RAPTOR
SERVER ANALYSIS SOFTWARE

INSTRUCTION FOR USE

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DISCLAIMER

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Please consult the relevant instructions for use of ALEX^2 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.

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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

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

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.

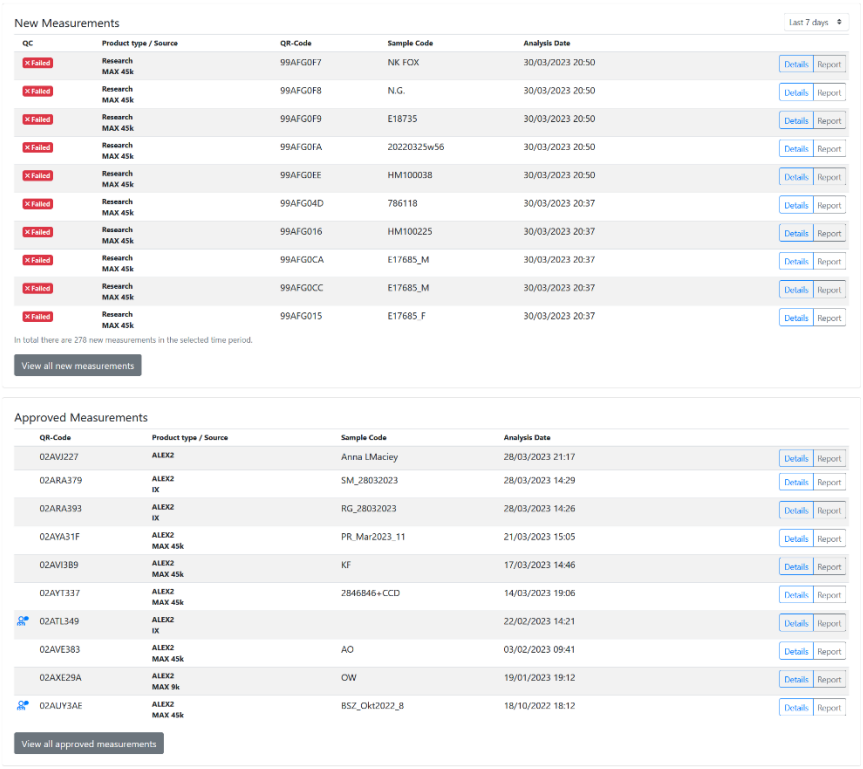
Your username

Your password

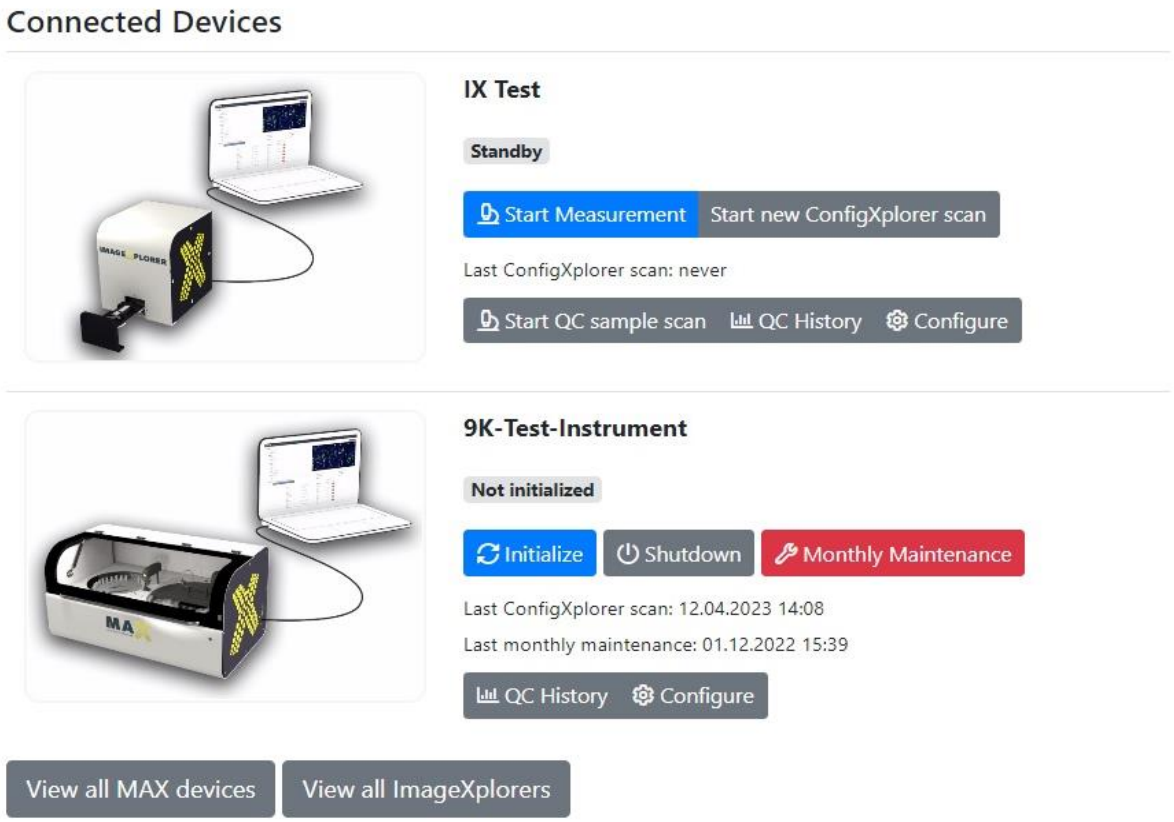
Log in

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.



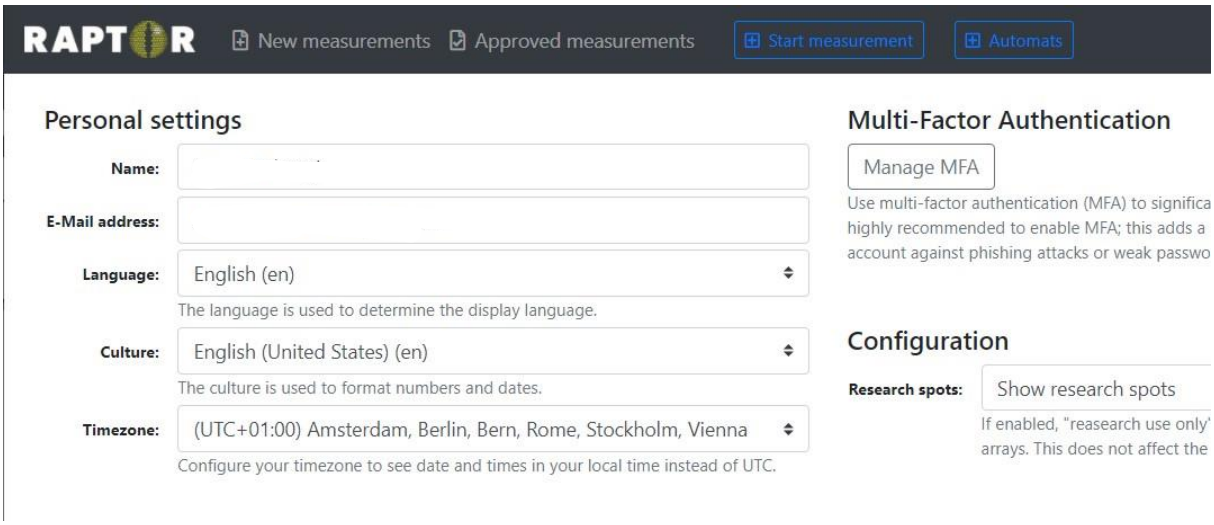
On the right side of the screen the connected devices and the date of their last ConfigXplorer scan and/or monthly maintenance (for MAX devices only) are shown. Furthermore, regular measurements as well as ConfigXplorer and QualityXplorer scans and monthly maintenance can be initiated via the dashboard. 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



