXplorer scans and monthly maintenance can be initiated via the dashboard. 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



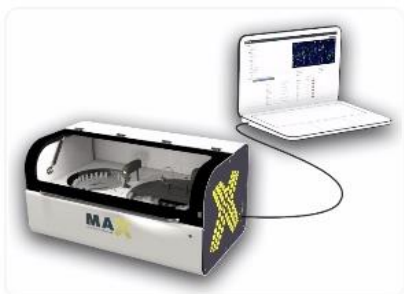
IX Test

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

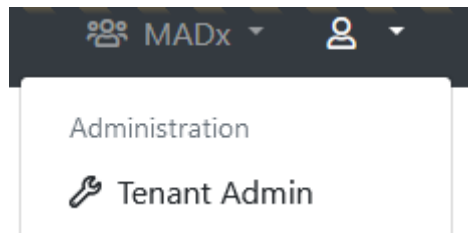
In "Personal Settings" you can select the user language, the culture (e.g., English (UK)) and the time zone. ALEX² contains 5 Research Use Only (RUO) allergen spots. These are deactivated by default. To make the RUO spots visible, the user can select "show research spots" in the drop-down menu. In addition, 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, since these details are included in the Data Protection Agreement (DPA) and Terms of Service (ToS). Download the documents, add your signature, and upload the signed documents by clicking on “Browse”.

NOTE: The use of RAPTOR SERVER is officially enabled only after submitting the signed DPA and ToS.



RAPTOR New measurements Approved measurements [Start measurement](#) [Automats](#) MADx Testtenant

Configure "MADx Testtenant"

General configuration

*** Name:** MADx Testtenant

Default timezone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm
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 template (FOX): FOX

Default report language: Deutsch (de)

Default MOD: < No MOD >

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

Automat default settings

*** Default Minimum RunId:** 10
When a new Automat is created, this value will be used for its Minimum Run Id

Interpretation

License Key: RAVEN_basic_DE

This license key is valid.

Holder:
-

Notes:
-

Valid until:
12/31/2025

Company Details

*** Legal Entity Name:** MacroArray Diagnostics GmbH

*** Street and Number:** Lemböckgasse 59/Top 4

*** Zip Code:** A-1230

*** City:** Vienna

*** Country:** Austria

*** Phone:** +43(0) 1 865 25 73

*** E-Mail:** office@macroarraydx.com

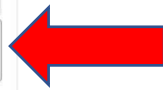
*** Legal Representative:** Christian Harwanegg

Website:

Vat Number:

Company Register Number:

ToS & DPA (signed): Choose file Browse [Download pre-printed PDF form for signing](#)





Company Details

* Legal Entity Name:	MacroArray Diagnostics GmbH
* Street and Number:	Lemböckgasse 59/Top 4
* Zip Code:	A-1230
* City:	Vienna
* Country:	Austria
* Phone:	+43(0) 1 865 25 73
* E-Mail:	office@macroarraydx.com
* Legal Representative:	Christian Harwanegg
Website:	
Vat Number:	
Company Register Number:	
ToS & DPA (signed):	<input type="button" value="Choose file"/> <input type="button" value="Browse"/> <input type="button" value="Download pre-printed PDF form for signing"/>

3

2 **1**

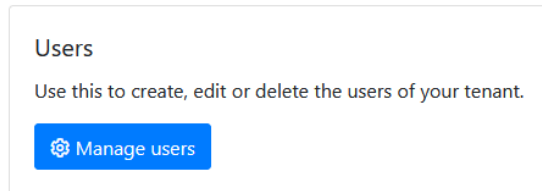
Other important pages of the Tenant Admin area are:

- ImageExplorers: Use this to configure existing ImageExplorers or add new ones. Every ImageExplorer 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 patient 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.

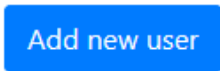


VII.1.4 ADD USER TO A TENANT

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".



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:	<input type="text" value="New user"/>	E-Mail address:	<input type="text" value="name@server.com"/>
Status:	<input type="text" value="Enabled (user can log in)"/>		

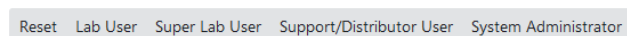
Login Credentials

Type:	<input type="text" value="Username and Password"/>	<small>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).</small>	
Username:	<input type="text"/>		
	<small>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.</small>	Password:	<input type="text" value="Automatically send invitation e-mail"/>

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.





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:

<input type="checkbox"/> 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 ImageExplorers	Can view agent devices	Can manage MAX devices	Can manage connections	Can manage users	Can manage users of Result Sharing Portal	Can manage report templates	Can manage measurement data completion	System Administration	Can unapprove measurements	Can use a custom calibration string	Can manage Run Configurati	Can skip f
<input type="checkbox"/> Another MADx Tenant	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/> MADx Tenant	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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

- 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.

Search: 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](#)

<input type="checkbox"/> 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 ImageX
<input checked="" type="checkbox"/> Another MADx Tenant	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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.

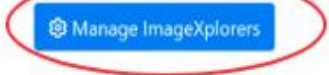


MADx [User Icon]

- Administration
- Tenant Admin

ImageExplorers

Use this to configure ImageExplorers, or add new ones. Every ImageExplorer needs to be known to **Raptor Server**, otherwise it won't be able to connect.



Add new ImageExplorer

General information

Name:

Key: Cxltclg8ok5wQ6CqJ4EZLWGnw2PdJ3
This key is required when installing an Agent.

ImageExplorer Serialnumber:
Serialnumber of connected ImageExplorer.

Notes:

Internal Notes:
For internal use only.

Disabled:

QR-Code image configuration

QR-Code Exposure:

Calibration configuration

Mode:

Array image configuration

Array Offset X:

Array Offset Y:

Array Width:

Array Height:

Array Exposure:

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

ImageExplorers for "MADx"

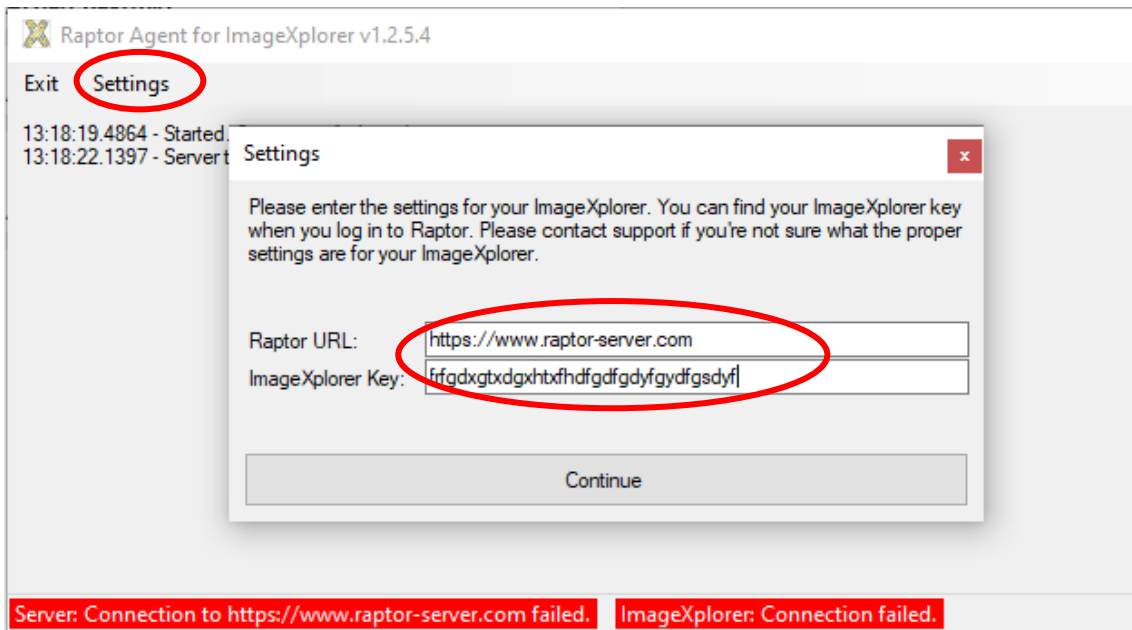
Carry out the installation of the ImageExplorer agent, as a regular installation process.



