

INSTRUCTIONS FOR USE

RAPTOR SERVER

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We reserve the right to make changes in course of technical development without previous notice.

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DISCLAIMER

MacroArray Diagnostics GmbH 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 GmbH 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 GmbH.

The herein described procedure is only for using the RAPTOR SERVER Analysis Software in combination with the ImageXplorer. For using the RAPTOR SERVER Analysis Software with the MAX 45k refer to the Instructions for Use for MAX 45k.

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



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LIABILITY STATEMENT

This guide was checked for correctness. The instructions and descriptions for the RAPTOR SERVER Software and ImageXplorer were correct at the time this guide was written. Subsequent guides may be changed without prior notice; however, MacroArray Diagnostics GmbH 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.

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1 ABBREVIATIONS

DPA	Data Protection Agreement
GD	Guide dots - special spots at the corners of the cartridge. Used for plausibility checks by RAPTOR SERVER Analysis Software.
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

2 INTENDED USE

2.1 ImageXplorer

The ImageXplorer is an imaging device to be used in combination with the RAPTOR SERVER Analysis Software to acquire images of ALEX² & FOX arrays after they have been processed by the laboratory user or medical professional.

2.2 RAPTOR SERVER Analysis Software

The RAPTOR SERVER Analysis Software (RAPTOR SERVER) is intended for in vitro diagnostic (IVD) use in combination with the ALEX² & FOX test kits. The cloud-based RAPTOR SERVER performs a quantitative analysis of allergen-specific Immunoglobulin E (sIgE) of processed ALEX² arrays, a semiquantitative analysis of total IgE (tIgE) of processed ALEX² arrays, or a semi-quantitative analysis of Immunoglobulin G (IgG) of processed FOX arrays. Additionally, it offers basic interpretation and comments for decision support. The testing system is an aid in the clinical diagnosis of patients with allergies in conjunction with other clinical and laboratory findings. The software is to be used in clinical laboratories by trained operators or medical professionals. The software can either be used in conjunction with ImageXplorer or MAX 45k, as an analysis tool and for sharing results with other users/referring physicians.

Currently available test kits for use with RAPTOR SERVER:

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

3 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 & FOX tests.

3.1 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.

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.

This version of the IFU is valid from the RAPTOR SERVER Version 1.2.5 onwards.

4 PRINCIPLES OF PROCEDURE

ALEX² & 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 the ImageXplorer. The test results are analyzed with MADx's RAPTOR SERVER. ALEX² test results are reported in allergen specific IgE units (kU_A/l), along with the total IgE results in IgE units (kU/l). FOX test results are reported in specific IgG units (µg/ml).

5 ENVIRONMENTAL CONDITIONS AND SHIPMENT






To ensure trouble-free operations of the ImageXplorer, it is important to place the instrument in an appropriate environment. Following specifications must be fulfilled:

Environmental conditions	Specifications
Operating Temperature:	15 to 30 °C
Humidity:	30 - 85%, non-condensing
Power supply:	The device is powered by a +5V USB 3.0 or USB 2.0 cable from either a personal computer or a USB power supply. No additional power supply is needed.
Weight and dimensions of work place:	The device fits on a normal work bench or desk, weight and dimension do not require special support structures
Dust:	Dust-free environment recommended
Operating system:	Windows 10

6 WASTE DISPOSAL

Waste disposal of the ImageXplorer must be performed in accordance with local guidelines.

7 GLOSSARY OF SYMBOLS

Symbol	Description
	CE Mark
	In vitro diagnostic medical device - Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.
	Serial number - Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Manufacturer - Indicates the medical device manufacturer



Symbol for the marking of EEE



Important Note

8 PRODUCT CONTENTS

Equipment	REF	Quantity
ImageXplorer	11-0000-01	1
ImageXplorer carriage	-	1
Connecting cable (PC - ImageXplorer)	-	1
RAPTOR SERVER Analysis Software	22-0000-01	1
USB Power Hub for constant +5V supply	-	optional

9 SAFETY INSTRUCTIONS

9.1 Operator Qualification

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

Carefully follow the procedure specified in these Instructions for Use for the operation and maintenance of the system. Maintenance which is not described in the Instructions for Use should be left to qualified service engineers.



DO NOT open the instrument housing!



Electronic equipment can be a source of electric shocks!



Service and Repair should only be carried out by authorized and qualified personnel of the manufacturer!

9.2 Data Backup

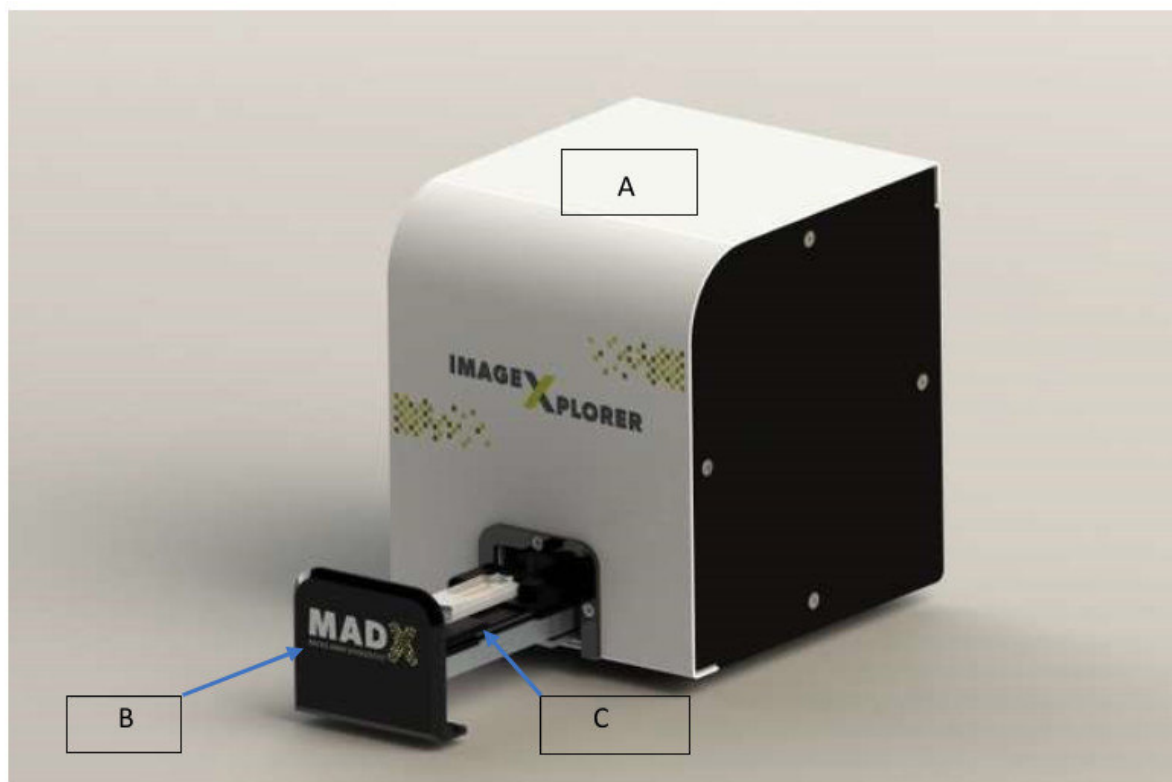
When using RAPTOR SERVER, all analytical and patient related data are stored according to the MADx Terms of Service Agreement in the Microsoft Azure Online Portal. Please also refer to the Online Services Terms (OST) of Microsoft, available at <https://www.microsoft.com/en-us/licensing/product-licensing/products>.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

9.3 Electromagnetic Compatibility

The ImageXplorer fulfils the requirements of Electromagnetic Compatibility (EMC) according to EN 61326 (Electrical equipment for measurement, control, and laboratory use).

Devices that emit electromagnetic waves may affect measurement data or cause the instrument to malfunction.

10 SYSTEM COMPONENTS



- A: chassis
- B: slider
- C: carriage

The relevant system components of the ImageXplorer are:

- CCD (charge-coupled device) Camera for image acquisition
- Custom LED light circuit board
- Carriage for inserting cartridges
- Stage for sliding the cartridge holder
- USB cable

11 WORKFLOW

1. Connect ImageXplorer to computer
2. Go to www.raptor-server.com on a web-browser
3. Log into your tenant account
4. Start measurement
5. Enter patient information
6. Analyze and verify result, then approve results
7. Export the data

12 INSTRUCTIONS

12.1 Connecting the ImageXplorer to the PC

The ImageXplorer is not a standalone device and must always be used in combination with RAPTOR SERVER. The ImageXplorer is plugged into a computer via the provided USB cable, and both the connection and the power supply are managed through the computer's USB 3.0 port by the provided USB cable. The thicker USB plug (USB B) is attached to the back of the ImageXplorer, whereas the thinner USB port (USB A) is attached to the computer.

Note: The device can also be used on an USB 2.0 port, but the analysis will require longer time because of lower data transmission rates.



USB B

USB A



12.2 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.



12.2.1 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.

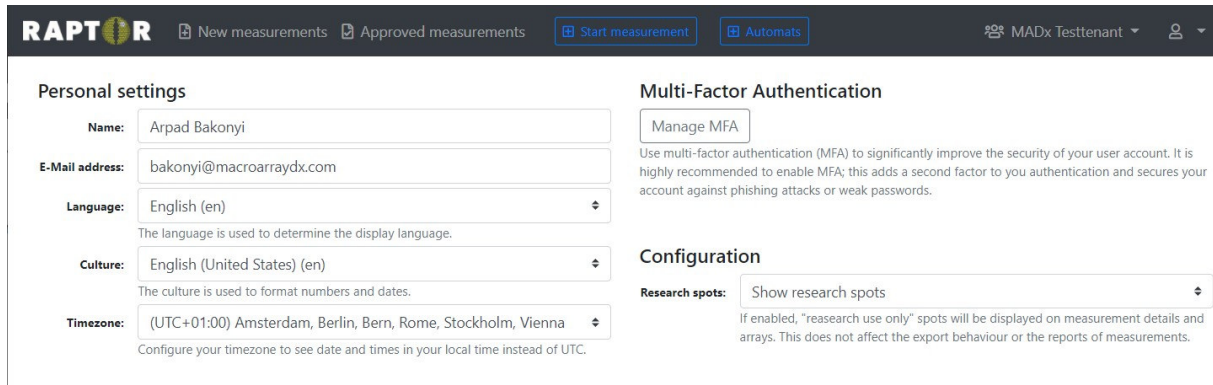
Multiple users can log in to a Tenant platform. Access to a Tenant on RAPTOR SERVER will only be available to users with a valid username and password specified by MADx or by an external directory service (Office 365/Azure Active Directory). User accounts are created by the tenant administrator (Local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



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	Log in with Username & password
<p>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.</p> <p> Log in</p>	<p>Please enter your username and password.</p> <p>Your username</p> <p>Your password</p> <p> Log in</p> <p>Forgot your password? No problem, you can request a new one.</p>

After successful login, the user has access to their tenant. A password can also be reset if forgotten.




The screenshot shows the Raptor user interface. At the top, there is a navigation bar with the Raptor logo, links for 'New measurements', 'Approved measurements', 'Start measurement', and 'Automats', and a user profile dropdown for 'MADx Testtenant'. The main content area is divided into two columns. The left column is titled 'Personal settings' and contains fields for 'Name' (Arpad Bakonyi), 'E-Mail address' (bakonyi@macroarraydx.com), 'Language' (English (en)), 'Culture' (English (United States) (en)), and 'Timezone' ((UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna). The right column is titled 'Multi-Factor Authentication' and includes a 'Manage MFA' button and a descriptive paragraph. Below that is a 'Configuration' section with a 'Research spots' dropdown menu set to 'Show research spots'.