VII.1.2 PERSONAL SETTINGS

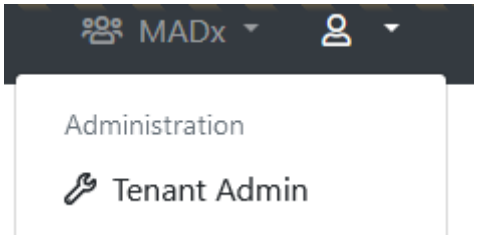
In "Personal Settings" you can select the user language, the culture (e.g., English (UK)) and the time zone. ALEX² contains 5 Research Use Only (RUO) allergen spots. These are deactivated by default. To make the RUO spots visible, the user can select “show research spots” in the drop-down menu. In addition, 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.



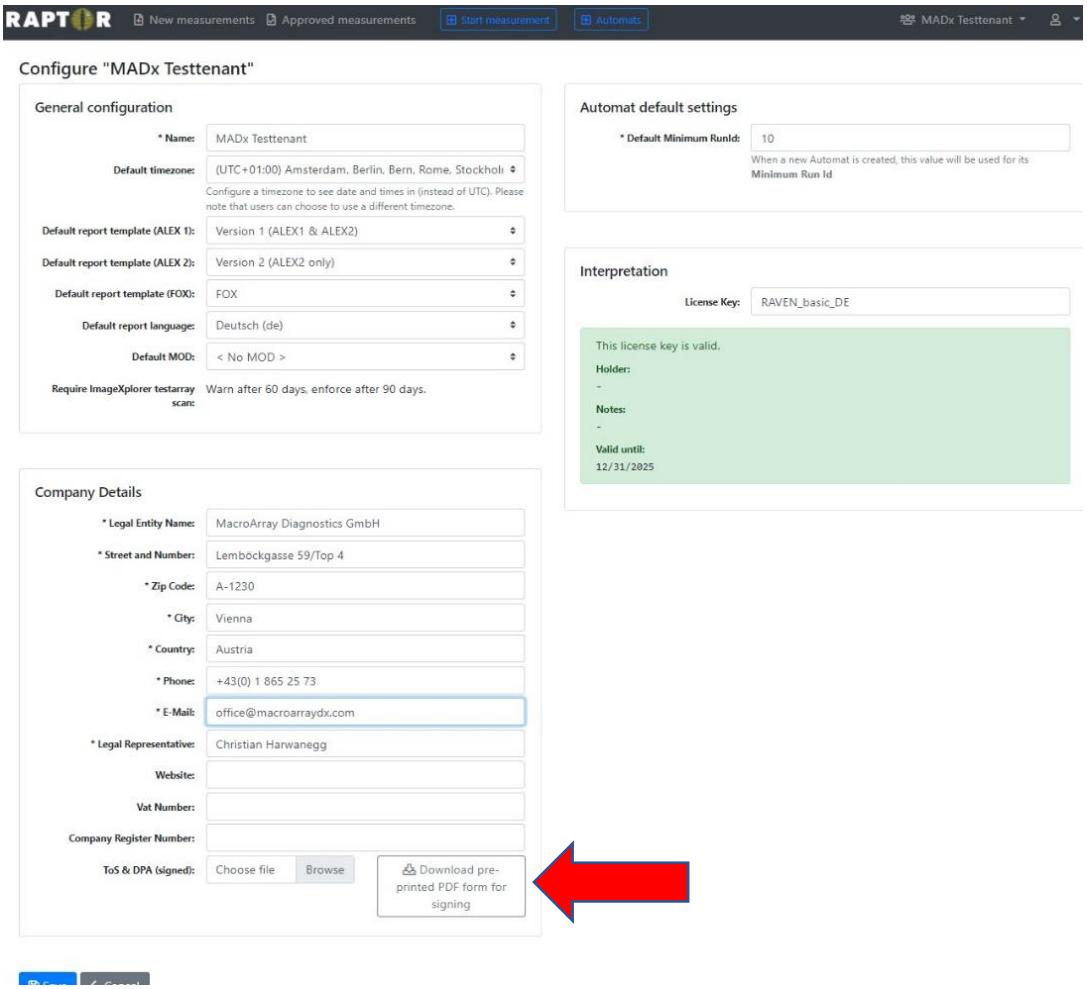
VII.1.3 TENANT ADMIN

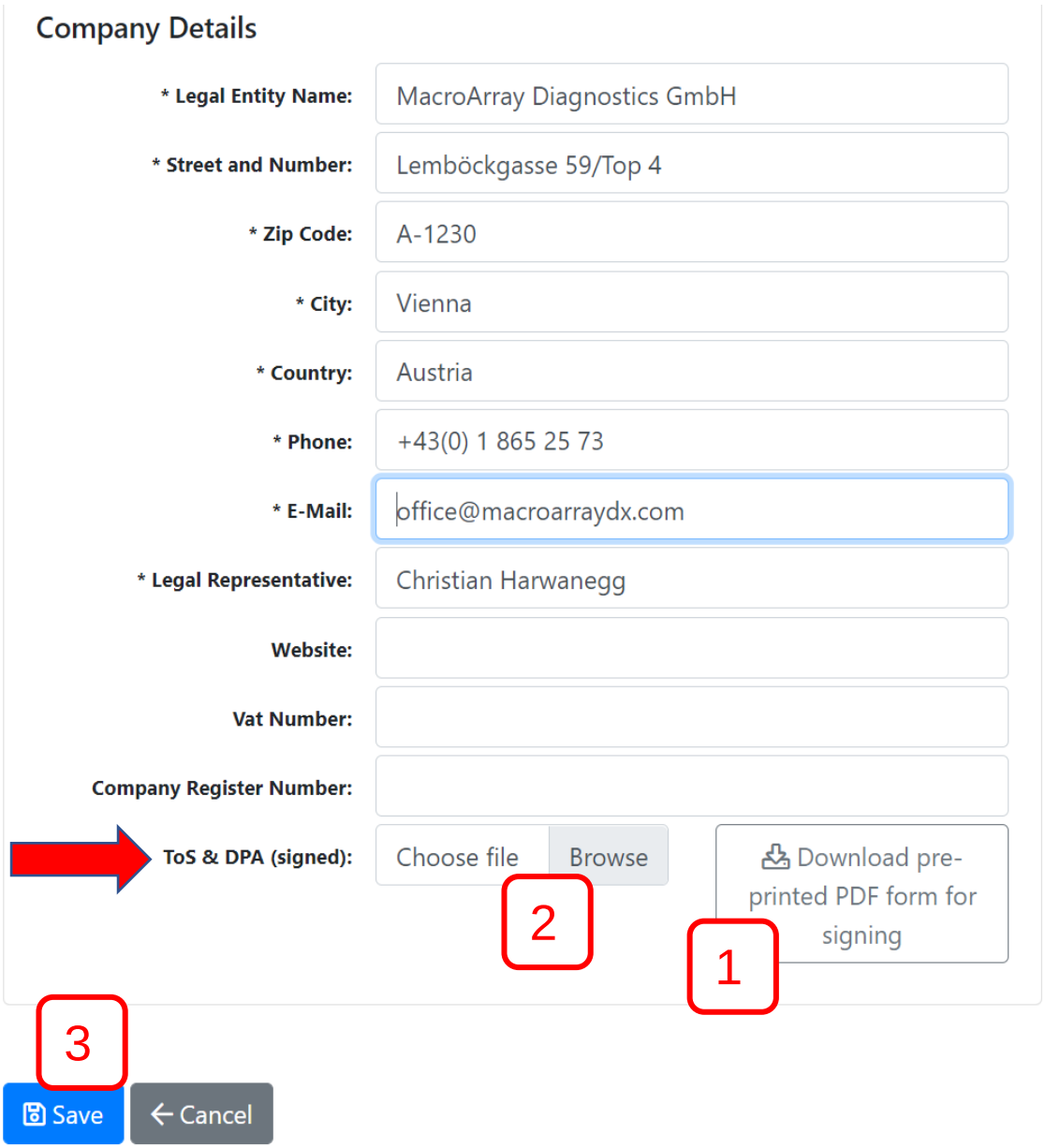
If you click on the menu icon in the upper right corner and select Tenant Admin, you will be directed to the Tenant Admin area, where you can set the preferences for your tenant.