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

B

A: Connection to RAPTOR SERVER

B: Connection to ImageXplorer

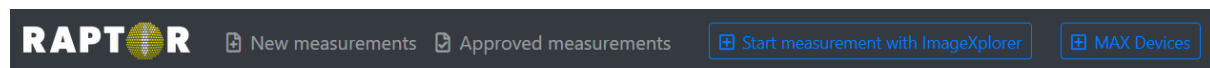


If a connection to both the RAPTOR SERVER and the ImageXplorer is established, both fields are highlighted in green. If one connection fails, refer to the troubleshooting section for further instructions.

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 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 (ALEX2 / FOX)
- corresponding allergen layout
- QC information
- Lot number of cartridge

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



RAPTOR

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

Details

Barcode: 02AE3488

Sample Code:

Requisition Code:

Sampling Date:

Assay Date:

Patient Code:

Patient Name:

Date of Birth:

Info:

Doctor Info:

Choose a doctor...

Tag:

MOD:

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

B

Received: 04.10.2021 16:23
Analysis: 04.10.2021 16:23

ImageXplorer: 22124137
Automatic QC: ✔ OK

* Only positive allergens

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

A: Patient and sample information fields

B: Analytical 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 and patient 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)

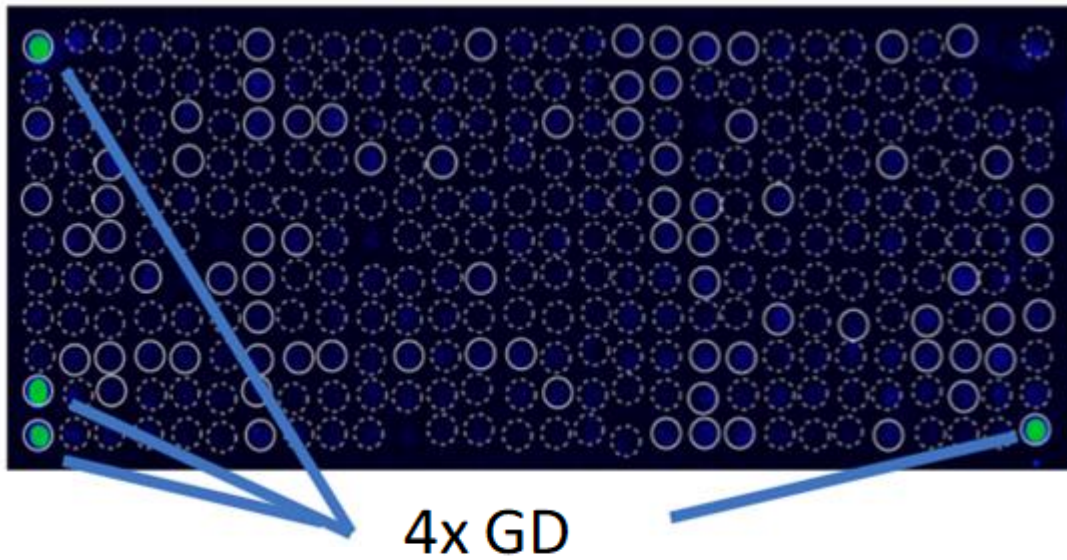
If you click on "Save" the entered information will be saved.

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. There are 4 guide dots on ALEX², and 3 guide dots on FOX.

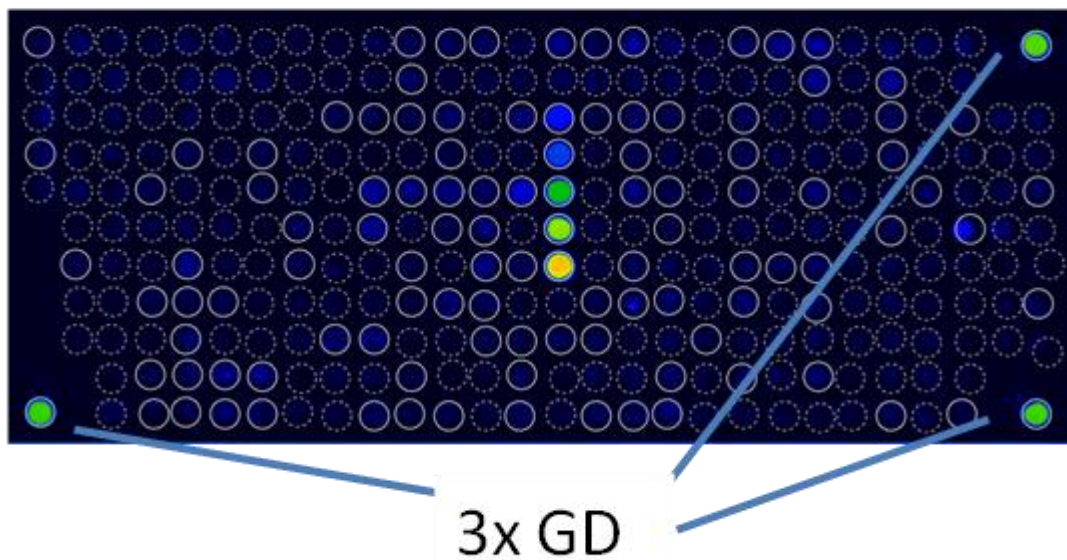
During the image acquisition of an ALEX² or FOX cartridge, RAPTOR SERVER evaluates the signal of all Guide Dots as well as the background signal of the membrane surface. If all quality criteria are fulfilled, the “automatic QC” field under the image is set to “OK”.



ALEX²



FOX





VII.1.7 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

Tags: Tag Info

MOD: < No MOD >

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

Report Save Save and approve

Received: 04.10.2021 16:23

Analysis: 04.10.2021 16:23

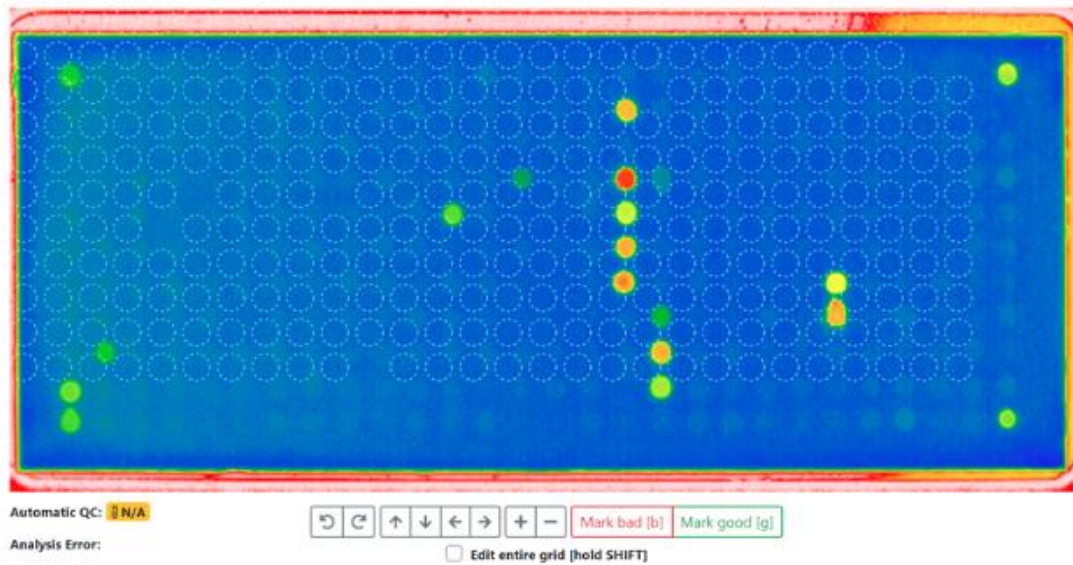
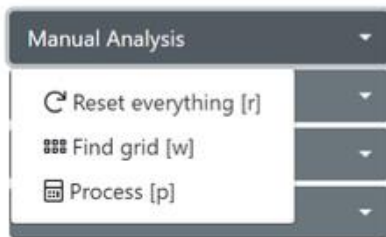
ImageExplorer: 22124137

Automatic QC: OK

Edit entire grid [hold SHIFT]
 Edit multiple features [hold CTRL]