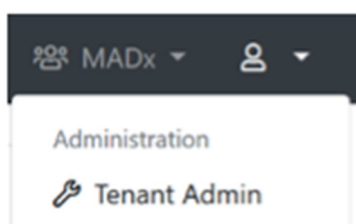
12.2.2 Personal Settings

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.

12.2.3 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:

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 language:

Default MOD:

Require ImageExplorer testarray scan:

Automat default settings

* Default Minimum RunId:

When a new Automat is created, this value will be used for its Minimum Run Id

Interpretation

License Key:

This license key is valid.

Holder: -

Notes: -

Valid until: 12/31/2025

Company Details

* Legal Entity Name:

* Street and Number:

* Zip Code:

* City:

* Country:

* Phone:

* E-Mail:

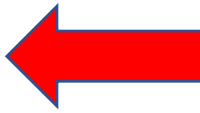
* Legal Representative:

Website:

Vat Number:

Company Register Number:

ToS & DPA (signed):



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

3 Save ← Cancel

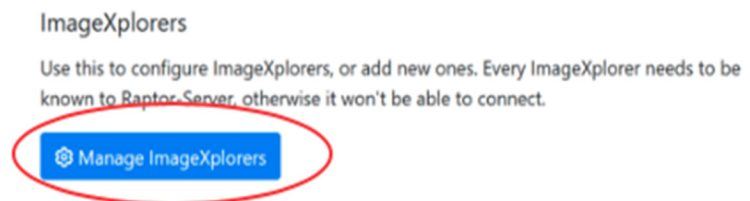
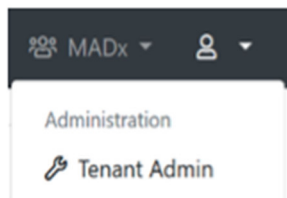
Other important pages of the Tenant Admin area are:

- ImageXplorers: Use this to configure existing ImageXplorers or add new ones. Every ImageXplorer 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
- User Portal: Use this to create, edit or delete users on the user portal for this tenant. Measurements can be shared with users of the User Portal, and users can use the User Portal to access those measurements.

12.2.4 Using the ImageXplorer

12.2.4.1 Download of the ImageXplorer Agent Software & ImageXplorer Definition

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



Add new ImageXplorer

General information

Name:

Key:
This key is required when installing an Agent.

Notes:

Internal Notes:
For internal use only.

Disabled:

Barcode image configuration

Barcode Exposure:

Calibration configuration

Mode:

Array image configuration

Array Offset X:

Array Offset Y:

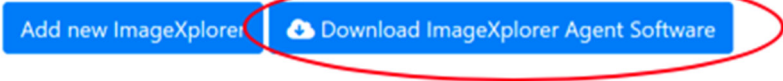
Array Width:

Array Height:

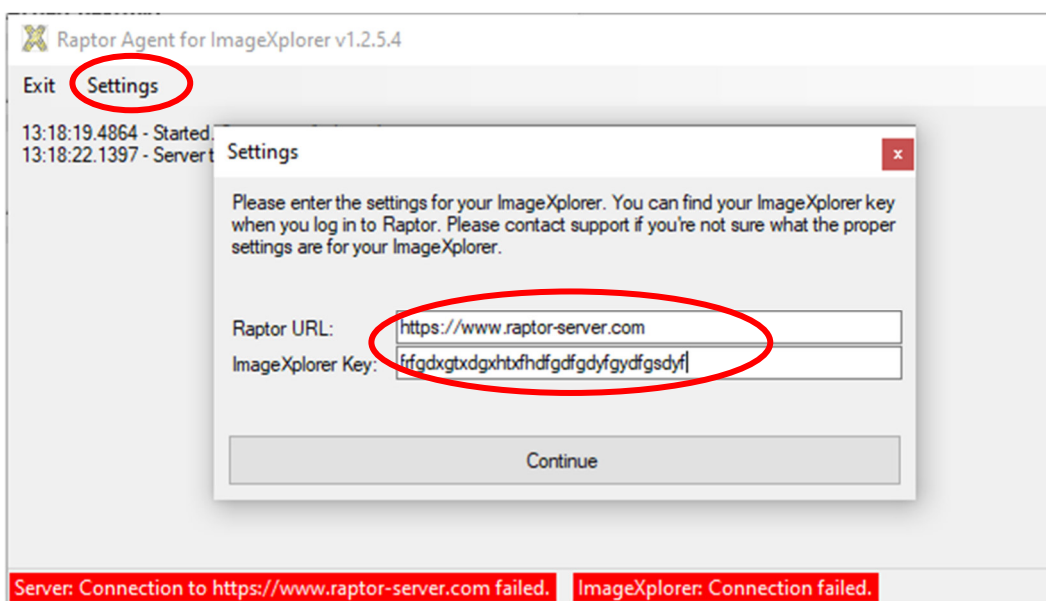
Array Exposure:

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

ImageXplorers for "MADx"


 Add new ImageXplorer | Download ImageXplorer Agent Software

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

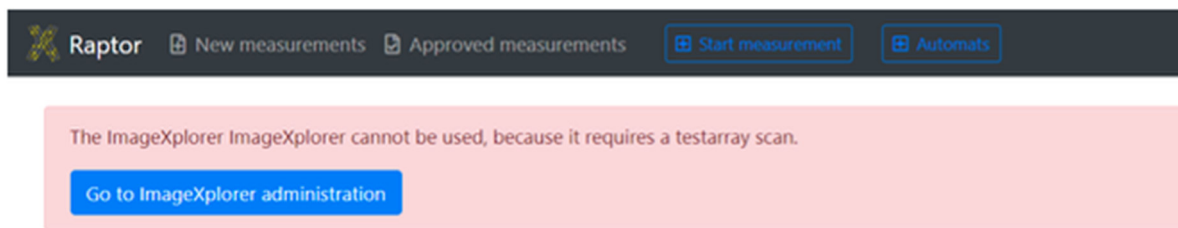
B: Connection to ImageXplorer

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

12.2.4.2 Adjusting the ImageExplorer Settings

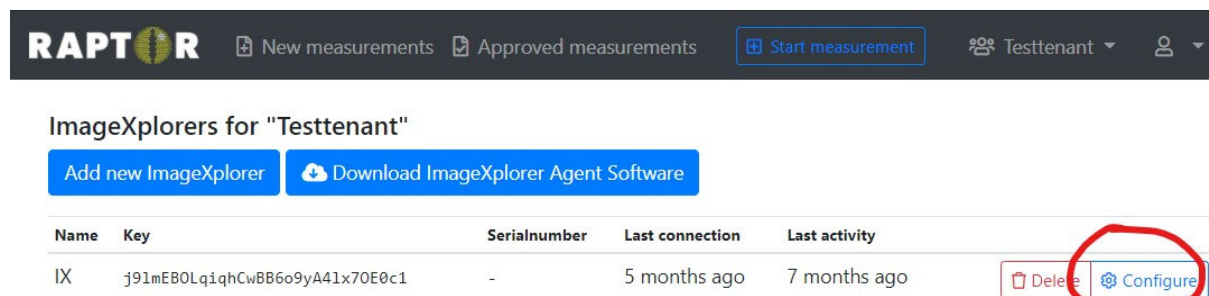
Each ImageExplorer has unique image settings that need to be calibrated (Test Array) during the first installation and then every 60 days.

Upon the first installation or upon starting the new RAPTOR SERVER version for the first time, no measurement can be made with the ImageExplorer without a Test Array run.



Every new ImageExplorer system will include a calibration test array with a special barcode starting with the digits "30" on the label (e.g. 30AAF267). The calibration test array is delivered in a resealable pouch and should always be stored in a dark place at room temperature.

After clicking "Configure" in the menu "Manage ImageExplorers" you are directed to the area where you can run a test array.



By clicking on "Start new test array scan", the calibration of the setting-adjustments starts (takes about 2-3 minutes).

Configure "ImageXplorer"

General information

Name: ImageXplorer

Key: ClgM3lFfsyJOcpY766DFSi6kN6ocQ
This key is required when installing an Agent.

Notes:

Internal Notes:
For internal use only.

Disabled: Not disabled

Testarray scans

[Start new testarray scan](#)

Please make sure that the ImageXplorer

There are no testarray scans y

This calibration measurement will identify and adjust the optimal settings for x, y, width and height of the array edges and the optimal exposure. After the calculation is finished, a report of the test array run is displayed. The user shall apply the new ImageXplorer settings by clicking "Apply detected settings".

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

Testarray run report for ImageXplorer

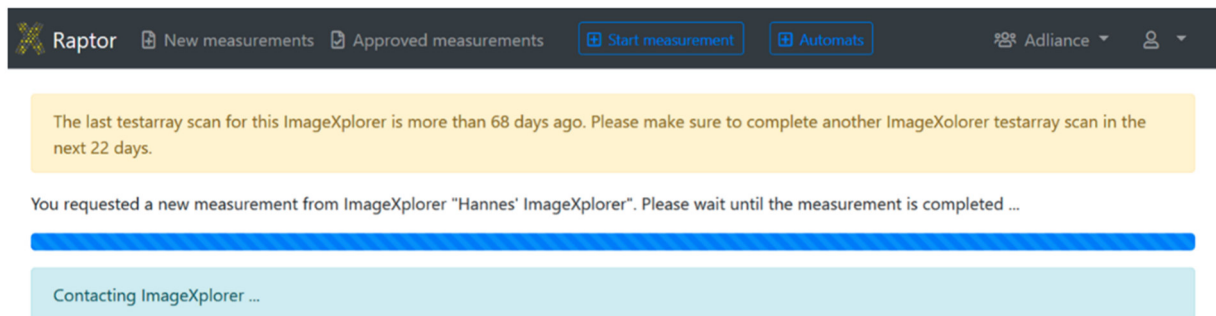
[← Back to ImageXplorer](#) [Download Report](#) [Apply detected settings](#)

Please check the automatically detected values for plausibility before applying them to your device.

Results

Detected offset X	404
Detected offset Y	348
Detected width	608
Detected height	276
Detected exposure	1046
Device Serialnumber	22899872
Acceptance Criteria	Passed
Completed	now

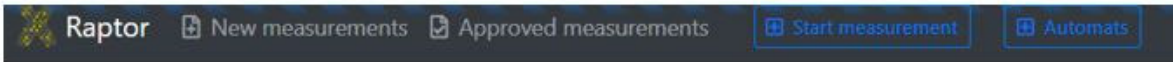
Running the test array on a regular base will ensure that the ImageXplorer uses the optimal configuration. Therefore, after 60 days a message will appear, which prompts you to repeat the ImageXplorer test array run within 30 days.



If you do not repeat the ImageXplorer test, no new measurements will be possible after 90 days. Previous results will be accessible as before.

The current ImageXplorer settings are to be found in the "Tenant Administration" area --> "Manage ImageXplorers" --> "Configure"

If the barcode is not recognized during the test array run, the "automatic exposure" under calibration configuration can be changed to --> "manual exposure". The Calibration Exposure is set to 2500 by default. However, it can be corrected a little bit up or down.



Configure "ImageExplorer"

General information

Name: ImageExplorer

Key: ClgM3IFfsyJOcpY766DFSi6kN6ocQ
This key is required when installing an Agent.

Notes:

Internal Notes:
For internal use only.