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 ImageXplorer 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

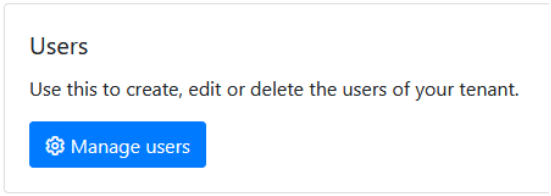


Other important pages of the Tenant Admin area are:

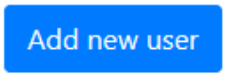
- ImageXplorers: Use this to configure existing ImageXplorers or add new ones. Every ImageXplorer needs to be registered as an entity to the Tenant on RAPTOR SERVER, otherwise a connection is not possible.
- Report Templates: Use this to create, edit or delete report templates for this tenant. Each template can have its specific look and configuration
- Measurement data completion: Manage pre-defined patient information that can be assigned to a measurement
- 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 Portalto 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".

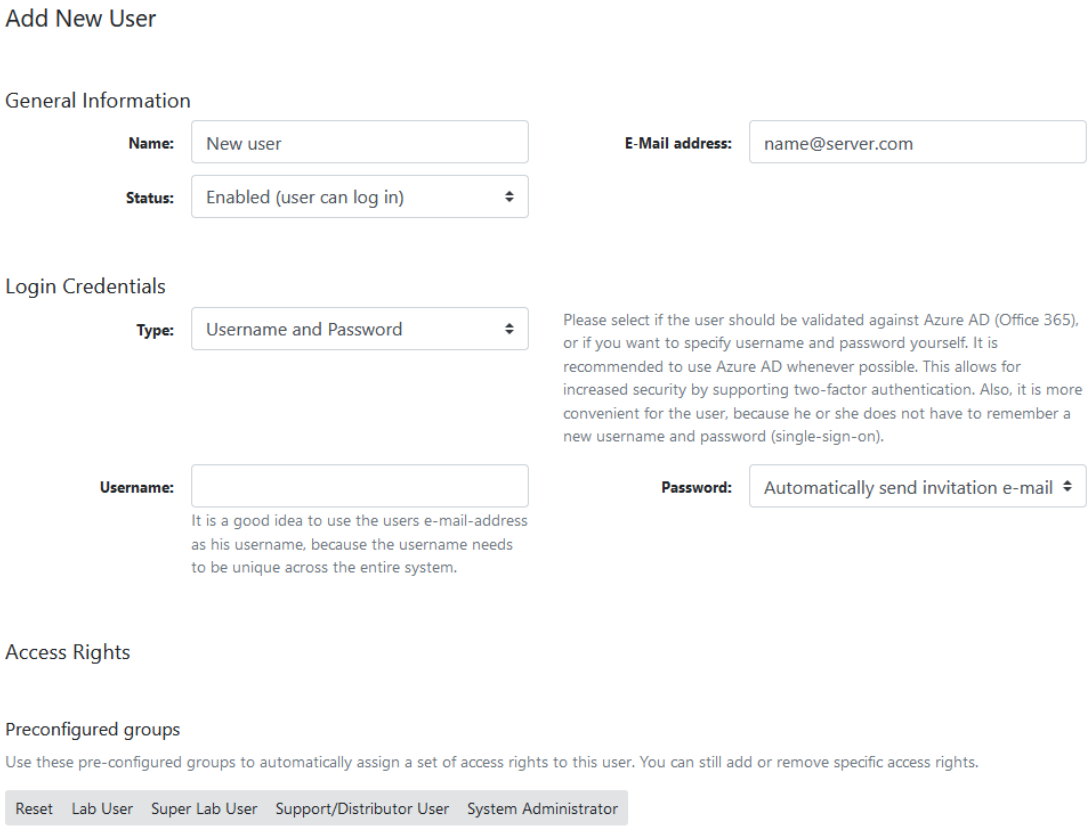


Subsequently, a list of all users of the current tenant is displayed. Via "Configure", the rights of an existing user can be adjusted. The "Add new user" button at the top of the page adds a new user to the tenant. Already existing users (from a different tenant) can be linked to the users via the option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

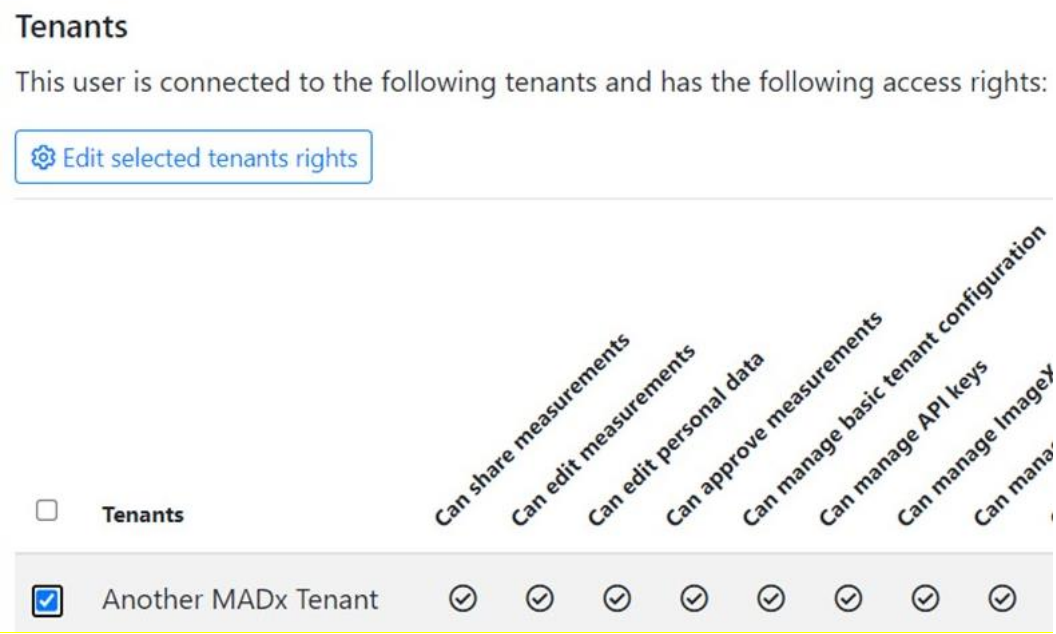
Via the predefined user groups (e.g.: laboratory staff, support, etc.), the user’s rights can be assigned to a specific group. In addition, the rights can also be adjusted individually for each user.