A B

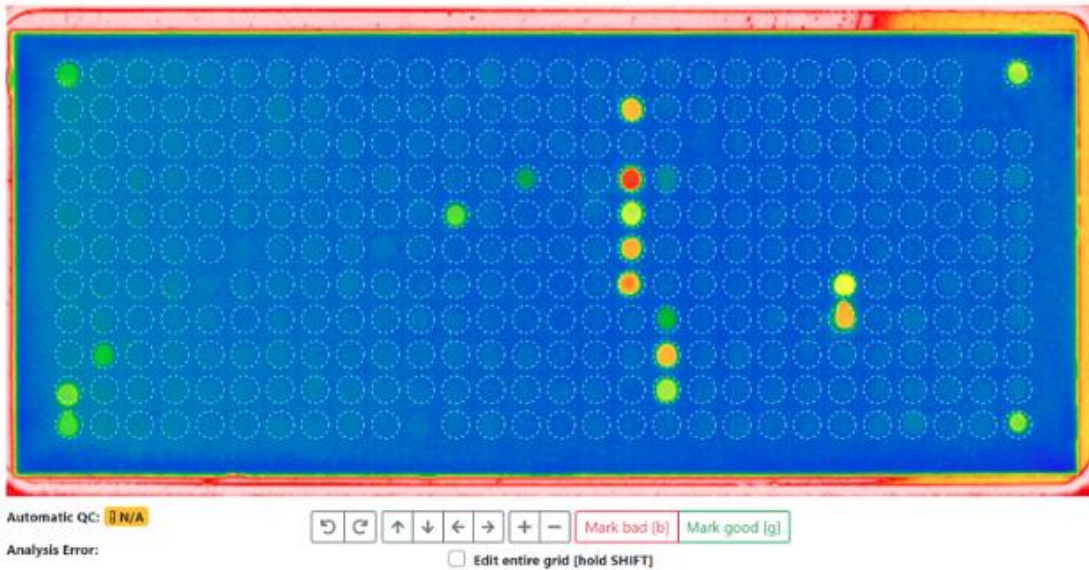
If the automatic position finding fails, the user will be alerted, and the measurement quality control (QC) will be set to FAIL. In this case, the user can try to manually position the array by resetting the grid by pressing “R” or go to “Manual Analysis --> Reset Grid”. After resetting, you can move 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.



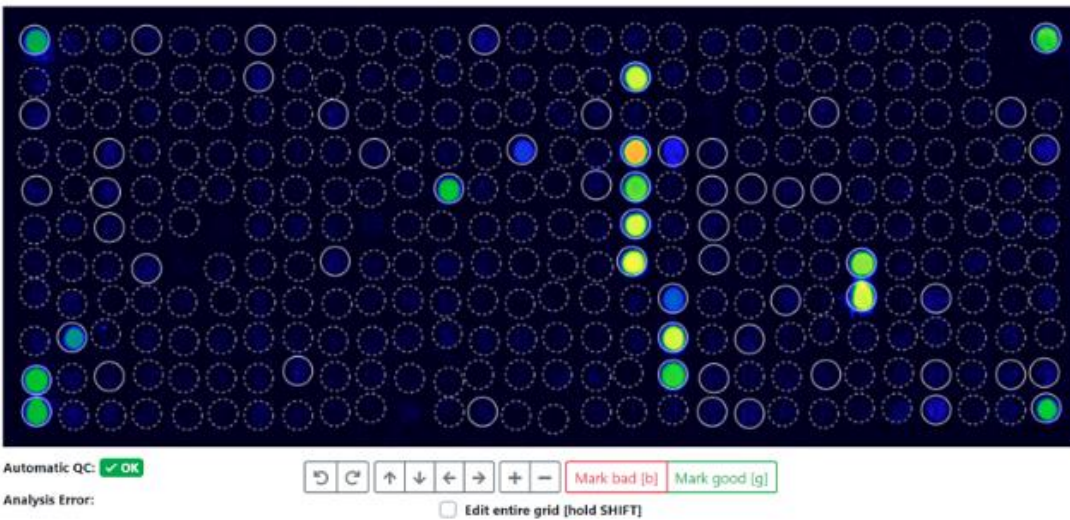
Press "R" or "Manual Analysis --> Reset Grid", then move the entire grid.

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".



- Manual Analysis ▾
- Image ▾
- Grid ▾
- More ▾
- Show Analysis & QC Logs**

 **Reset everything and reprocess**

This discards all modifications to the array, and re-runs the complete analysis process from the original image data. Please note that any manual changes will be irreversible lost.