Disabled: Not disabled

Tes

S
Plea

Barcode image configuration

Barcode Exposure: 3000

Calibration configuration

Mode: Use manual exposure

Exposure: 2500

Array image configuration

Array Offset X: 400

Array Offset Y: 350

Array Width: 600

Array Height: 280

Array Exposure: 1600

Save

← Cancel

Raptor
New measurements
Approved measurements
Start measurement
Automats

Configure "ImageXplorer"

General information

Name:

Key:
This key is required when installing an Agent.

Notes:

Internal Notes:
For internal use only.

Disabled:

Barcode image configuration

Barcode Exposure:

Calibration configuration

Mode:

Array image configuration

Array Offset X:

Array Offset Y:

Array Width:

Array Height:

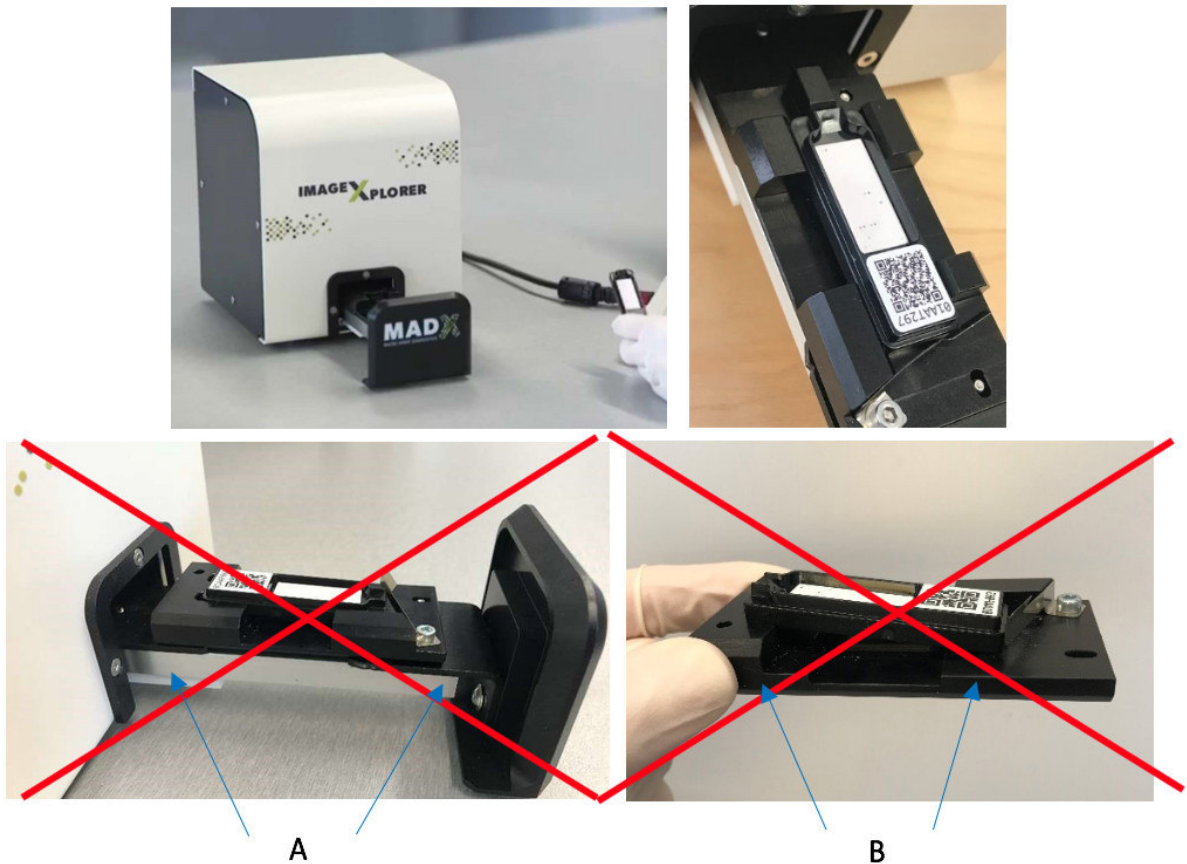
Array Exposure:

Testarra:

Please mak

12.2.4.3 Inserting a Cartridge into the ImageXplorer

The ImageXplorer has an insertion mechanism for loading one processed cartridge at a time into the device. Carefully take the cartridge (don't touch the membrane of the cartridge) and insert it by facing the barcode to the MADx logo on the ImageXplorer into the carriage. Make sure that the cartridge is completely inserted into the carriage and neither in front nor in the back raised up (see pictures below). After inserting a cartridge, close the slider by moving it forward gently until it stops.

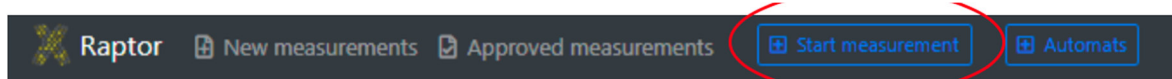


A: slider
B: carriage

12.2.4.4 Image Acquisition, Barcode Reading and Grid Finding

On the overview page you will find a tab "New measurements", a tab "Approved measurements", a button for "Start measurement" and if there is a MAX 45k (automated processing unit), a button for Automat. The tab "New measurements" contains all new and unapproved measurements, the tab "approved measurements" contains all hitherto approved measurements.

Click on "Start Measurement" in the RAPTOR SERVER browser window to acquire an image and start the analytic sequence.



If only one ImageXplorer is connected, the analysis will start immediately. If several ImageXplorers are connected to the tenant on RAPTOR SERVER, the user must first select which ImageXplorer they want to use. RAPTOR SERVER automatically recognizes the barcode, which is the basis of all further processing and assigns the identified barcode to the new measurement.

Attention: Be aware of which ImageXplorer you are using, to have the correct test results for a given patient !

The barcode on each cartridge contains the following information:

- type of test array (ALEX² / FOX)
- corresponding allergen layout
- QC information
- Lot number of cartridge
- batch specific correction of calibration for specific and total IgE

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.

The screenshot displays the Raptor software interface. On the left, the 'Details' section contains patient and sample information fields (labeled A). In the center, an analytic image of the array is shown (labeled B). Below the image, a table lists allergen results (labeled C).

Details (A):

- Barcode: 02AD0942
- Sample Code: [Field]
- Sampling Date: tt.mm. [Field]
- Assay Date: 02.07.2020
- Patient Code: [Field]
- Patient Name: [Field]
- Date of Birth: tt.mm. [Field]
- Info: [Field]
- Doctor Info: [Field]
- Tags: [Field]
- MOD: < No MOD >

Analytic Image (B):

Received: 29.06.2020 17:32
ImageXplorer: 22124140
Analysis: 02.07.2020 16:10
Automatic QC: ✔ OK

Allergen Results (C):

Name	Code	Biochemical	Tissue & Exposure	I/M	Feature	IJ KUA/l
German Cockroach <i>Blattella germanica</i>	i100	Cockroach Group 1	Insects Inhalation	M	Bla g 1	30.03
<i>Alternaria alternata</i>	m229	Alt a 1-Family	Microorganisms & Spores Inhalation	M	Alt a 1	17.56
Dog <i>Canis familiaris</i>	e302	Lipocalin	Animal Origin Inhalation	M	Can f 4	10.98
Alder <i>Alnus glutinosa</i>	t101	Polcalcin	Pollen Inhalation	M	Aln g 4	10.90
Cat <i>Felis domesticus</i>	e94	Uteroglobulin	Animal Origin Inhalation	M	Fel d 1	10.80
Dog <i>Canis familiaris</i>	e221	Serum Albumin	Animal Origin Inhalation	M	Can f 3	10.44
German Cockroach <i>Blattella germanica</i>	i301	Arginine kinase	Insects Inhalation	M	Bla g 9	10.27
American house dust mite <i>Dermetophagoides farinose</i>	d101	NPC2 Family	Mites Inhalation	M	Der f 2	9.74

A: Patient and 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 and patient information can be added manually:


- sample code
- sampling date
- assay date
- patient code
- name of the patient
- date of birth
- additional information
- name of the referring physician and
- a tag
- MOD panel

Details

Barcode: 02AD0942


Sample Code: 12

Sampling Date: 11.11.2019 

Assay Date: 02.07.2020 

Patient Code: MA

Patient Name: Martina



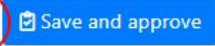
Date of Birth: 01.10.2000 

Info: Info

Doctor Info: Dr. A

Tags: Tag Info

MOD: < No MOD >

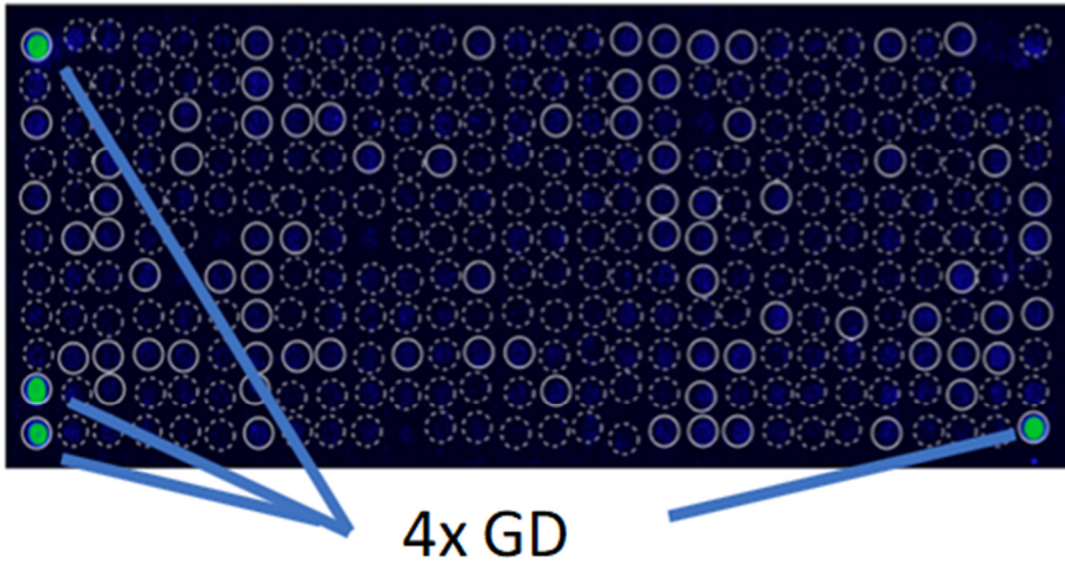
  

If you click on "Save" the entered information will be saved.

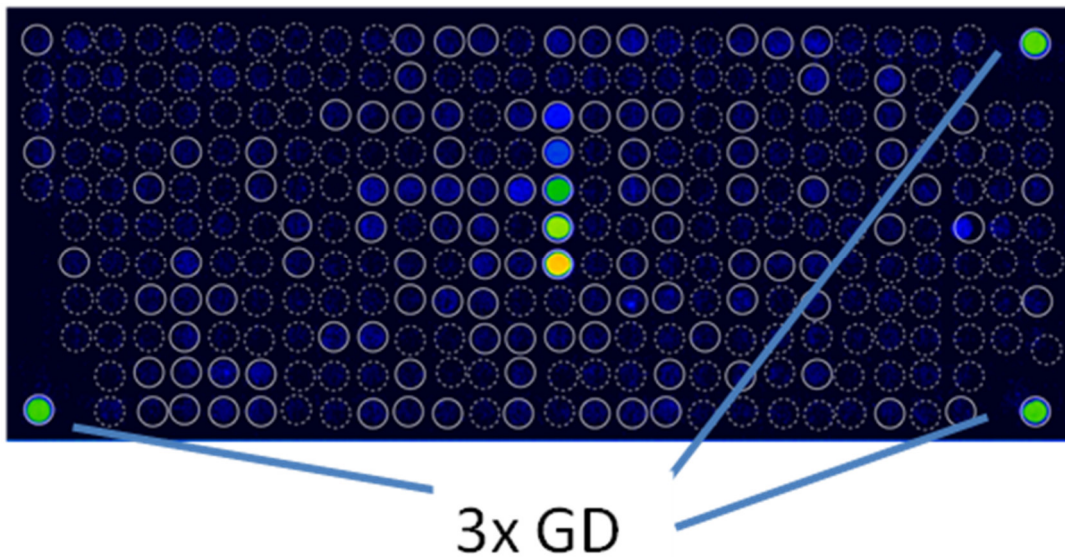
The array of the measurement with grid is displayed in the analytical image area. The software automatically identifies the position of the array in the image data based on the guide dots. There are 4 guide dots on ALEX², and 3 guide dots on FOX.