A user can also be added to multiple tenants at once using the feature at the bottom of the page.
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.

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.

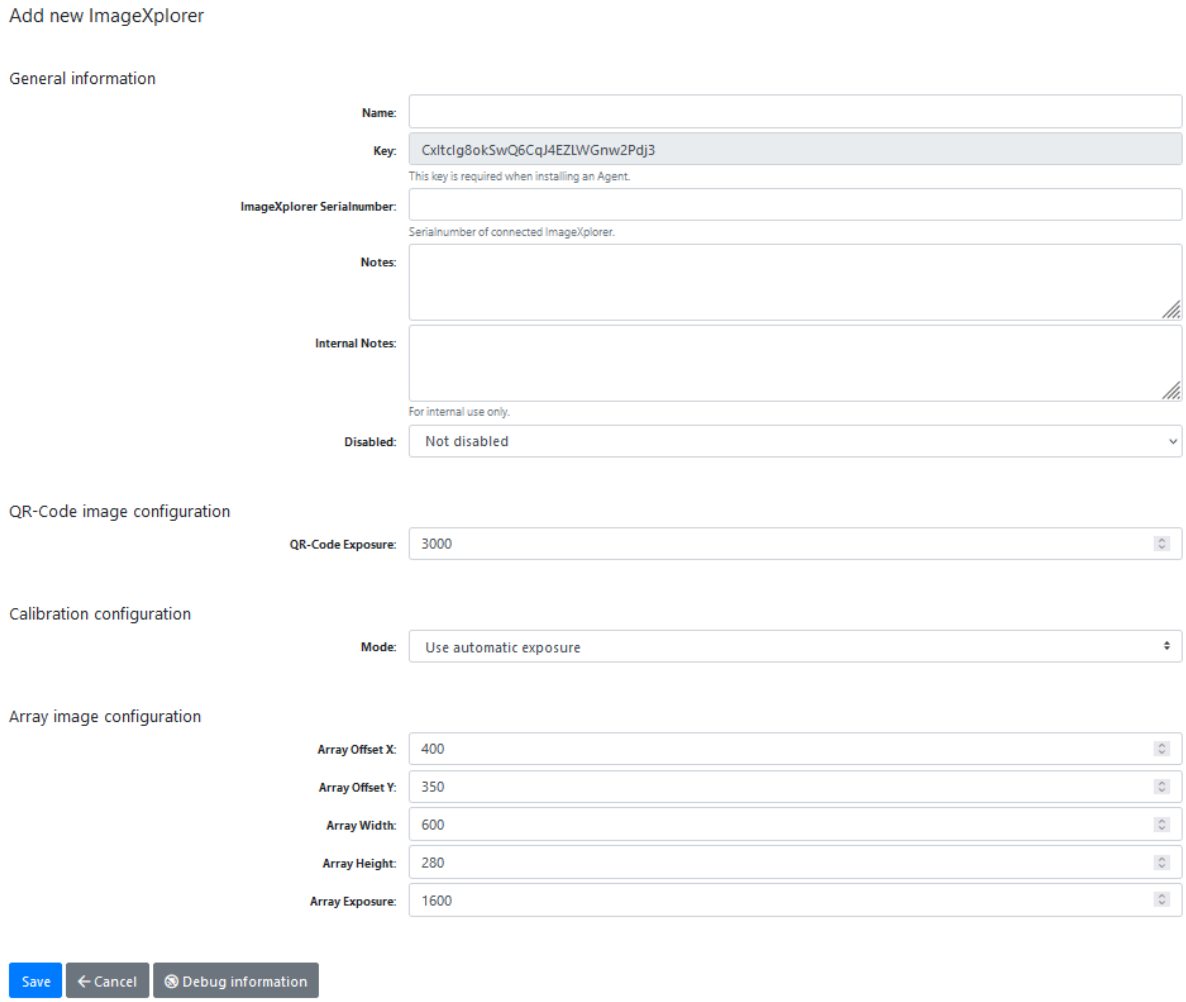
You can edit the user rights of the user in a bulk, corresponding to multiple tenants at once, using the tabular overview of tenants/user rights. Select the tick-boxes of the tenants for which you'd like to set this particular user rights. After selecting, a button will appear on the top to edit the 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!



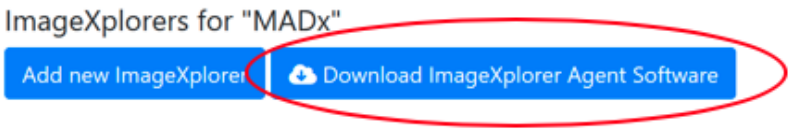
After clicking "Save" at the end of the page, the user receives a welcome email. Via this email, the user can now log in to the RAPTOR SERVER.

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.