 **Back to Measurement**

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 '02_ALEXII_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 601ms.
Parsing calibration string ...
Using calibrators from QR-Code.
Total IgG (tIgG) normalized by calculating 0,330999755859375E-07x*+0,05697999954223633x+-30,69269921875
(x=8515), which results in 515.
'ReQuantify' took 57ms.
```

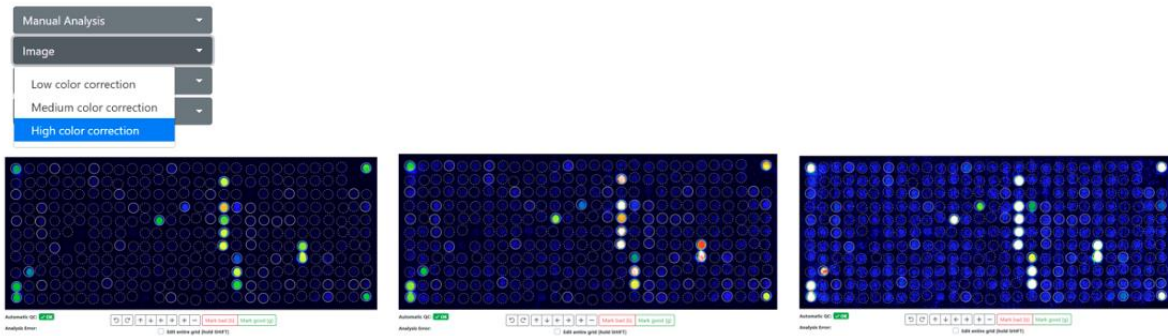
```
QC Log
These are the values used for QC (ALEX v2): Curve Correction=0,9997370867894242, tIge=8515, GD1=28985
(SNR=185.38), GD2=29369 (SNR=185.28), GD3=28569 (SNR=147.53), GD4=28305 (SNR=128.1)
Reference values are as follows: Guide Dots must have a value above 5000; each Guide Dot spot must exist
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 14.071, the minimum
6.012 and the maximum 64.965.
```

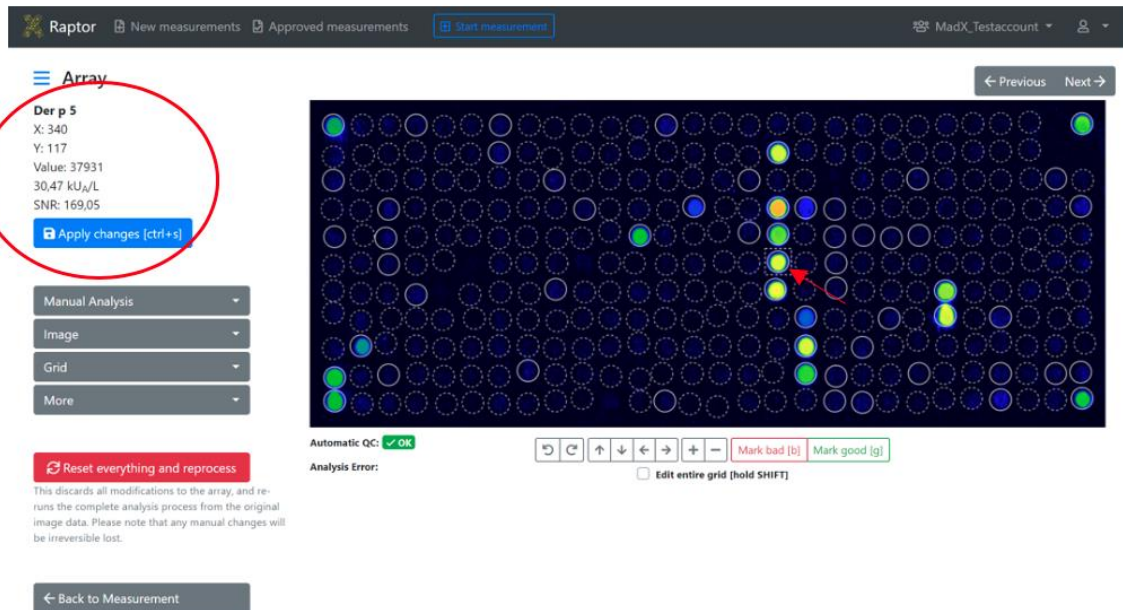



VII.1.7.1 IMAGE ANALYSIS

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.

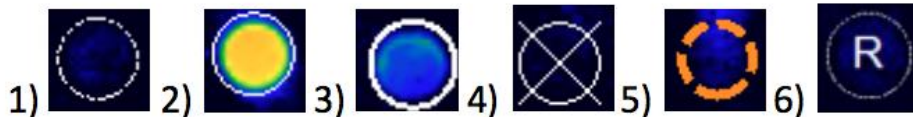


Each allergen is surrounded by a circle. The graphic depiction of the circle represents the automatic interpretation by the software or the modification by the user:

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



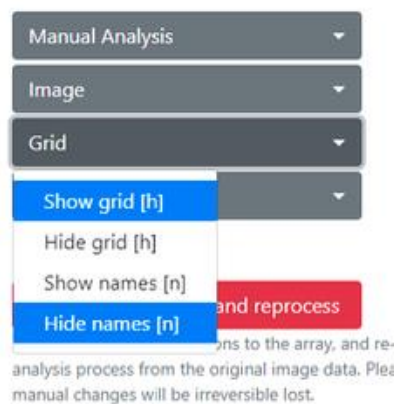
5. Circle with a thick dashed orange line: Spots to be inspected by the user with poor signal-to-noise ratio but a quantitative result above the system cut-off. Those spots should be set to “good” or “bad” by the user.
6. Research Use Only Spots (RUO) are marked with a “R” inside of the circle and will 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.1.7.2 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.



Apply changes [ctrl+s]

Manual Analysis

Image

Grid

More

Reset everything and reprocess

This discards all modifications to the array, and re-runs the complete analysis process from the original image data. Please note that any manual changes will be irreversible lost.

← Back to Measurement

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.

Raptor New measurements Approved measurements Start measurement

Array

Apply changes [ctrl+s]

Manual Analysis

Image

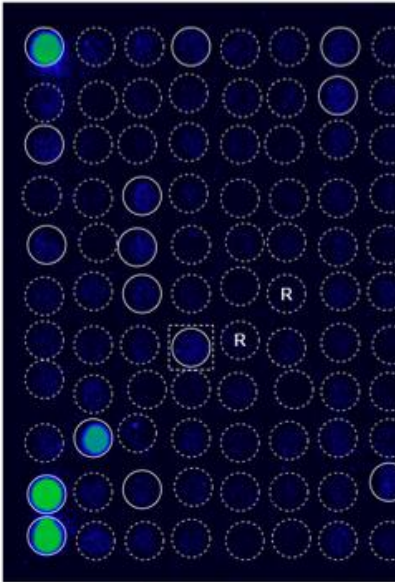
Grid

More

Reset everything and reprocess

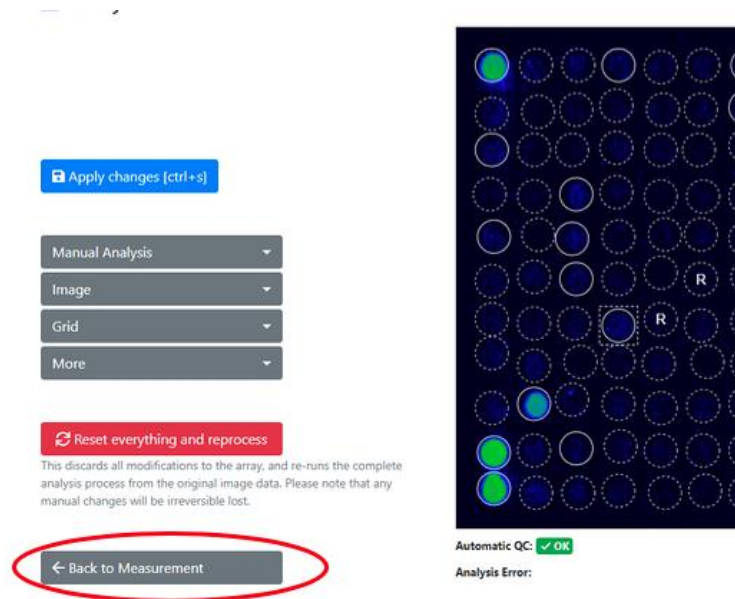
This discards all modifications to the array, and re-runs the complete analysis process from the original image data. Please note that any manual changes will be irreversible lost.

← Back to Measurement



Automatic QC: ✓ OK
Analysis Error:

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.



VII.1.7.3 ANALYTICAL RESULTS

In the detailed results list, below the patient 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
- Tissue & exposure route
- Allergen extract or molecular allergen
- Feature name
- In case of ALEX² - IgE value expressed as kU_A/l (color coded)
- In case of FOX - IgG value expressed as µg/ml (color coded)

⌵ All allergens

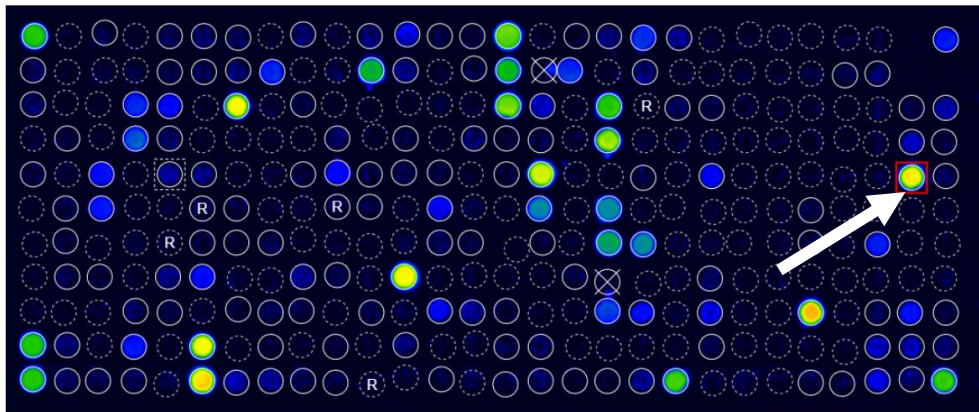
! Name	Code	Biochemical	Tissue & Exposure	E/M	Feature	kUA/L
Acacia <i>Acacia mimosa</i>	t19		Pollen Inhalation	E	Aca m	≤ 0.10
Acarus siro <i>Acarus siro</i>	d70		Mites Inhalation	E	Aca s	7.11
Alder <i>Alnus glutinosa</i>	t101	Polcalcin	Pollen Inhalation	M	Aln g 4	0.94
Alder <i>Alnus glutinosa</i>	t100	PR-10	Pollen Inhalation	M	Aln g 1	≤ 0.10
Almond <i>Prunus dulcis</i>	f20		Plant Food Food	E	Pru du	≤ 0.10
Alternaria alternata <i>Alternaria alternata</i>	m230	Enolase	Microorganisms & Spores Inhalation	M	Alt a 6	≤ 0.10
Alternaria alternata <i>Alternaria alternata</i>	m229	Alt a 1-Family	Microorganisms & Spores Inhalation	M	Alt a 1	2.12



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.

Tissue &	Filter	Value	kUA/L
Pollen	All allergens	E Aca m	≤ 0.10
Inhalation	Only positive allergens		
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.1.8 OVERVIEW OF MEASUREMENTS

New and unapproved measurements can be displayed in the “New Measurements” overview, which 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 ...									
<input type="checkbox"/>	Source	QC	Tags	Product type	QR-Code	Sample Code	Patient Code	Patient Name	Analysis Date
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT957				29.04.2021 10:51
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT956				29.04.2021 10:55
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT955				29.04.2021 10:50
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT954				29.04.2021 10:51
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT953				29.04.2021 10:51