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



12.2.5 Image Processing Mode

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

The screenshot shows the Raptor software interface. At the top, there are navigation tabs: 'New measurements', 'Approved measurements', and 'Start measurement'. The 'Details' section on the left contains the following information:

- Barcode: 02AAB377
- Sample Code: 12
- Sampling Date: 11.11.2019
- Assay Date: 12.12.2019
- Patient Code: MA
- Patient Name: Martina
- Date of Birth: 01.01.2010
- Info: Info
- Doctor Info: Dr.
- Tags: (empty)

At the bottom of the details section are buttons for 'Report', 'Save', and 'Save and approve'. To the right, there is a large grid of measurement points. A red arrow points to a specific point on the grid. Below the grid, the following information is displayed:

- Received: 14.11.2019 10:22
- ImageXplorer: 22124136
- Analysis: 14.11.2019 10:22
- Automatic QC: ✔ OK

The screenshot shows the Raptor software interface in 'Array' mode. The 'Array' section on the left contains the following information:

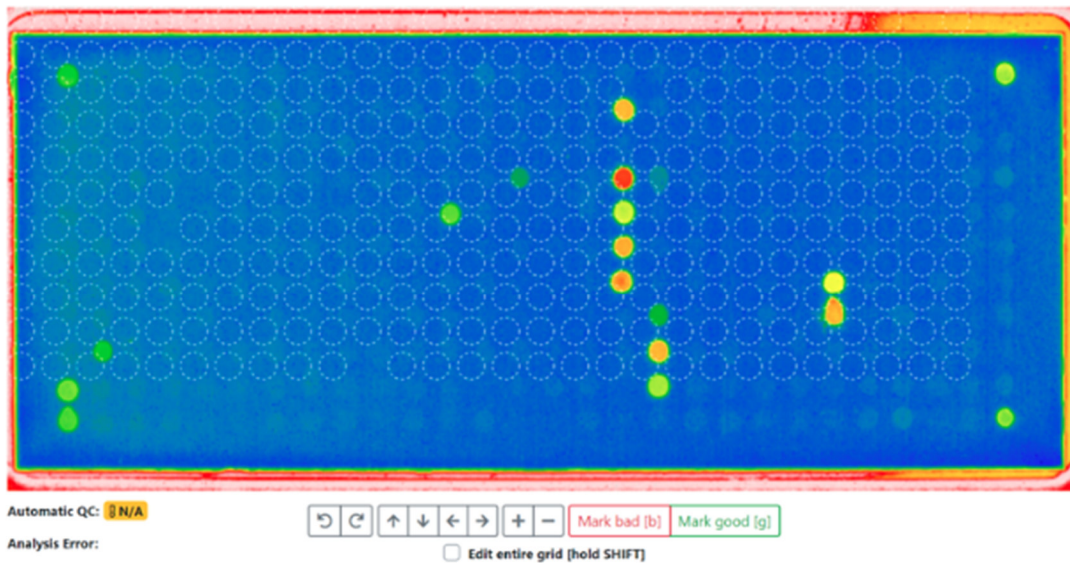
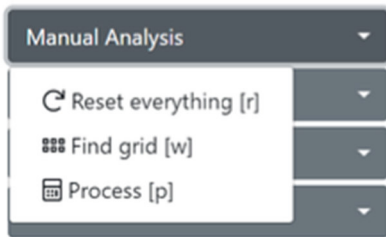
- Manual Analysis (dropdown)
- Image (dropdown)
- Grid (dropdown)
- More (dropdown)
- ⚠ Reset everything and reprocess
- This discards all modifications to the array, and re-runs the complete analysis process from the original image data. Please note that any manual changes will be irreversible lost.
- ← Back to Measurement

The main area shows a large grid of measurement points. Below the grid, there is a toolbar with the following controls:

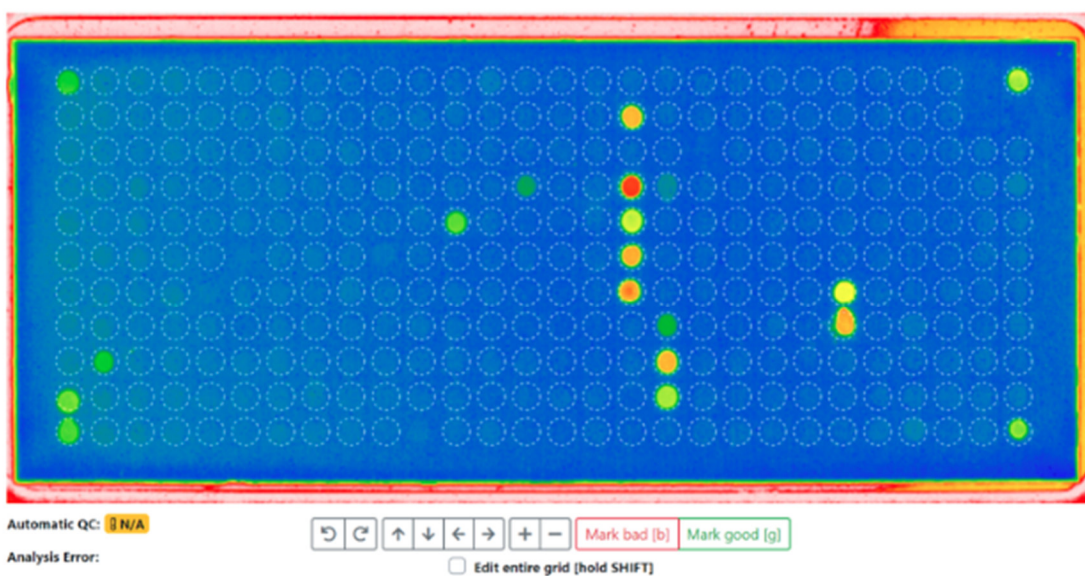
- Automatic QC: ✔ OK
- Analysis Error: Edit entire grid (hold SHIFT)
- Buttons: ↺ ↻ ↑ ↓ ← → + - Mark bad [b] Mark good [g]
- Buttons A and B (pointing to the rotation buttons in the toolbar)

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". The grid can also be found automatically by selecting "Manual Analysis --> Find grid" or by pressing "W". To turn the grid clockwise, click the buttons "A" or "B" according to the picture above.

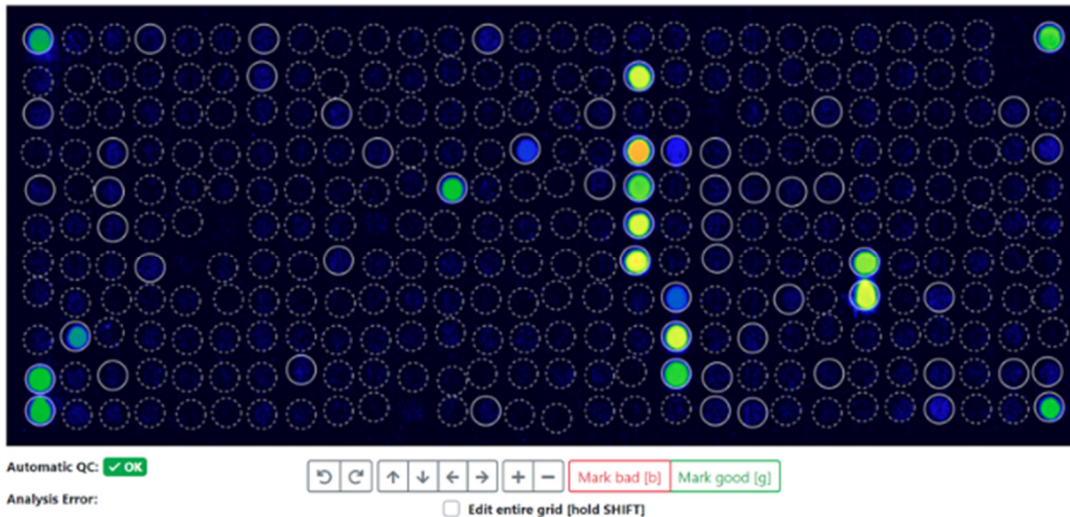
The position of the grid can be confirmed by pressing "P" or "Manual Analysis --> Process".



Press "R" or "Manual Analysis --> Reset Grid"



Press "W" or "Manual Analysis --> Find Grid" or manually move the entire grid



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

If the image is reset manually, or with the button "Reset everything and reprocess", a button "Show analysis & QC logs" appears.



If you click on this button, an area will open with the explanation for QC fail or QC OK. For the QC to be OK, the background must be within a certain range and all guide dots must reach a special value.

Analysis Log

Parsing calibration string ...
 Total IgG (tIgG) normalized by calculating $1,38E+06 \times 10,01310999956677246 \times +20,14980078125 (x=16242)$, which results in 557.
 'ReQuantify' took 426ms.

QC Log

These are the values used for QC (ALEX v2): Curve Correction=0,9999008677496417, tTgE=16242, GD1=17802 (SNR=109.89), GD2=14754 (SNR=70.66), GD3=16849 (SNR=65.77), GD4=17381 (SNR=88.36)
 QC (ALEX v2) succeeded.

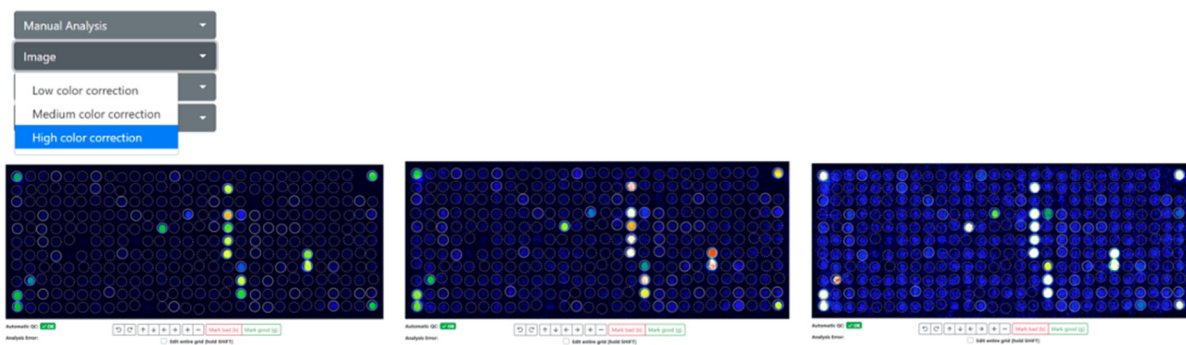
Background Log

Calculated background statistics for 204 pixels (from a total of 226, skipped smallest 11, and highest 11 pixels). The average is 9 970, the minimum 7822 and the maximum 12187 (minimum and maximum is calculated including skipped pixels). This results in an average difference of 516, which is an SD of 36,23 and a CV of 0,36%.
 For comparison, there is an overall total of 171360 pixels. The overall average is 15 663, the minimum 5 197 and the maximum 65 187.