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

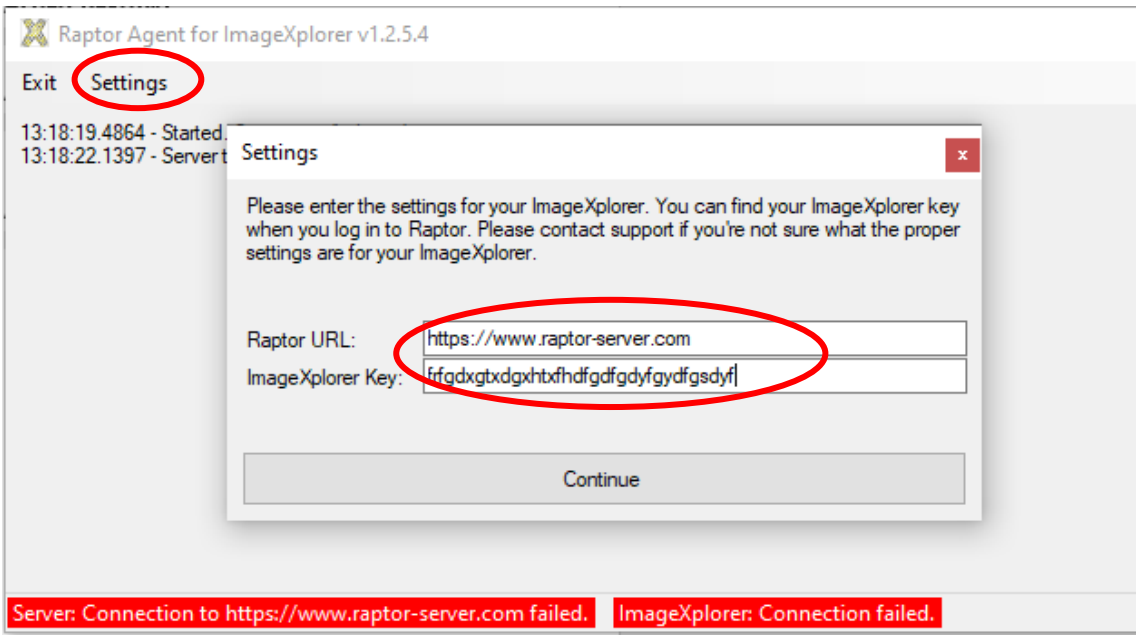


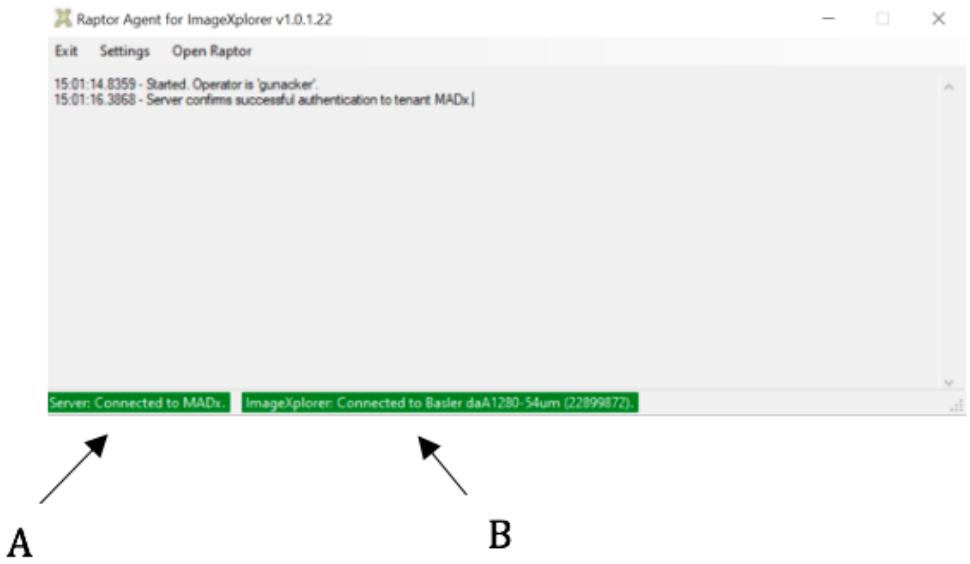
Carry out the installation of the ImageXplorer agent, as a regular installation process.

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

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

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





A: Connection to RAPTOR SERVER

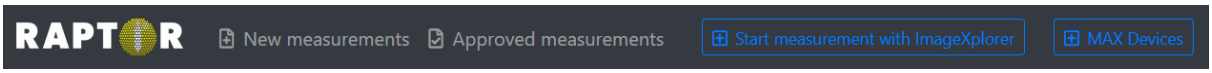
B: Connection to ImageXplorer

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

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

VII.1.6 IMAGE ACQUISITION, QR-CODE READING AND GRID FINDING

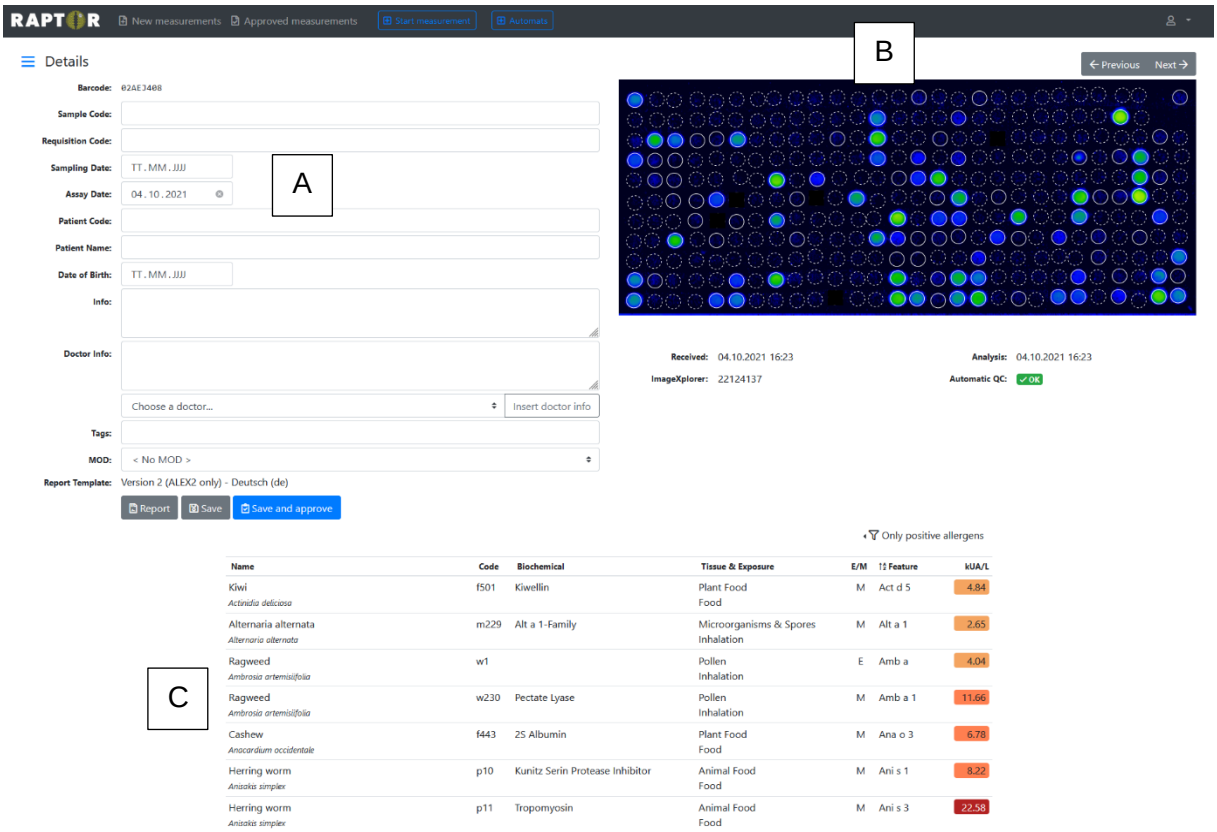
On the overview page you will find a tab "New measurements", a tab "Approved measurements", a button for "Start measurement with ImageXplorer" and a button for MAX devices. The tab "New measurements" contains all new and unapproved measurements, the tab "approved measurements" contains all hitherto approved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