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT952				29.04.2021 10:50
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT951				29.04.2021 10:53
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT950				29.04.2021 10:56
<input type="checkbox"/>	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. Patient 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 ...									
<input type="checkbox"/>	Source	QC	Tags	Product type	QR-Code	Sample Code	Patient Code	Patient Name	Analysis Date
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT957				29.04.2021 10:51
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT956				29.04.2021 10:55
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT955				29.04.2021 10:50
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT954				29.04.2021 10:51
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT953				29.04.2021 10:51
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT952				29.04.2021 10:50
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT951				29.04.2021 10:53
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT950				29.04.2021 10:56
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT949				29.04.2021 10:56

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

New Measurements

Search by QR-Code, patient, sample, tag, analysis date, approval date ...									
Selected measurements ▾									
<input type="checkbox"/>	Source	QC	Tags	Product type					
<input type="checkbox"/>	IX	✓ OK		ALEX2					
<input checked="" type="checkbox"/>	IX	✓ OK		ALEX2					
<input checked="" type="checkbox"/>	IX	✓ OK		ALEX2					
<input checked="" type="checkbox"/>	IX	✓ OK		ALEX2					

Selected measurements ▾

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

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 ...									
<input type="checkbox"/>	Source	QC	Tags	Product type	QR-Code	Sample Code	Patient Code	Patient Name	Analysis Date
<input type="checkbox"/>	IX	✓ OK		ALEX2	02AGT957				29.04.2021 10:51



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

<input type="checkbox"/>	Source	QC	Tags	Product type
<input type="checkbox"/>	Recaptured	✓ OK	recaptured	ALEX1
<input type="checkbox"/>	Recaptured	✓ OK	recaptured	ALEX1
<input type="checkbox"/>	QR-Code was scanned more than once.		recaptured	ALEX1

VII.1.9 APPROVING AND EXPORTING MEASUREMENTS

After analysis and careful revision of the results, the measurements can be approved by two ways:

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

The screenshot shows the RAPTOR software interface. At the top, there is a navigation bar with 'RAPTOR' and tabs for 'New measurements' and 'Approved measur'. Below this is a 'New Measurements' section with a search bar and a 'Selected measurements' dropdown. A table of measurements is displayed with columns for Source, QC, Tags, Product type, and QR-Code. Three rows are shown, all with 'IX' as the source and 'ALEX2' as the product type. The 'Approve' option in the dropdown menu is circled in red.

<input type="checkbox"/>	Source	QC	Tags	Product type	QR-Code
<input checked="" type="checkbox"/>	IX	✓ OK		ALEX2	02AMC180
<input checked="" type="checkbox"/>	IX	✓ OK		ALEX2	02AMC078
<input checked="" type="checkbox"/>	IX	✓ OK		ALEX2	02AKV2D9

- Selected measurements ▾
 - Download CSV format
 - Download Excel format
 - Approve**
 - Update interpretation
 - Re-Process
 - Move
 - Delete

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:

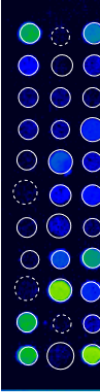
Info:

Doctor Info:

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". No patient information can be changed or added here. 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

	Source	Tags	Product type	QR-Code	Sample Code	Patient Code	Patient Name	Date of Birth	Analysis Date	Approval Date
<input type="checkbox"/>	IX		FOX	88AAH848	Ton1	Stark	Avengers	11.10.1988	01.07.2021 15:10	01.07.2021 15:12
<input type="checkbox"/>	IX		ALEX2	02A15310	Wanda	Vision	Avengers	07.05.1983	01.07.2021 15:06	01.07.2021 15:12
<input type="checkbox"/>	IX		FOX	88AAH848	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 will be displayed as < 0.1, and values over 50 kU_A as >50 instead of the absolute value.

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”.

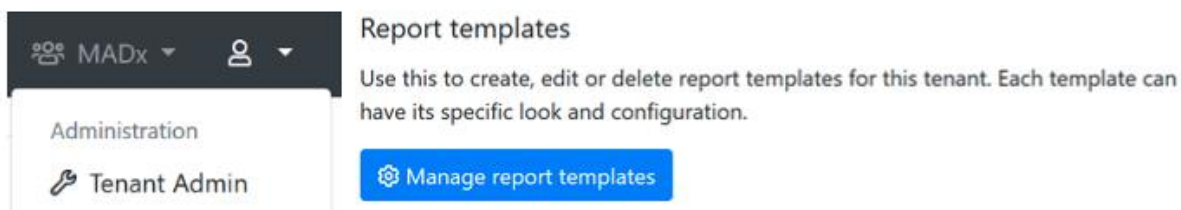
Export requested	# of measurements included	Export completed
8/16/2021 11:07 AM	4	0 / 4
8/16/2021 11:06 AM	4	8/16/2021 11:06 AM
8/16/2021 11:04 AM	3	8/16/2021 11:04 AM