If these QC criteria are still not fulfilled after manually adjusting the spots on the image, please contact your local distributor.

12.2.5.1 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 3 levels (low color correction, medium color correction or high color correction).

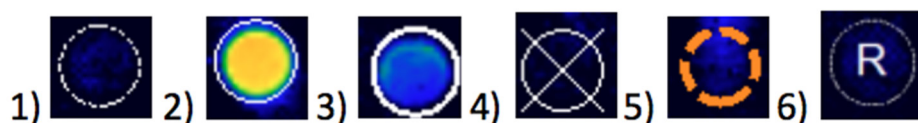


Pictures above from left to right: High color correction (default) - Medium color correction - Low color correction

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.

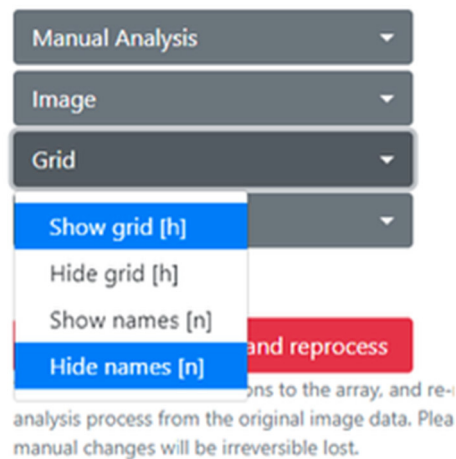


Spots are editable by the user:

- 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".



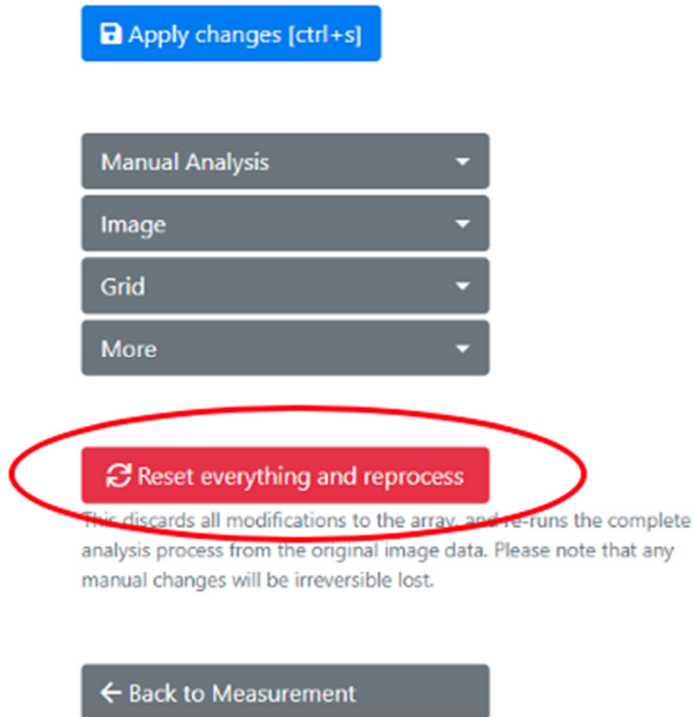
12.2.5.2 Shortcut Summary

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 needs 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 barcode, 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.

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.

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:

12.2.5.3 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	0.00
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	0.00
Alder <i>Alnus glutinosa</i>	t101	Polcalcin	Pollen Inhalation	M	Aln g 4	0.00
Almond <i>Prunus dulcis</i>	f20		Plant Food Food	E	Pru du	0.00
Alternaria alternata <i>Alternaria alternata</i>	m229	Alt a 1-Family	Microorganisms & Spores Inhalation	M	Alt a 1	0.00
Alternaria alternata <i>Alternaria alternata</i>	m230	Enolase	Microorganisms & Spores Inhalation	M	Alt a 6	0.00
American Cockroach <i>Periplaneta americana</i>	i206		Insects Inhalation	E	Per a	0.00
American Cockroach <i>Periplaneta americana</i>	i300	Tropomyosin	Insects Inhalation	M	Per a 7	0.11
American house dust mite <i>Dermatophagoides farinae</i>	d100	Cysteine protease	Mites Inhalation	M	Der f 1	3.69
American house dust mite <i>Dermatophagoides farinae</i>	d101	NPC2 Family	Mites Inhalation	M	Der f 2	30.01

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		kUA/L
E	Aca m	0.00
E	Aca s	0.39

By clicking on the name of an allergen in the list of allergen results, the corresponding spot on the array image is highlighted by a red rectangular box.

The screenshot shows the Raptor software interface. At the top, there are navigation tabs: "New measurements", "Approved measurements", "Start measurement", and "Automats". A search bar contains "MADx". Below the navigation is a "Previous" button and a "New" button. The main area displays a microarray image with a grid of spots. A red rectangular box highlights a spot in the lower right quadrant, with a white arrow pointing to it. To the left of the image are several dropdown menus and a "[ctrl+s]" button. Below the image, there is a "Flag and reprocess" section with a red background and text: "Flag and reprocess", "Changes to the array, and re-runs process from the original image any manual changes will be". Below this are four dropdown menus. To the right of the image, there is a metadata section: "Barcode: 02AIS02D", "Sample Code: E18028noCCD", and "Automatic QC: OK". Below the metadata are navigation controls (90°, 180°, 90°, up, down, left, right, +, -) and two buttons: "Mark bad [b]" and "Mark good [g]". At the bottom right, there are two checkboxes: "Edit entire grid [hold SHIFT]" and "Edit multiple features [hold CTRL]". Below the image is a "Filter" section with a dropdown menu set to "Only positive allergens". Below the filter is a table of allergen results.

Name	Code	Biochemical	Tissue & Exposure	E/M	Feature	kUA/L
Acacia <i>Acacia mimosa</i>	t19		Pollen Inhalation	E	Aca m	0.48
Alder <i>Alnus glutinosa</i>	t100	PR-10	Pollen Inhalation	M	Aln g 1	37.73
Almond <i>Prunus dulcis</i>	f20		Plant Food Food	E	Pru du	0.44

12.2.6 Overview of Measurements

New and unapproved measurements can be displayed in the "New Measurements" overview.

The screenshot shows the Raptor software interface with the "New Measurements" overview. At the top, there are navigation tabs: "Raptor", "New measurements", "Approved measurements", and "Start measurement". Below the navigation is a search bar with the text "Search by barcode, patient, sample, tag ...". Below the search bar is a table of new measurements.

QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
OK		02AAB320				14.11.2019 10:54
OK		02AAB306				14.11.2019 10:54
OK		02AAB387				14.11.2019 10:54
OK		02AAB388				14.11.2019 10:53
Failed		02AAB389				14.11.2019 10:53

Clicking on the barcode 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.

QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
✓ OK		02AAB320	<input type="text"/>			14.11.2019 10:54
✓ OK		02AAB386				14.11.2019 10:54
✓ OK		02AAB387				14.11.2019 10:54
✓ OK		02AAB388				14.11.2019 10:53
✗ Error		02AAB389				14.11.2019 10:53

In the search field, measurements can be searched for by their barcode, patient name, sample code or tag.

QC	Tags	Barcode	Sample Code	Patient Code	Patient Name	Analysis Date
✓ OK		02AAB320				14.11.2019 10:54

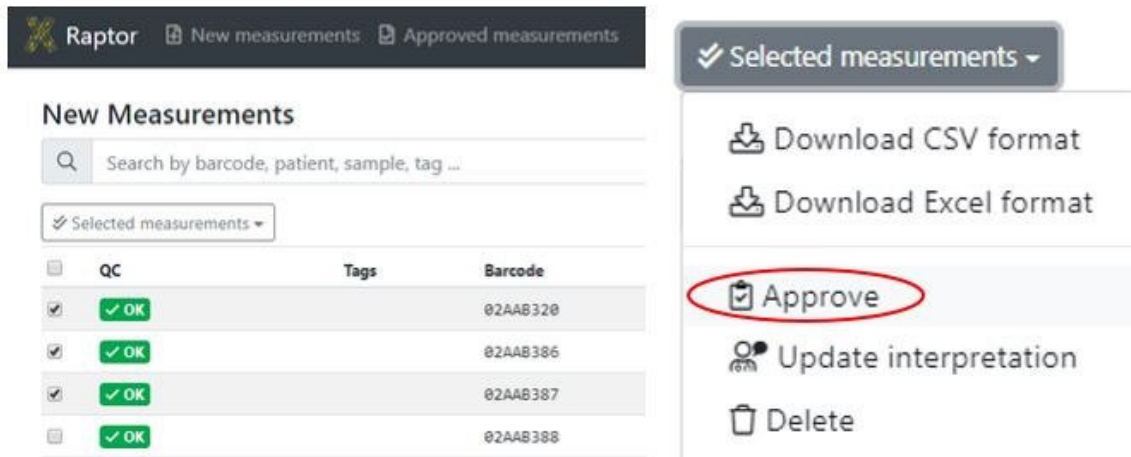
It is possible to duplicate the barcode and the measurement data in the data repository if cartridge is acquired several times. However, this is indicated by a triangle with an exclamation mark during measurement.

QC	Tags	Barcode
⚠ ✓ OK		02AAB160
⚠ ALEX barcode was scanned more than once.		02AAB160

12.2.7 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:

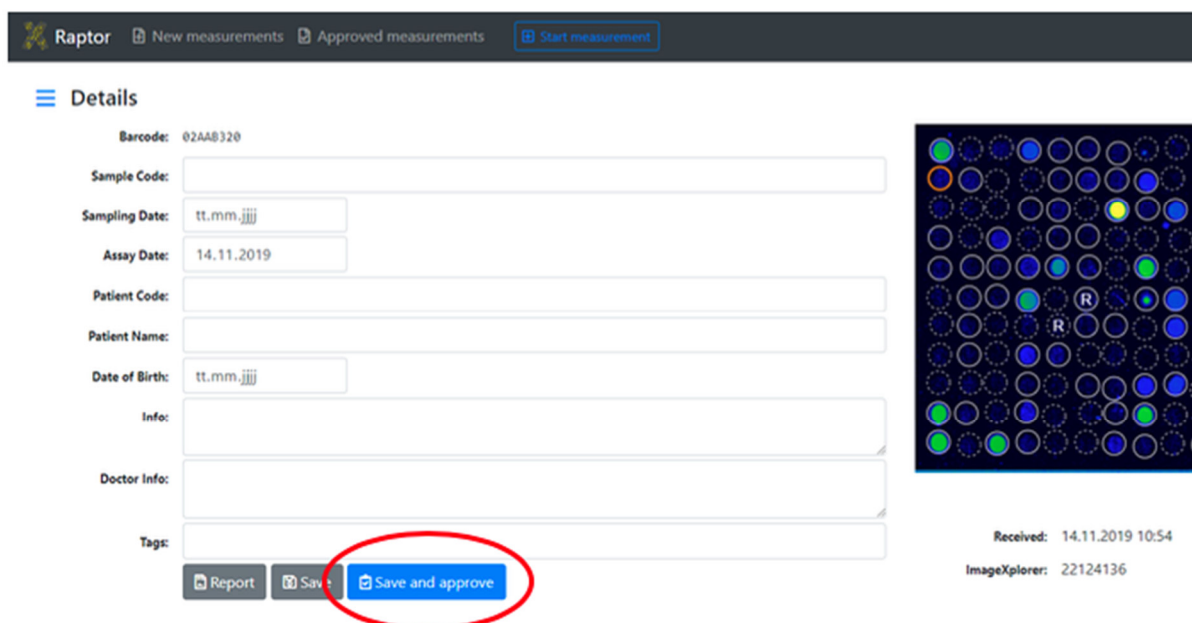


The screenshot shows the Raptor software interface. At the top, there are navigation tabs for "New measurements" and "Approved measurements". Below this is a "New Measurements" section with a search bar and a "Selected measurements" dropdown menu. A table lists four measurements with their QC status (all marked "OK") and barcode numbers. To the right, a context menu is open for the selected measurements, showing options: "Download CSV format", "Download Excel format", "Approve" (highlighted with a red circle), "Update interpretation", and "Delete".