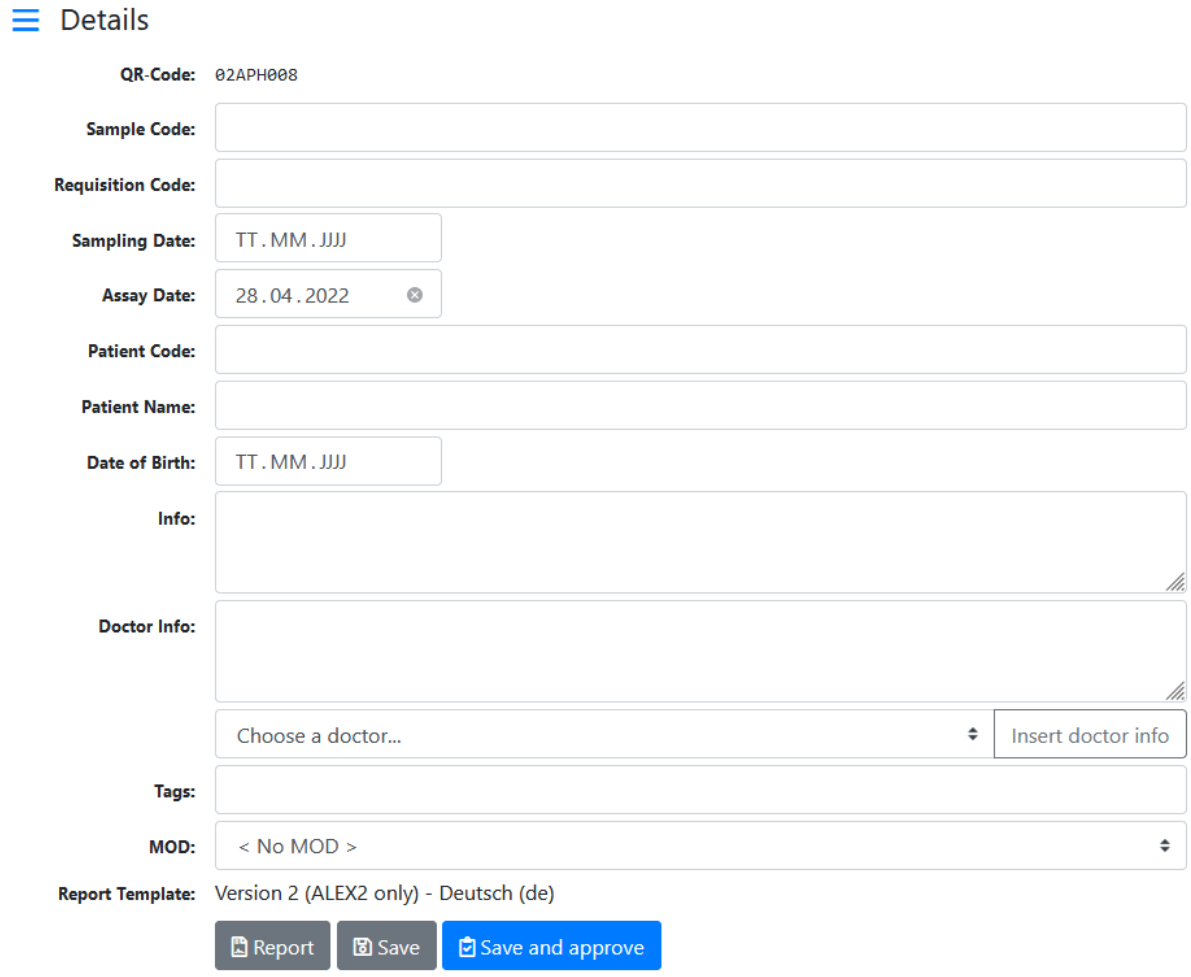
A: Patient and sample information fields
B: Analytic image
C: Result view

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
- 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**

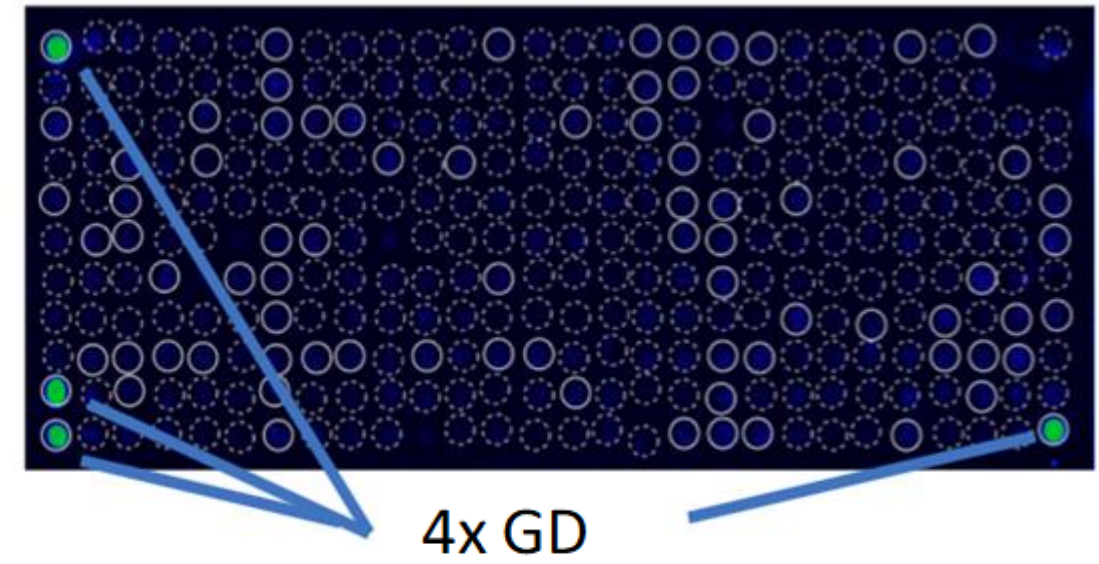


If you click on "Save" the entered information will be saved.

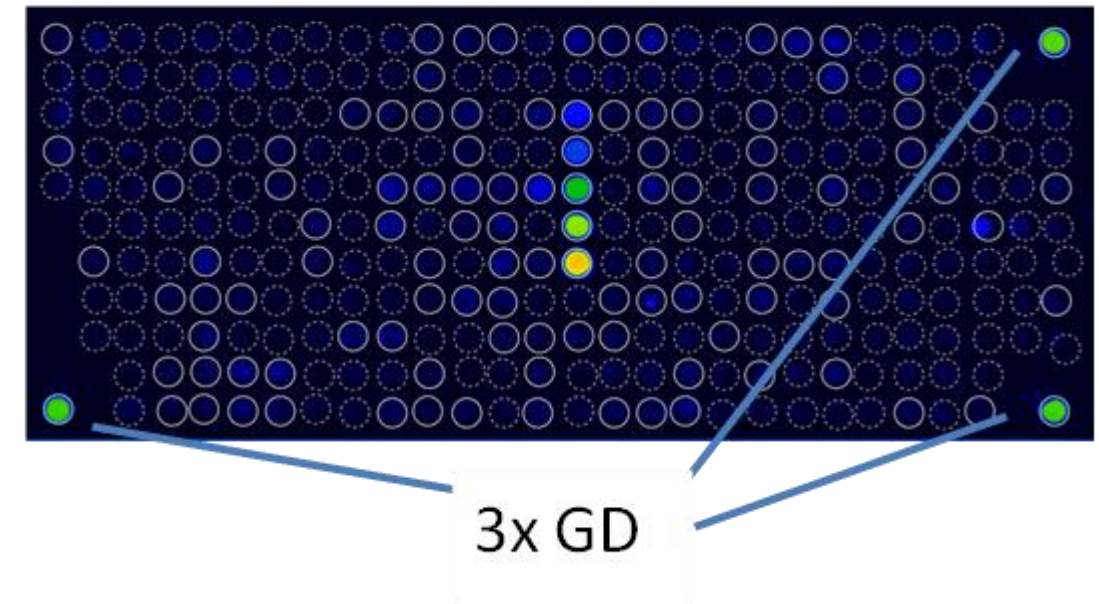
The array of the measurement with grid is displayed in the analytical image area. The software automatically identifies the position of the array in the image data based on the guide dots. There are 4 guide dots on ALEX², and 3 guide dots on FOX.