VII.2 REPORT

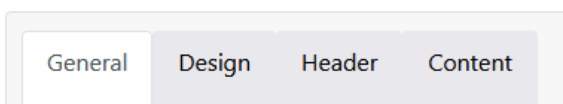
VII.2.1 CREATING A CUSTOM REPORT TEMPLATE

Reports can be customized by clicking on “Tenant Admin” and then “Manage report templates”.



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

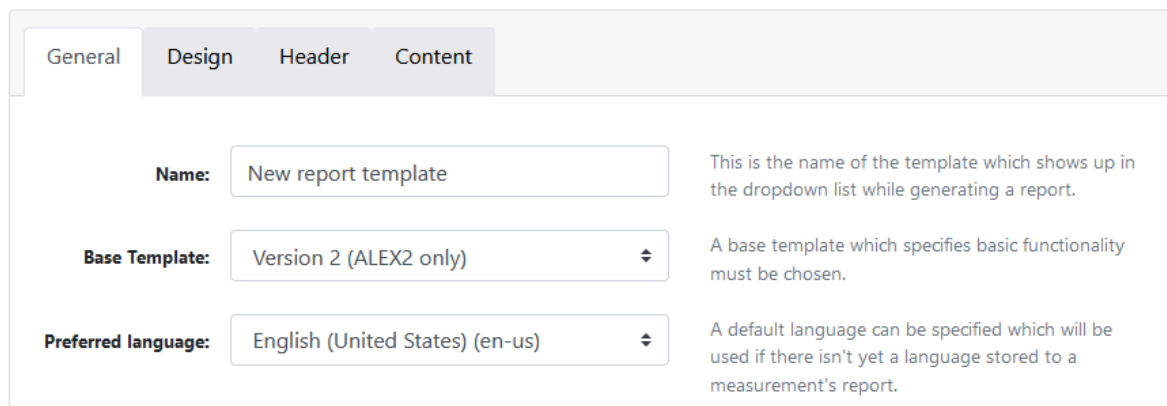


VII.2.1.1 GENERAL SETTINGS FOR CUSTOM REPORT TEMPLATE

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

- Name of the report template
- Base template (ALEX² Version 2, FOX, PEX)
- Preferred language (you can still change the language for every report separately)

Configure report template "New report template"





- 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



VII.2.1.2 DESIGN SETTINGS FOR CUSTOM REPORT 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 a configuration interface with four tabs: General, Design, Header, and Content. The 'Design' tab is active. It contains three main settings:

- PDF format:** Radio buttons for 'A4' (selected) and 'Letter'. A note states: 'Specifies the paper size of the output PDF.'
- Font:** A dropdown menu showing 'Arial'. A note states: 'The font family of the whole report texts can be adjusted.'
- Background image:** A text input field followed by a 'Browse' button. A note 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:

Logos

Logo (left): 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 in the **top middle** of the first page of the report.

Logo (right): Maximum file size 1 MB
This logo will appear on the **top right corner** of the first page of the report.

Small logo: Maximum file size 1 MB
This logo is used on all detail pages. If not set, the default logo is used.

Signatures

Left: Maximum file size 1 MB
This signature or image will appear on the last page, left aligned.

Center: Maximum file size 1 MB
This signature or image will appear on the last page, center aligned.

Right: 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.2.1.3 HEADER SETTINGS FOR CUSTOM REPORT 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 ID
- 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	<input type="checkbox"/>	Doctor Information	<input type="checkbox"/>
Patient Name	<input checked="" type="checkbox"/>	None	<input type="checkbox"/>
Custom headline			
Date of Birth	<input type="checkbox"/>	None	<input type="checkbox"/>
Sample ID	<input type="checkbox"/>	None	<input type="checkbox"/>
QR-Code	<input type="checkbox"/>	Additional Info text	<input type="checkbox"/>
Analysis Date	<input type="checkbox"/>	None	<input type="checkbox"/>
Amount of tested allergens	<input type="checkbox"/>	None	<input type="checkbox"/>
Test method	<input type="checkbox"/>	Quality Control text	<input type="checkbox"/>



VII.2.1.4 CONTENT SETTINGS FOR CUSTOM REPORT TEMPLATES

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:	<input checked="" type="checkbox"/>		Whether the allergen overview should be printed or not.
Include product type in overview:	<input checked="" type="checkbox"/>		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.

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

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

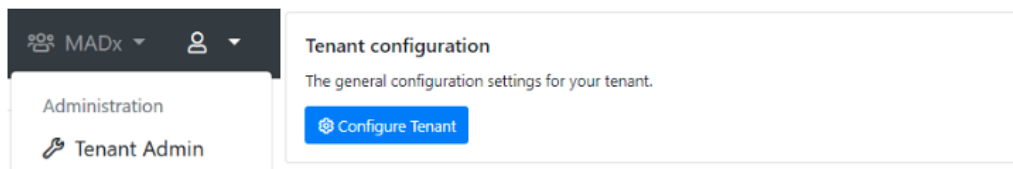
The following languages are available:

- Azerbaijani
- Albanian
- Arabic
- Arabic (Saudi Arabia)
- Bulgarian
- Chinese
- Croatian
- Czech
- Dutch
- English
- English (India)
- English (United Kingdom)
- English (United States)



- Estonian
- Farsi (Iran)
- French
- Georgian
- German
- Greek
- Hindi
- Hungarian
- Italian
- Latvian
- Lithuanian
- Norwegian
- Persian
- Polish
- Portuguese
- Portuguese (Brasil)
- Romanian
- Russian
- Slovak
- Slovenian
- Spanish
- 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 ALEX² and FOX.





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 template (FOX): FOX ⌵

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: TT . MM . JJJJ

Assay Date: 28 . 04 . 2022 ✕

Patient Code:

Patient Name:

Date of Birth: TT . MM . JJJJ

Info:

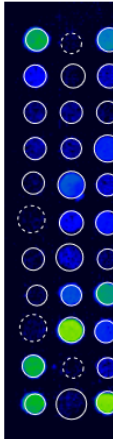
Doctor Info:

Choose a doctor... ⌵

Tags:

MOD: < No MOD > ⌵

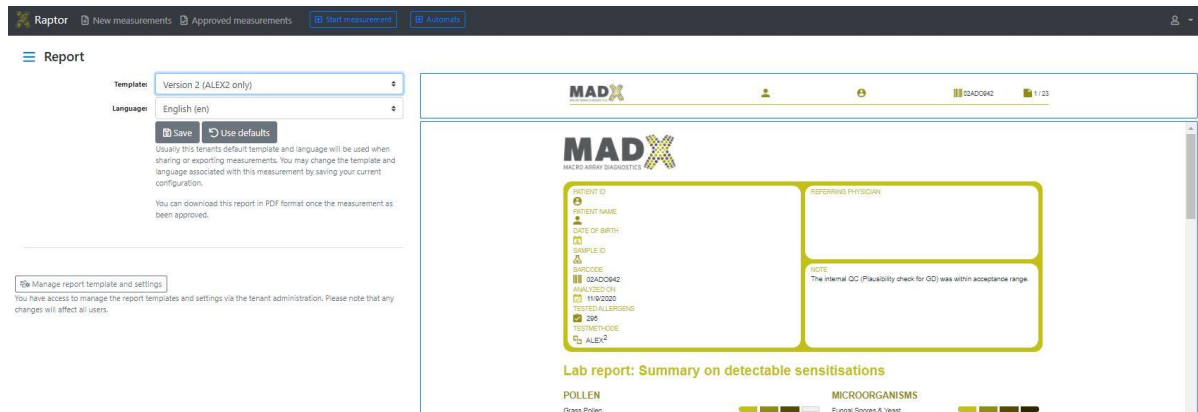
Report Template: Version 2 (ALEX2 only) - Deutsch (de)



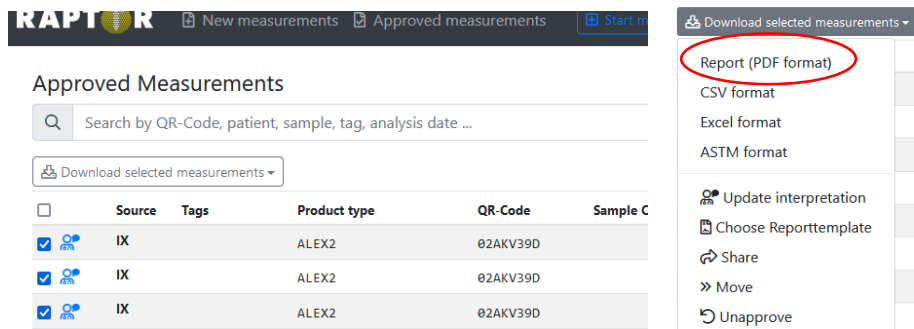
Re
ImageX
Analysi



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.



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.



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

ImageExplorer: 23167844

Tags:

MOD:

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