QC	Tags	Barcode
✓ OK		02AAB320
✓ OK		02AAB386
✓ OK		02AAB387
✓ OK		02AAB388

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".



The screenshot shows the "Details" page for a measurement in the Raptor software. The page includes a "Barcode" field with the value "02AAB320" and several input fields for "Sample Code", "Sampling Date", "Assay Date", "Patient Code", "Patient Name", "Date of Birth", "Info", and "Doctor Info". At the bottom, there are three buttons: "Report", "Save", and "Save and approve" (highlighted with a red circle). To the right, there is a grid of measurement results (a microarray image) and a "Received" timestamp of "14.11.2019 10:54" and an "ImageXplorer" ID of "22124136".

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.

Barcode	Analysis Date
02AAB320	14.11.2019 10:54

Approve these measurements

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.

Raptor New measurements Approved measurements Start measurement

Approved Measurements

Search by barcode, patient, sample, tag ...

Tags	Barcode	Sample Code	Patient Code	Patient Name	Date of Birth	Approval Date
<input type="checkbox"/>	02AAB319	119				10.12.2019 14
<input type="checkbox"/>	02AAB318	118				10.12.2019 09
<input type="checkbox"/>	02AAB317	117				10.12.2019 09

The results of selected measurements in the approved measurements section can be downloaded as PDF report, as EXCEL, CSV or ASTM file.

Approved Measurements

Search by barcode, patient, sample, tag ...

Download selected measurements ▾

<input type="checkbox"/>	Tags	Barcode	Sample Code
<input checked="" type="checkbox"/>		02AAB319	119
<input checked="" type="checkbox"/>		02AAB318	118
<input checked="" type="checkbox"/>		02AAB317	117

Approved Measurements

Search by barcode, patient, sample, tag ...

Download selected measurements ▾

	Barcode	Sample Code
Report (PDF format)	02AAB319	119
CSV format	02AAB318	118
Excel format	02AAB317	117
ASTM format		

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".

RAPTOR 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 download your requested exports. Please note that you can keep working, all exports are done in the background and you can download 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

12.2.8 Report

12.2.8.1 Creating a Custom Report Template

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

MADx

Report templates

Use this to create, edit or delete report templates for this tenant. Each template can have its specific look and configuration.

Administration

Tenant Admin

Manage report templates

The following settings can be selected:

- Name of the report template
- Base template (ALEX² Version 1 or Version 2, FOX)
- Preferred language (you can still change the language for every report separately)
- Allergens overview: tlgE (ALEX²)
In case of an ALEX² test, total IgE (tlgE) is highlighted in blue on the summary page of the report. It is possible to hide tlgE in the report if you deselect tlgE.
- Additional Information: yes or no
- Dates shown on the report:
 - Sample date
 - Assay date
 - Test date
 - Approval date
 - Print date
- Allergen details:
 - Include allergens (which results 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)
 - 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.
 - Include overview
- Export settings of PDF Report:
 - Setting Type: Automatic --> choose from the following options:
 - Patient ID
 - Patient Name
 - Sample ID
 - Measurement Barcode
 - Date & Time
 - Setting Type: Manual --> select options the way you prefer
Example: Report_{PatientID}_{DateAndTime}

- Header: To upload a logo on the left or right side, please press "Browse" and select a JPG or TIFF format.
- Signature: In addition, a picture of a signature can be uploaded to be added at the end of the report.

Add new report template

General configuration

Name:

Base Template:

Preferred language:

Dates shown

Include sample date:

Include assay date:

Include test date:

Include approval date:

Include print date:

Export Settings

Setting Type:

Include Patient ID:

Include Patient Name:

Include Sample ID:

Include Measurement Barcode:

Include Date & Time:

Header

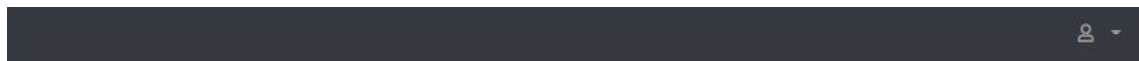
Logo (left):
Maximum file size 976,0KB

Text:

Signatures

Left:

Center:



Allergens Summary

Include Total IgE:
Include Additional Information:

Allergen Details

Include allergens: All allergens
Allergens sort order: Alphabetically by allergen
Cross-reactive information: Include text
Include Interpretation:
Include Overview:

Logo (right):
Maximum file size 976,0KB

Martina Aumayr (aumayr@macroarraydx.com) ist angemeldet.

Right:

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

The following languages are available:

- Arabic
- Bulgarian
- Chinese
- Croatian
- Czech
- Dutch
- English
- French
- Georgian
- German
- Greek
- Hungarian
- Italian
- Latvian
- Lithuanian
- Persian
- Polish
- Portuguese
- Romanian
- Russian
- Slovak
- Slovenian
- Spanish
- Spanish-Mexico
- Turkish
- Ukrainian

To define your "default" template, that 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 template.

Tenant configuration
The general configuration settings for your tenant.

[Configure Tenant](#)

Configure "MADx"

General configuration

* Name: MADx

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

Default report template: New report template

Default report language: English

Require ImageXplorer calibration: Warn after 60 days; enforce after 90 days

A report of an unapproved measurement can be displayed by clicking on one measurement from the "New measurement" tab and selecting "Report"

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

Details

Barcode: 02AAB320

Sample Code:

Sampling Date:

Assay Date:

Patient Code:

Patient Name:

Date of Birth:

Info:

Doctor Info:

Tags:

[Report](#) [Save](#) [Save and approve](#)

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.

The screenshot displays the Raptor web application interface for generating a report. The top navigation bar includes 'Raptor', 'New measurements', 'Approved measurements', 'Start measurement', and 'Autosave'. The left sidebar shows a 'Report' section with options for 'Template' (Version 2 (ALEX2 only)) and 'Language' (English (en)).

The main content area shows a report preview for patient ID 02AD0942. It includes fields for Patient ID, Patient Name, Date of Birth, Sample ID, and Referring Physician. A note indicates that the internal QC (Plausibility check for IQ) was within acceptance range.

The report is titled 'Lab report: Summary on detectable sensitisations' and is categorized into several groups:

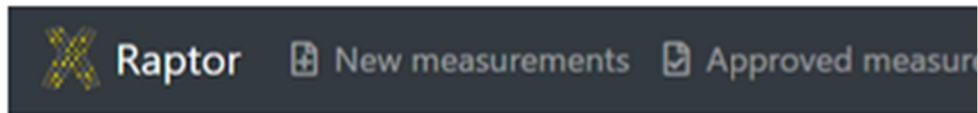
- POLLEN:** Grass Pollen, Tree Pollen, Weed Pollen.
- MITES:** House Dust Mites & Storage Mites.
- PLANT-BASED FOOD:** Legumes, Grain, Spices, Fruits, Vegetables, Nut & Seeds.
- INSECTS & VENOMS:** Ant, Bee, Wasp, Cowdrea.
- MICROORGANISMS:** Fungal Spores & Yeast.
- ANIMAL-DERIVED FOOD:** Milk, Egg, Fish & Seafood, Meat.
- EPITHELIAL TISSUES OF ANIMALS:** Pets, Farm Animals.
- OTHERS:** Flou, CCD, Parasite.

A legend indicates the highest measured IgE concentration per allergen group, ranging from <math>< 0.3 \mu\text{g/L}</math> to > 15 $\mu\text{g/L}$. The report also includes a table of allergen concentrations:

Name	EMV	Allergen	Function	MIU/L
POLLEN				
Grass Pollen				
Bermuda grass		Cyn d		1.73
		Cyn d 1	Beta-Euphrasin	3.33
Parthenocaryopsis		Lol p 1	Beta-Euphrasin	2.84
Barn grass		Poa n		2.20
Timothy grass		Phl p 1	Beta-Euphrasin	3.32
		Phl p 2	Euphrasin	2.38
		Phl p 5/101	Grass Group 5/5	9.13
		Phl p 5	Grass Group 5/5	2.25
		Phl p 7	Poacean	8.78
		Phl p 12	Poacean	4.10

Legend: |||| Allergen Extract, ● Molecular Allergen, |E| <math>< 0.3</math> Negative or in question.

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.

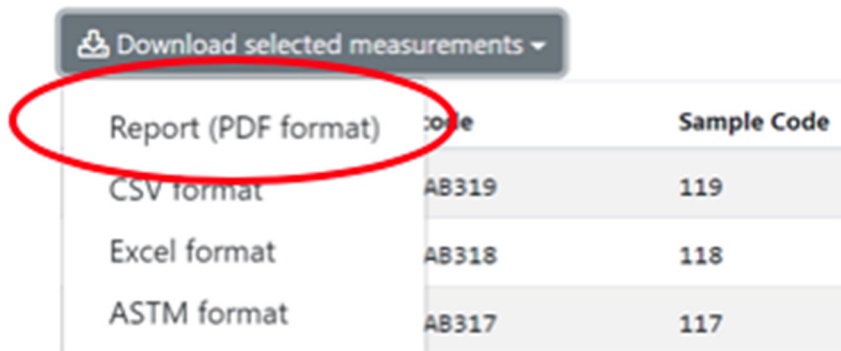


Approved Measurements

Search by barcode, patient, sample, tag ...

Download selected measurements ▾

<input type="checkbox"/>	Tags	Barcode	Sample Code
<input checked="" type="checkbox"/>		02AAB319	119
<input checked="" type="checkbox"/>		02AAB318	118
<input checked="" type="checkbox"/>		02AAB317	117



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.

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

Details

Barcode: 02AAB021

Sample Code:

Sampling Date:

Assay Date: 18.12.2019

Patient Code:

Patient Name:

Date of Birth:

Info:

Doctor Info:

Analysis: 18.12.2019 09:20

Approved: 18.12.2019 10:16

ImageXplorer: 22899872

Tags:

[Download](#) [Report](#) [Save](#)

Raptor [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.