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

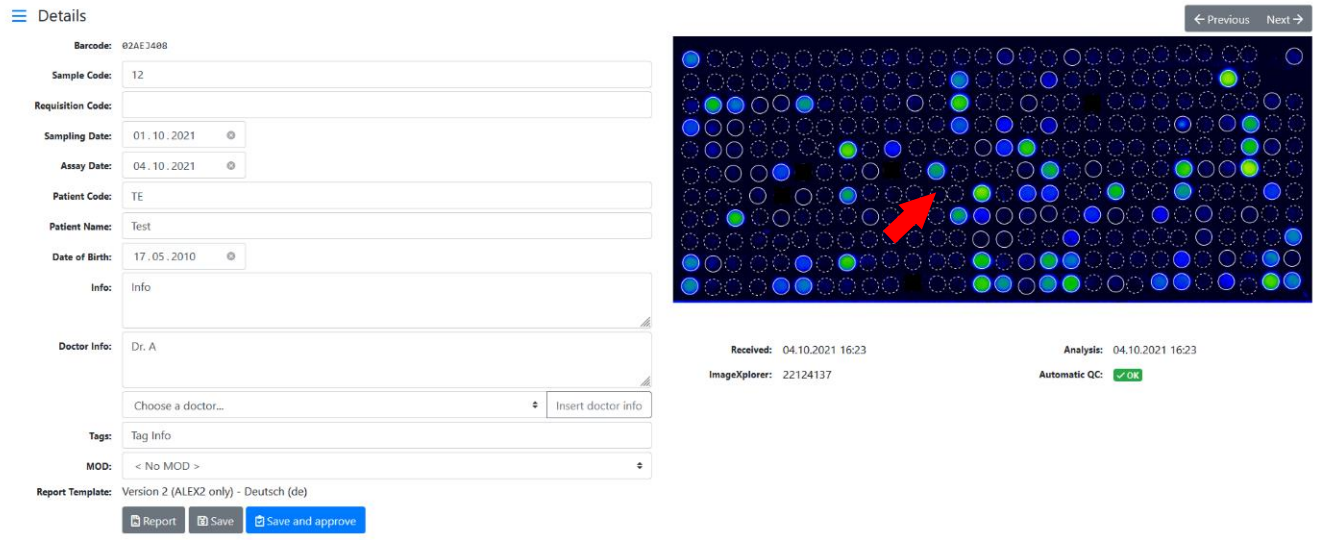


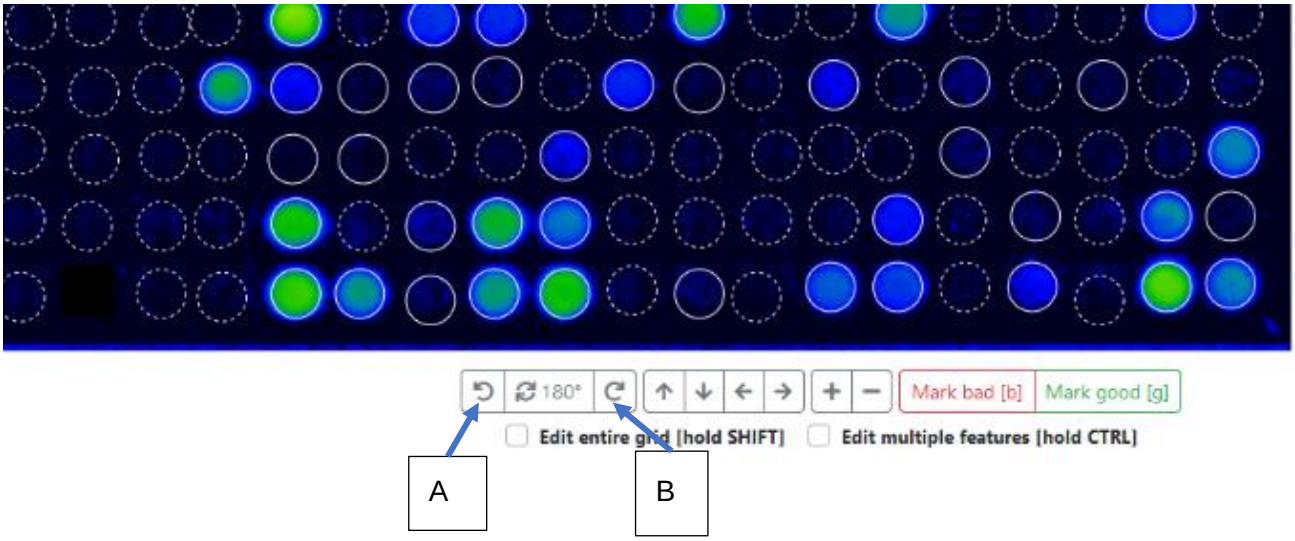
FOX



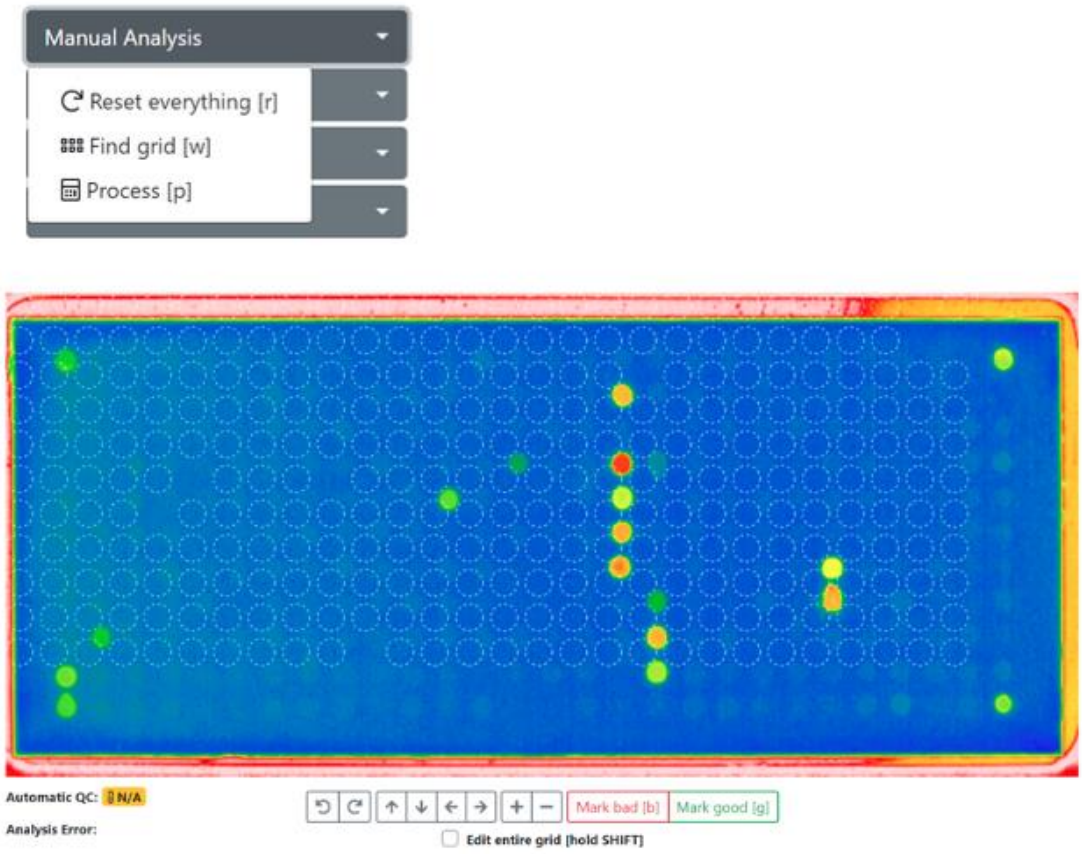
VII.1.7 IMAGE PROCESSING MODE

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





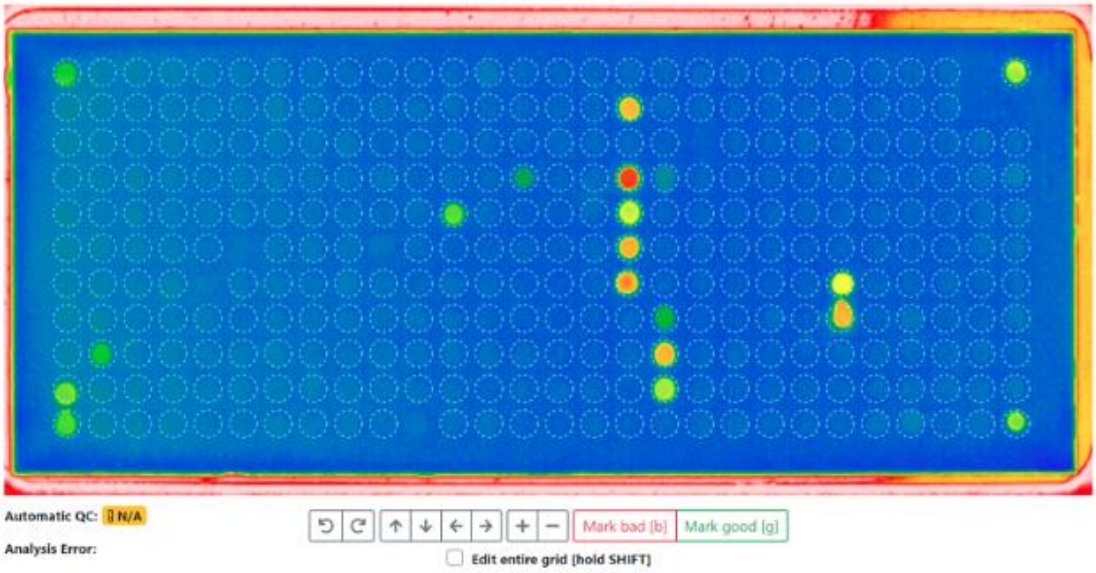
If the automatic position finding fails, the user will be alerted, and the measurement quality control (QC) will be set to FAIL. In this case, the user can try to manually position the array by resetting the grid by pressing “R” or go to “Manual Analysis --> Reset Grid”. After resetting, you can move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