[Download](#) [Report](#) [Save](#) [» Move to other tenant](#)



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

Report

Template:

Language:

[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
	Spices
Plant-Based Food	Fruits
	Vegetables
	Nuts & Seeds
	Milk

VII.2.2 REQUESTING INTERPRETATION GUIDANCE

A special software module has been implemented to support the interpretation of ALEX² results: RAVEN interpretation guidance.

For using this service, a license key must be requested from your local distributor.

The license key received must be entered in the Tenant Admin area under "Configure Tenant". **To add a license key, full company details, a data processing agreement document, and a term of service document must be uploaded.**

Tenant configuration

The general configuration settings for your tenant.

[Configure Tenant](#)

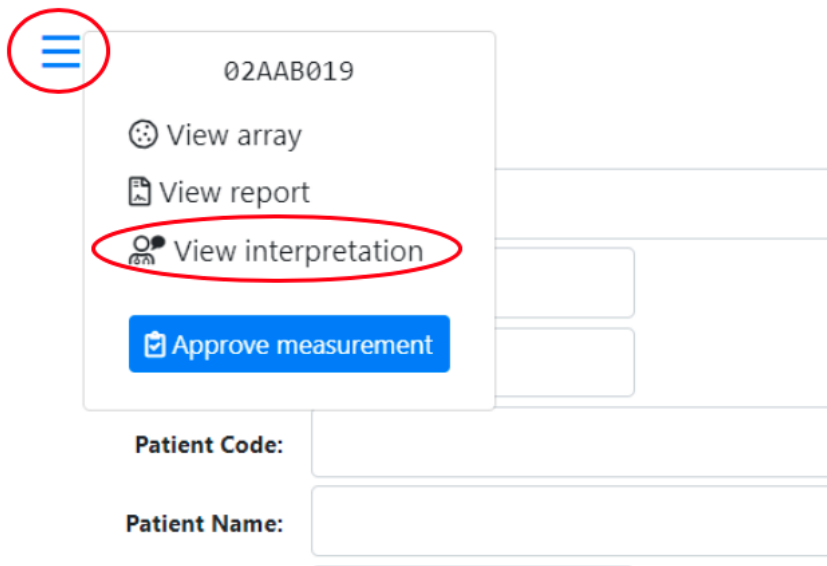
Interpretation

License Key:



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 patient information (age, gender, environment) and patient symptoms can be entered.



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

After entering these, the query can be started with the button "Request interpretation".




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	Interpretation Raven Interpretation Summary Sample Information The sample was tested on ALEX ² 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: <ul style="list-style-type: none">• 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.
---	---

[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.

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
- Delete



VII.2.3 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".

Raptor | New measurements | Approved measurements | Start measurement | Automations

Details

Barcode: 024E1852

Sample Code:

Sampling Date:

Assay Date:

Patient Code:

Patient Name:

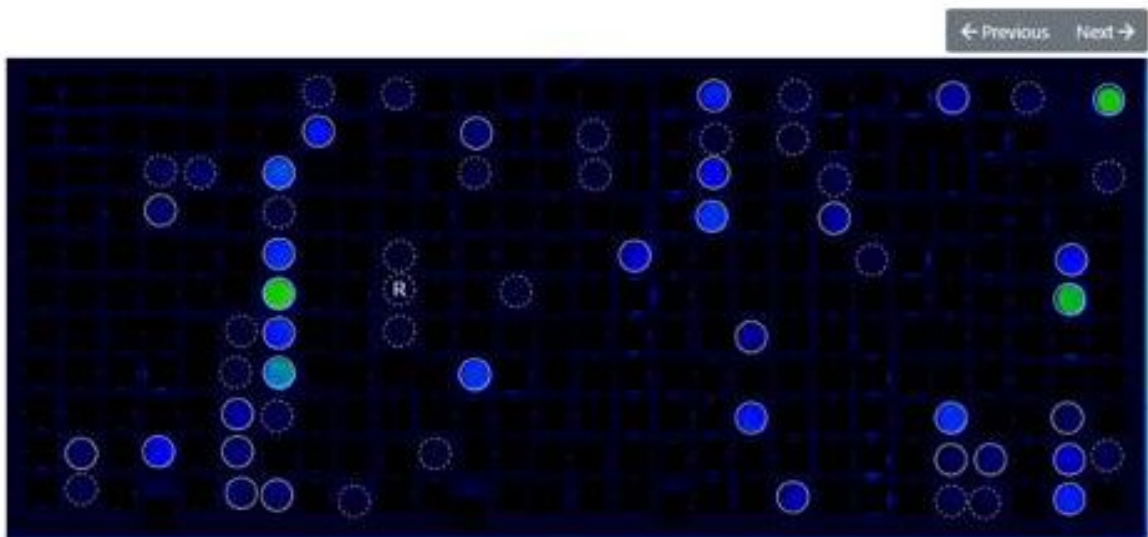
Date of Birth:

Info:

Doctor Info:

Tags:

MODs:



Received: 07.10.2020 14:44 | Analysis: 07.10.2020 14:44
ImageXplorer: 23156891 | Automatic QC: OK

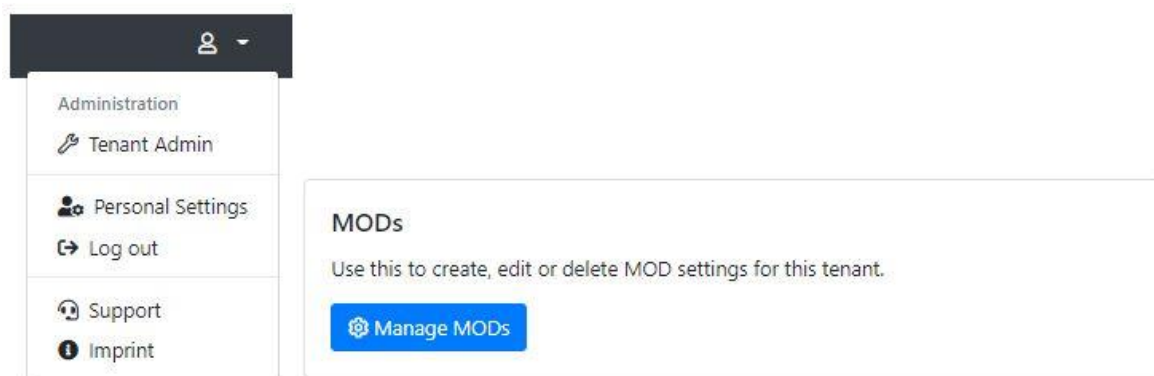


CAUTION! After approval of the measurement, the allergen results, which were not included in the MOD, will be deleted from both image and data. The unselected allergens are then listed in the report as “-“.

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.

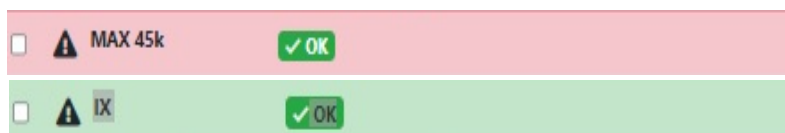
Allergens:

Enter one allergen (2"

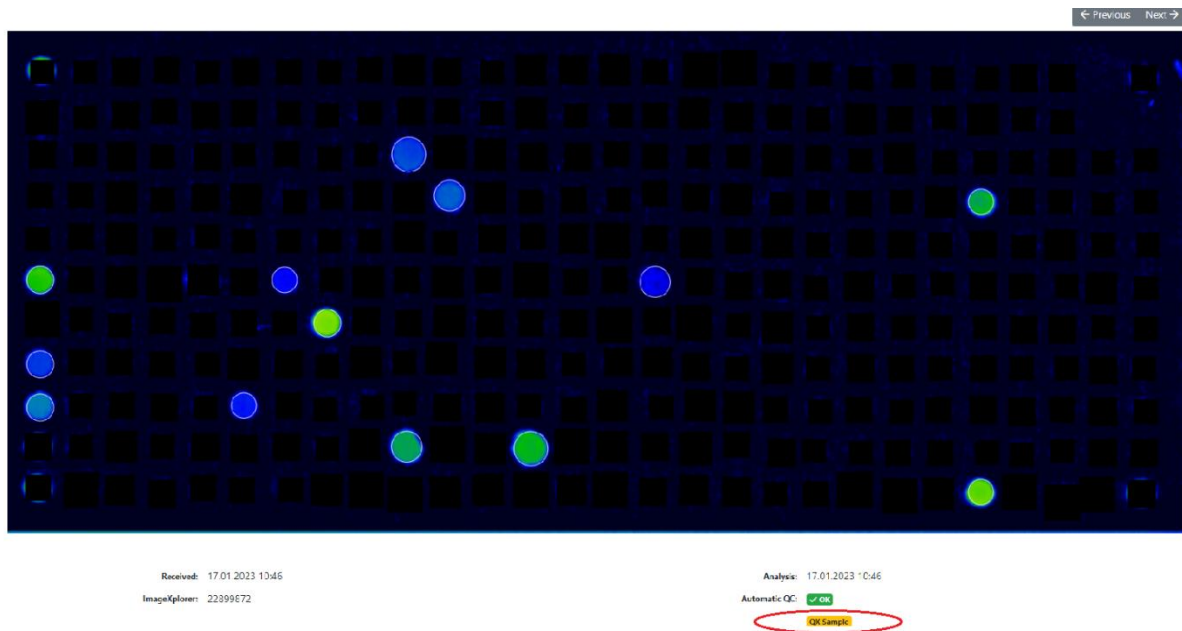
VII.3 MEASUREMENTS OF QUALITYXPLOER SAMPLES

The QualityXplorer is an accessory to control the assay procedure of ALEX2 tests. It is to be used as quality control for monitoring the specific limits in combination with the ALEX2 assay. (see also QualityXplorer Instructions for Use). The QualityXplorer has to be considered as “normal” sample in combination with an ALEX2 chip. A sample of the QualityXplorer will be recorded with the corresponding barcode (310000xxxx – please see also Instruction for Use ImageXplorer or MAX45k and MAX 9k).

New QX measurements 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 QX measurement shows the analysis picture with all allergens of the QualityXplorer. 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 QX sample.



The detailed results of the QualityXplorer 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).

MAX devices for "MADx Auftragstestung"

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

Name	Type	Key	Serialnumber	Last connection	Last activity	
MAX_45k_1912TR02	Max45k	P206ueFIGrnLxiUttTsxSkfxhspkcG	19120002	vor 4 Tagen	vor 4 Tagen	QC Configure Disable
MAX_45k_20010006	Max45k	d1cy0J0Ziv8fdPstbq20RXRF5irD0U	20010006	vor 21 Minuten	vor 26 Sekunden	List View Disable
MAX_9k_22070003 Produktionslabor	Max9k	trQw4sPCY3LFowjk4WU9JettWJQqioN	22070003	vor einem Monat	vor einem Monat	Chart Trend View Disable

A QX report of a QualityXplorer measurement can be loaded via the option "List View" and "View Results".

The option "Chart Trend View" shows all acceptance criteria for the allergens of the QualityXplorer in graphic form, with the acceptance interval also being marked in colour (with at least two measurements).

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 QualityXplorer allergen can be determined precisely.

It is also possible to use "Lyphochek Allergen IgE, Panel A" from Bio-Rad Laboratories as a quality sample. Acceptance criteria for selected allergens of the respective Lyphochek lot (lot