MAD
MACRO ARRAY DIAGNOSTICS

Patient ID:	
Patient Name:	
Date of Birth:	
Sample ID:	
Barcode:	02AAB
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

12.2.8.2 Requesting Interpretation Guidance

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

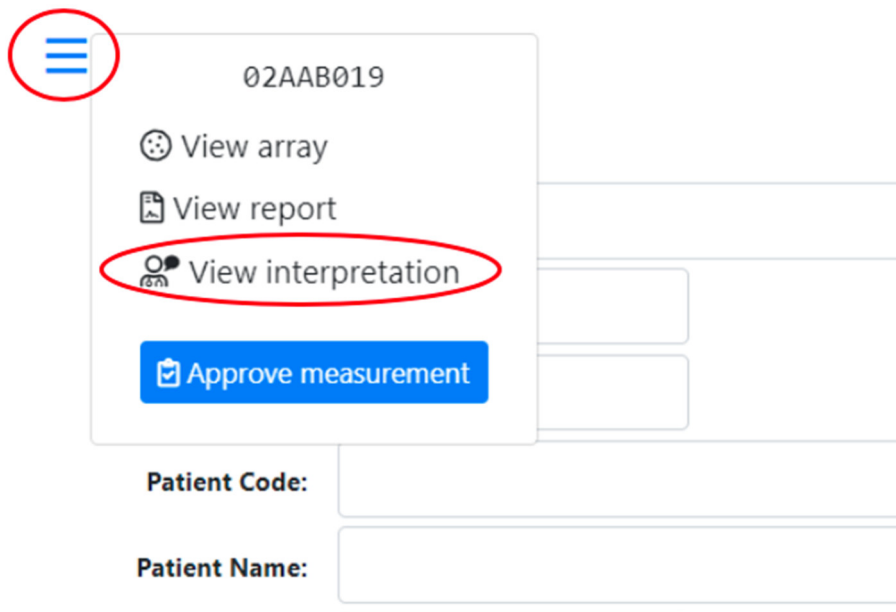
For using this service, a license key must be requested from your local distributor.

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

The image shows a screenshot of a web interface. At the top, there is a section titled "Tenant configuration" with the subtitle "The general configuration settings for your tenant." Below this is a blue button labeled "Configure Tenant". Below the "Tenant configuration" section is a larger section titled "Interpretation". Inside the "Interpretation" section, there is a label "License Key:" followed by a text input field. A red oval is drawn around the "License Key:" label and the input field.

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".



02AAB019

- View array
- View report
- View interpretation
- Approve measurement

Patient Code:

Patient Name:

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

Patient symptoms

Asthma	<input type="text" value="None"/>
Rhinitis	<input type="text" value="None"/>
Conjunctivitis	<input type="text" value="None"/>
Urticaria	<input type="text" value="None"/>
Angioedema	<input type="text" value="None"/>
Oral Allergy Syndrome	<input type="text" value="None"/>
Eczema	<input type="text" value="None"/>
Anaphylaxis	<input type="text" value="None"/>
GastroentericSymptoms	<input type="text" value="None"/>

☰ Interpretation

Settings


Language:

Patient information

Gender:

Age: years

Environment:

 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 ALEX² Barcode 02AAB019, interpretation date 12/19/2019.

Of the tested 295 allergens, 25 were above the detection limit of 0.3 kU_A/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, Pfl 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

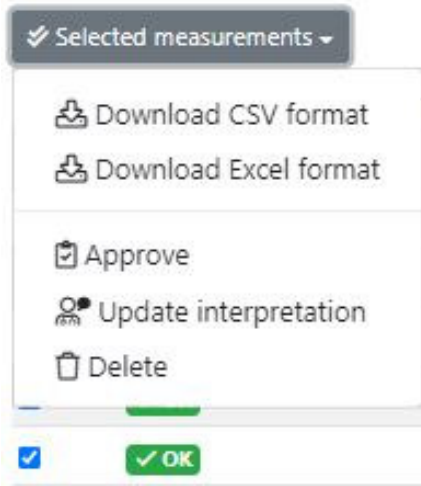
This measurement already has an interpretation stored. Usually, it should not be necessary to request those again, but it could be necessary when the patients information has changed.

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

query are indicated by the following symbol:



In addition, several queries can also be queried in 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.



12.2.8.3 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".

 A screenshot of the "Details" form in the Raptor software. The form includes fields for Barcode (02AE1852), Sample Code, Sampling Date (tt.mm.jjj), Assay Date (07.10.2020), Patient Code, Patient Name, Date of Birth (tt.mm.jjj), Info, Doctor Info, and Tags. The "MOD" field is set to "Pollen allergens" and is circled in red. At the bottom, there are three buttons: "Report", "Save", and "Save and approve".

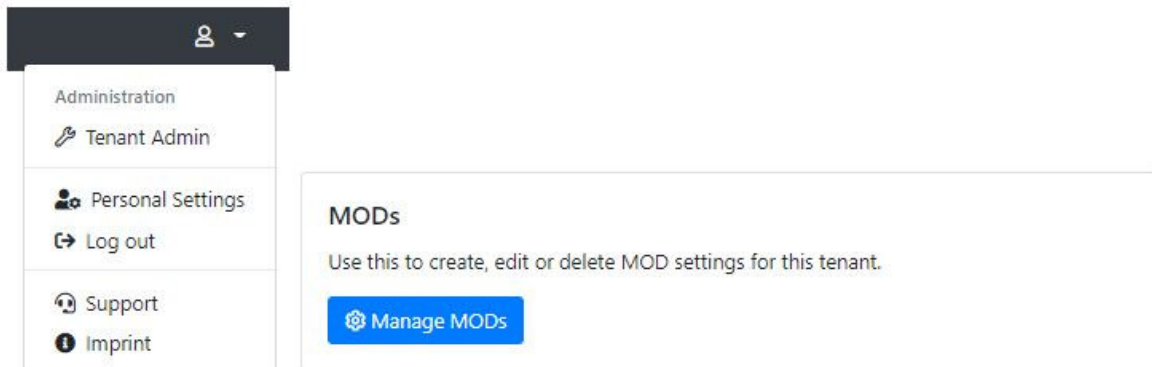


CAUTION ! After approval of the measurement, the allergen results, which were not included in the MOD, will be deleted from both image and data. The unselected allergens are then listed in the report as “-”.

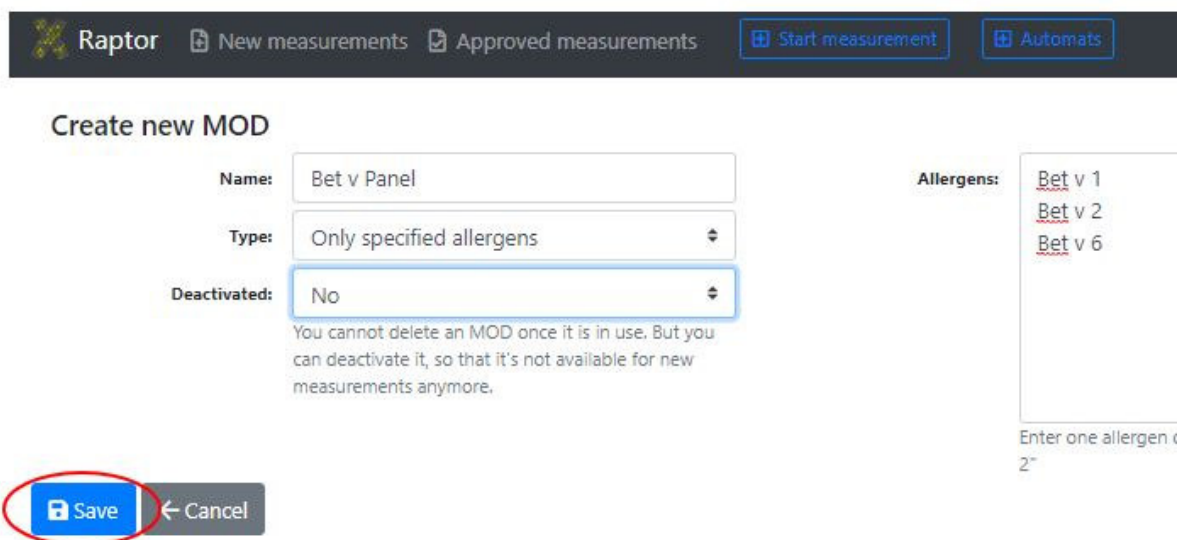
The following allergen panels can be selected as the predefined MODs:

- 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".

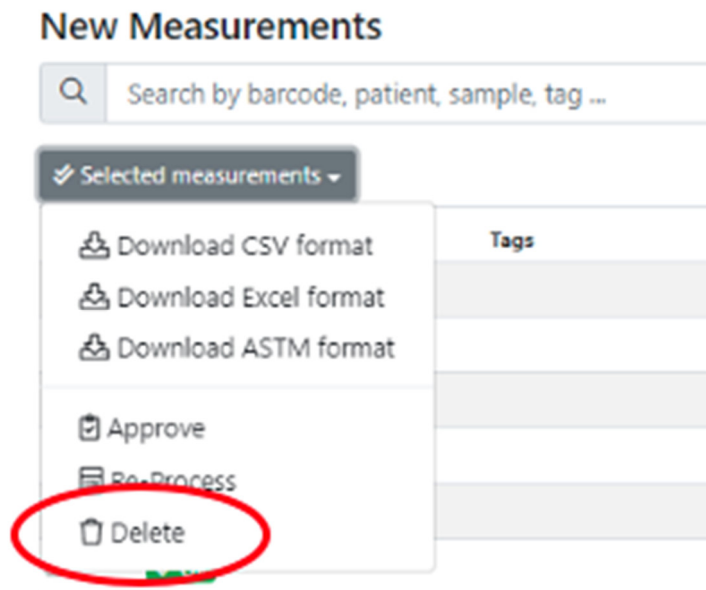


Enter a name of the panel, the type (only specified allergens, or all allergens except the specified ones), and the allergens (by their code) you would like to include in the panel.



12.2.9 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.



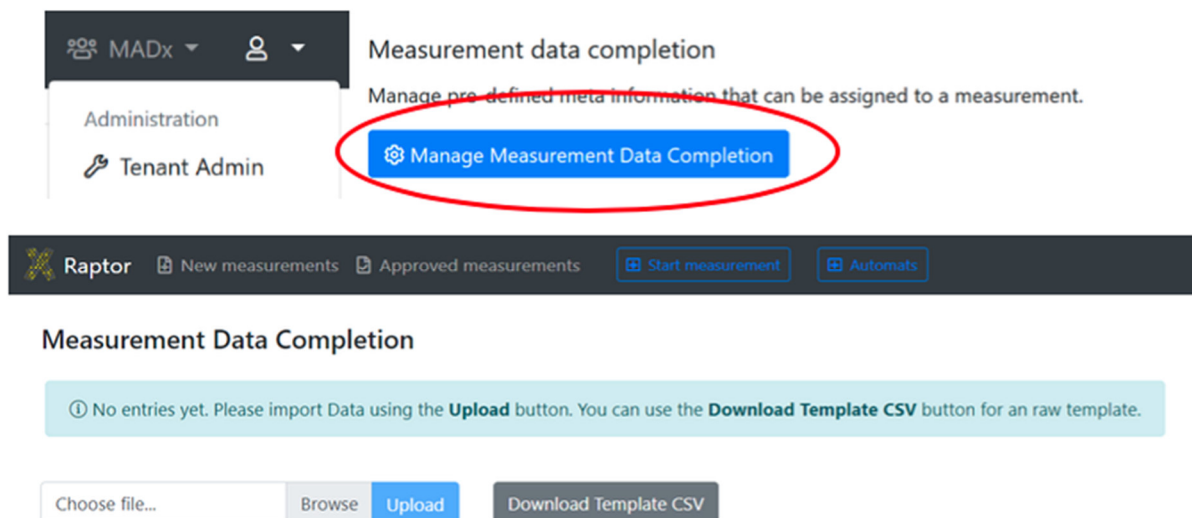
Delete measurements

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

12.2.10 Importing the patient information from a file

Patient information corresponding to a certain sample barcode 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).