22650, lot 22640, lot 22630, lot 22620) are stored in the RAPTOR SERVER. The results can also be tracked via the device-specific QC-module (incl. report and graphic view).

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

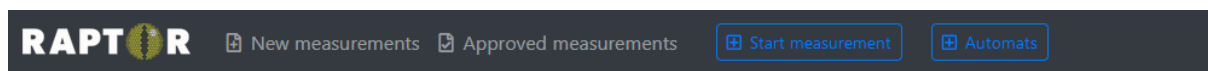
You are about to delete the following measurements. Please note that this action is irreversible and cannot be undone.

Barcode	Analysis Date
02AAB160	16.12.2019 13:41



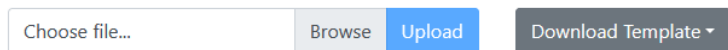
VII.5 IMPORTING THE PATIENT INFORMATION FROM A FILE

Patient 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).



Measurement Data Completion

ⓘ No entries yet. Please import Data using the **Upload** button. You can use the **Download Template** button for an raw template.



After downloading the template file, you can type in patient 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



Add new user on Result Sharing Portal

General configuration

First name:

E-Mail address:

Username:

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

Status:

- Enabled (user can log in)
- Locked (user cannot log in)

Last name:

Password:

Doctor Info Text:

This information will be printed on a patients report.

Measurement Data Completion

Search by QR-Code or patient name.

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	

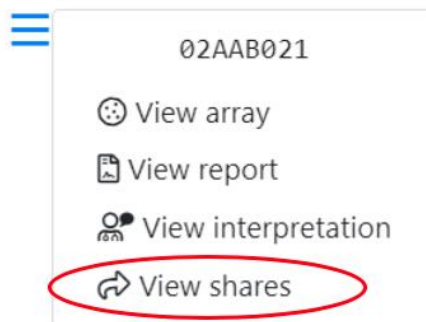
If an image is acquired and the information for the corresponding test QR-Code was uploaded before, the patient information is automatically imported into the software.

VII.6 RESULT SHARING PORTAL

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".



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



Alternatively, the user can log in to their account on the following website (<https://resultshare.raptor-server.com>) and see the measurement shared with him.

≡ 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:

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.

 Result Sharing Portal English (en) ▾

Welcome to the Result Sharing Portal

The Raptor-Server Result Sharing Portal allows users to view shared measurements. You will need a username and password to log in to view all measurements that have been shared with you. Also, a sharing link will allow to view specific shared measurements.

Please enter your username and your password:

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

After logging in, the user can view the patient details of the measurements which have been shared with them and open the report. The user can change their password if desired by clicking on “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.

Search by barcode, patient or sample.

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

When clicking on a measurement the report language can be chosen for each measurement individually.

Result Sharing Portal English (en) Change password Log out

Measurement 02AAA021

Product: ALEX2
Patient:
Date of Birth:

Report Language: Deutsch

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:

RAPTOR New measurements Approved measurements Start measurement with ImageExplorer Automats MADx Testtenant

Share

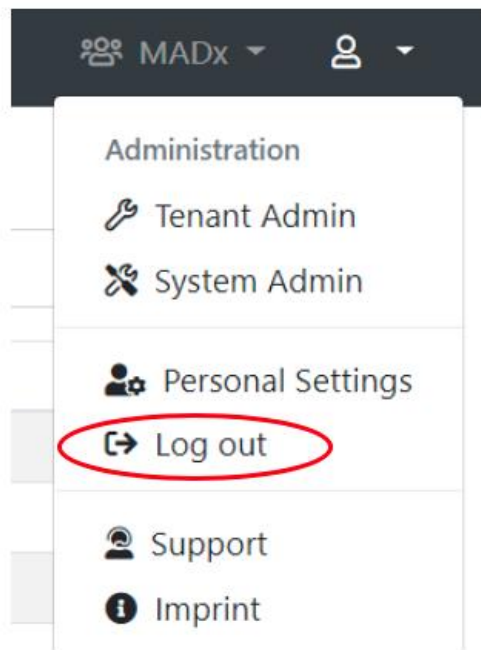
Share this measurement

User	Link	Shared	
RP Bak	https://resultshare.raptor-server.com/s/07PXEpC7ZNythM4PdRfmc4NR5pUtWq5FJcqOY7Ry6oEx08USj	7 months ago	



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.



VII.8 TECHNICAL SUPPORT

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

VII.9 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:

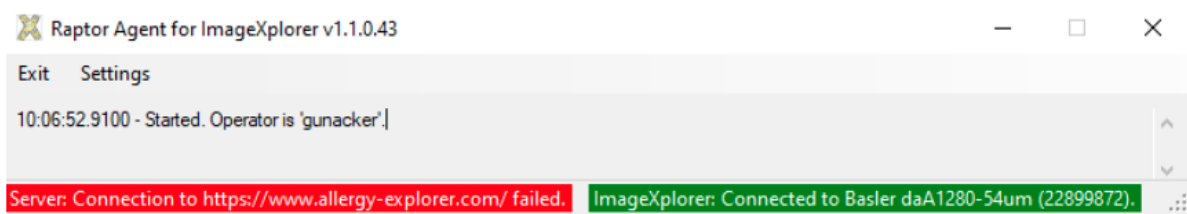
- www.raptor-server.com
- <https://api.raptor-server.com/swagger>
- <https://resultshare.raptor-server.com>
- www.macroarraydx.com



VII.10 TROUBLESHOOTING

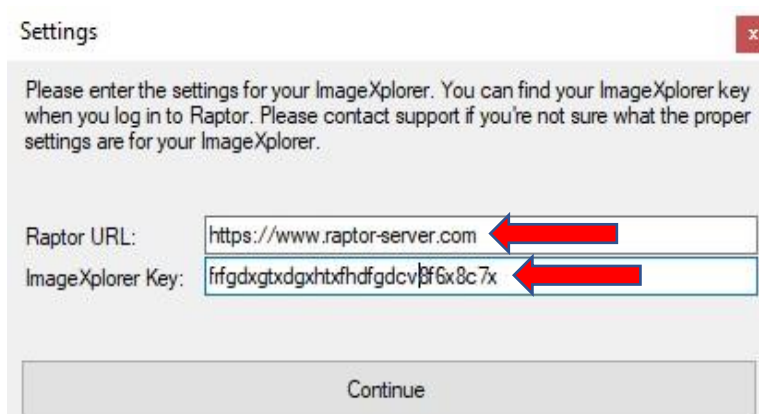
The following errors are the most common ones and therefore explained here in more detail.

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



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



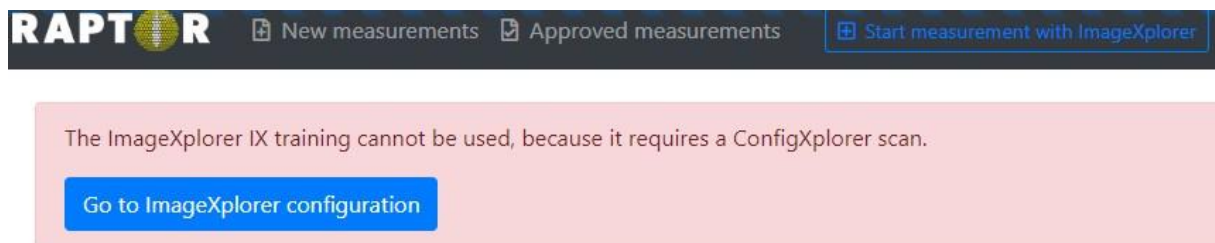


Possible Solutions:

- 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



Start Measurement is not possible:



Possible Solutions:

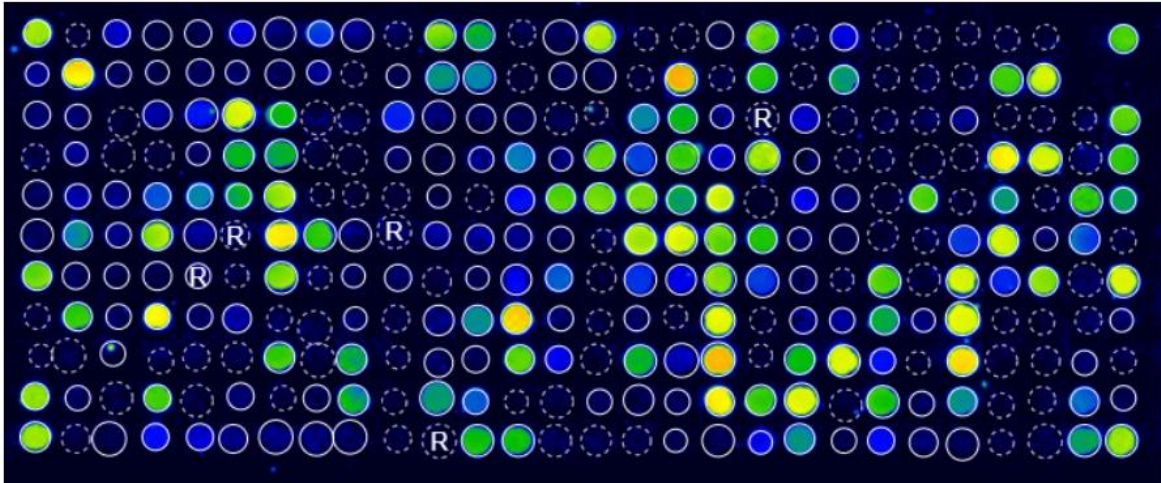
- Check if ImageXplorer is connected
- Check if the last required ConfigXplorer Scan has been performed

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 MacroArray Diagnostics, please contact your local distributor.



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