The screenshot shows the 'Measurement data completion' page. The 'Manage Measurement Data Completion' button is highlighted with a red circle. Below the interface, a table shows the data structure for the CSV template.

	A	B	C	D	E	F	G	H	I
1	Barcode	Sample ID	Patient ID	Patient Name	Date Of Birth	Sampling Date	Assay Date	Referring Physician	Additional Info
2	02AAB159	12	Ma	Martina	01.01.2010	11.11.2019	11.11.2019	Dr. A	Info
3									

After downloading the Template file, you can type in patient information for the corresponding barcode, save it on your computer, upload the document again and click "Apply Changes".

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

Verify Changes

	Barcode	CreatedAtUtc	SampleId	PatientId	PatientName	DateOfBirth	Sample
+	02AAB159	-	12	Ma	Martina	01.01.2010	11.11

Apply Changes Cancel

Measurement Data Completion

Barcode	CreatedAtUtc	SampleId	PatientId	PatientName	DateOfBirth	SamplingDate
02AAB159	12.12.2019 13:46:41	12	Ma	Martina	01.01.2010	11.11.2019

If an image is acquired and the corresponding sample barcode with the information was uploaded before, the patient information is automatically imported into the software.

12.2.11 User 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 User Portal for the doctor. To create the account, go to "Tenant Admin --> User 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".

Add new user on User 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:

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

Password:

Doctor Info Text:

This information will be printed on a patients report.

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".

☰

02AAB021

-
-
-
-

Patient Code:

Patient Name:

Date of Birth:

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://doctorportal.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: 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

 User Portal
English ▾

Welcome to the User Portal

The Allergy Explorer User Portal allows users to view shared measurements. You will need a username and password to log in, and 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:

Log in

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. However, the user cannot change anything. The user can also change their password if desired by clicking on "Change password".

User Portal English Log out

Shared Measurements

These are the measurements that have been shared with you. You may view the details of each measurement, or download the report PDF file.

Measurement	Patient	Sample
02AAB021		View Details View Report

Imprint Privacy v0.0.1.10

It is possible to request a RAVEN interpretation guidance for shared measurements too. For this purpose, fill out the patient data accordingly and click on "Request interpretation". Then, to view the patient report, click on "View Report".

Details of measurement

Measurement:

Product Type: ALEX2

Patient Name:

Patient Code: 1199516

Date of Birth:

Sample Code: 596697

Info:

Doctor Info:

Sampling Date:

Processed Date: 6/14/2020

Assay Date: 6/14/2020

Approval Date: 6/16/2020

Interpretation

Settings

Language: Español (es)

Patient information

Gender: Female

Age: 20 years

Environment: Mediterranean

Patient symptoms

Asthma: None

Rhinitis: None

Conjunctivitis: None

Urticaria: None

Angioedema: None

Oral Allergy Syndrome: None

Eczema: None

Anaphylaxis: None

Gastroenteric Symptoms: None




Request interpretation

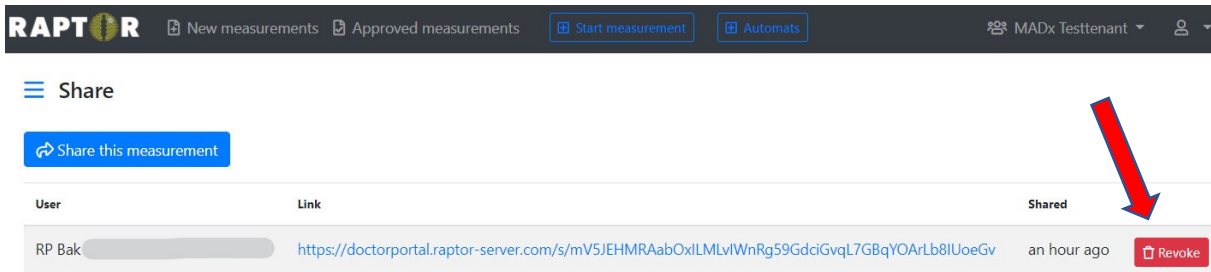
Back

View Report



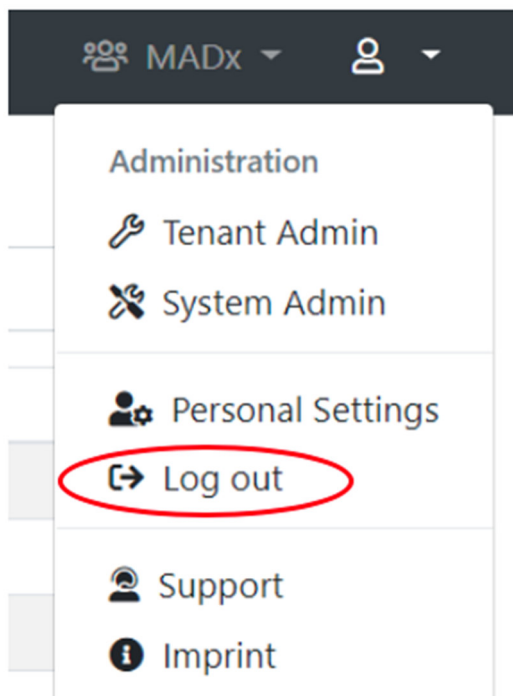
Measurements that have been shared are marked with the following symbol in the list of approved measurements: 

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



12.2.12 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.



12.2.13 Technical Support

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

12.2.14 Technical Data

This chapter summarizes the specifications of the ImageXplorer.

Features	Parameters
Compatible Test Formats	ALEX ² or FOX cartridges
Cartridge Dimensions (W x D x H)	53 x 18 x 7 mm
Maximum Scan Area / (W x D)	50 x 30 mm
Light Source	White light LED
Applicable Dyes	Colorimetric Dyes
Scan Resolution	Up to 600 dpi
Sensitivity	≤ 0.3 kU _A /L
Scan Speed	CPU dependent, < 5 s per cartridge
Dynamic Range	2.5 logs
Repeatability	R ² ≥ 99 %, CV ≤ 5 %
Focus Distance	80 ± 10 mm
Image File Format	BMP 16 Bit
Voltage	5 V USB
Power	< 5 Watts
Size (W x D x H)	160 x 180 x 180 mm
Weight	1.2 kg
Barcode Identification	QR Barcode
Operating System	PC with MS Windows® 10
Connection	USB 2.0 or higher
Temperature Range	Room Temperature

12.2.15 Maintenance

The ImageXplorer is a sensitive imaging device and should be handled carefully. For accurate results, it is essential that the instrument be maintained dust-free state as much as possible. To this end, the external ImageXplorer housing must be regularly cleaned with a lint-free cloth. Do not use any detergents for cleaning. The carriage which holds the cartridges can be separately cleaned if necessary, using mild detergents or alcoholic solutions.

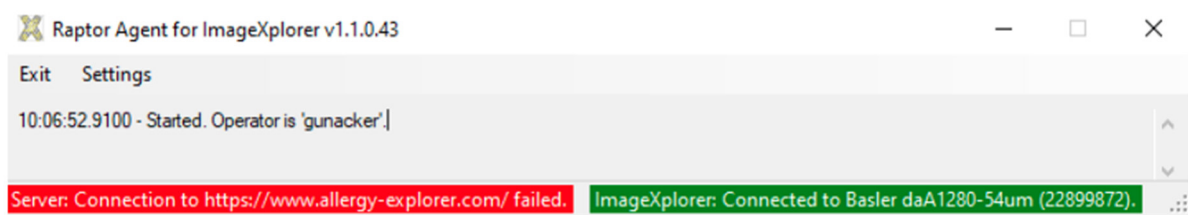


DO NOT open the instrument chassis!

12.2.16 Troubleshooting

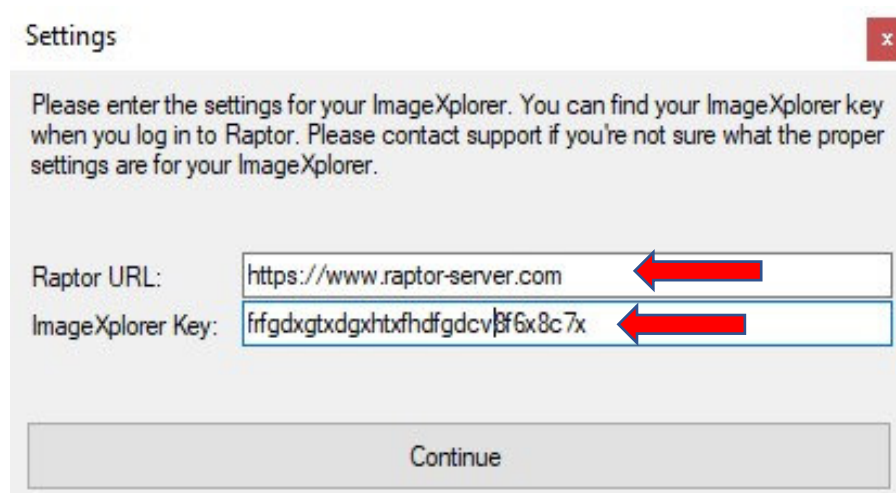
The following errors are the most common ones and therefore explained here in more detail.

- **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
-

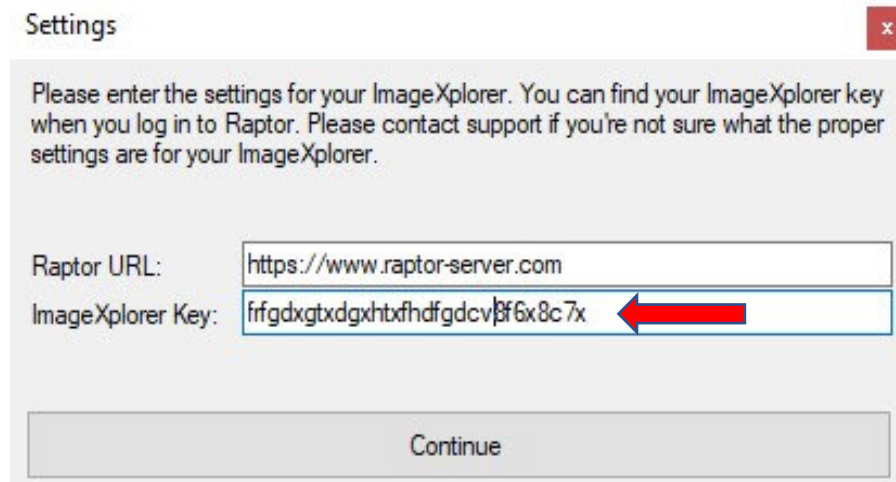


- **ImageXplorer Connection failed (Agent flags connection in red color):**

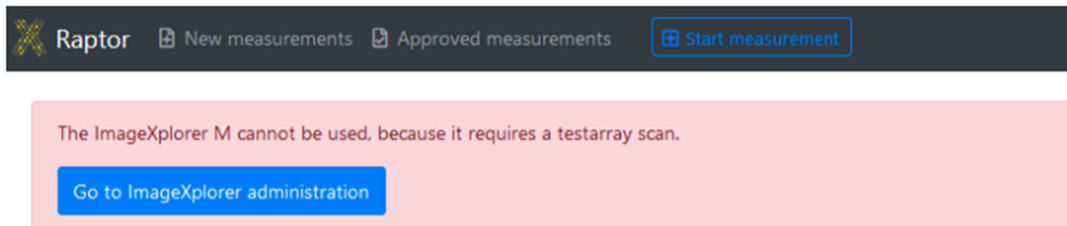


Possible Solutions:

- 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 Test Array run has been performed

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



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