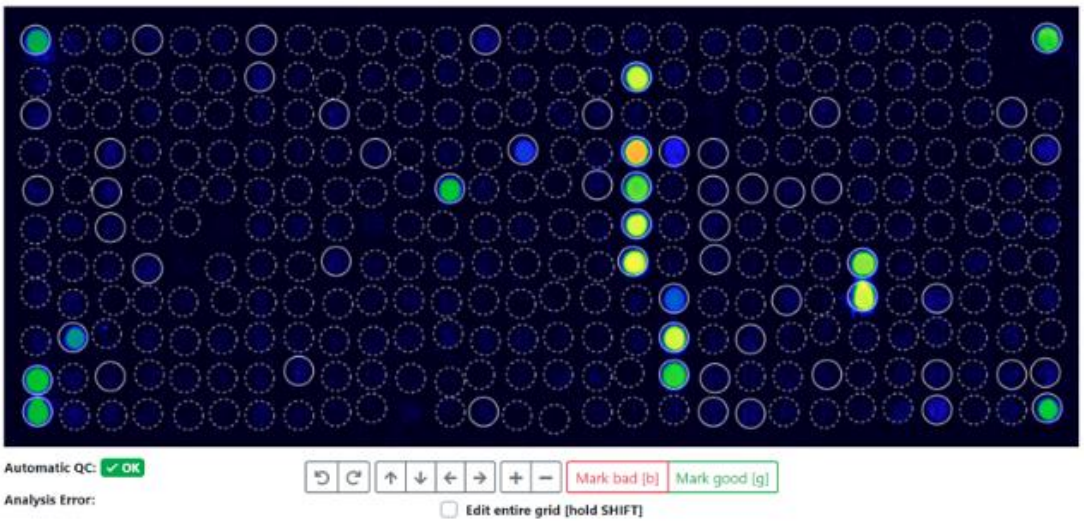
Press "R" or "Manual Analysis --> Reset Grid", then move the entire grid.

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

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

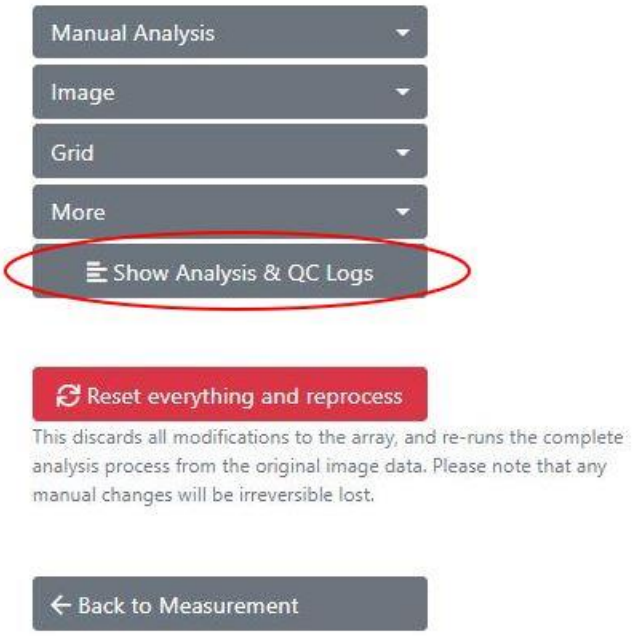


Finalize the grid-finding and analysis by pressing “P” or Manual Analysis -> Process.



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

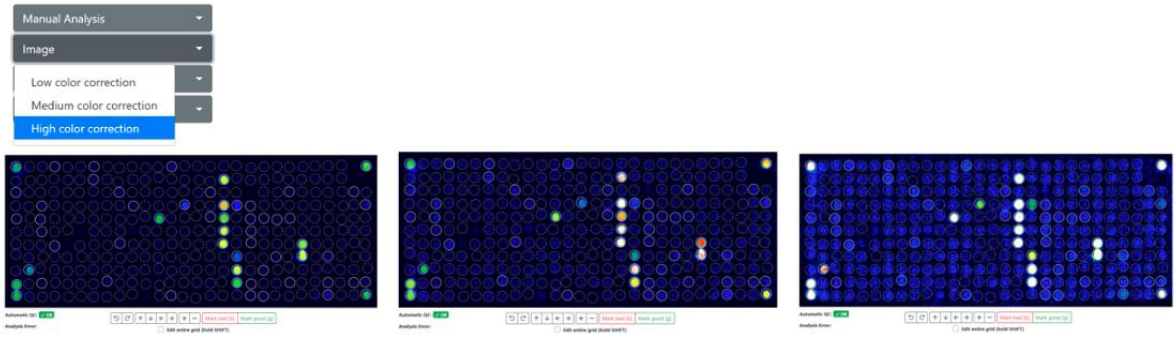
All processed measurements have information about the image analysis under "Show analysis & QC logs".



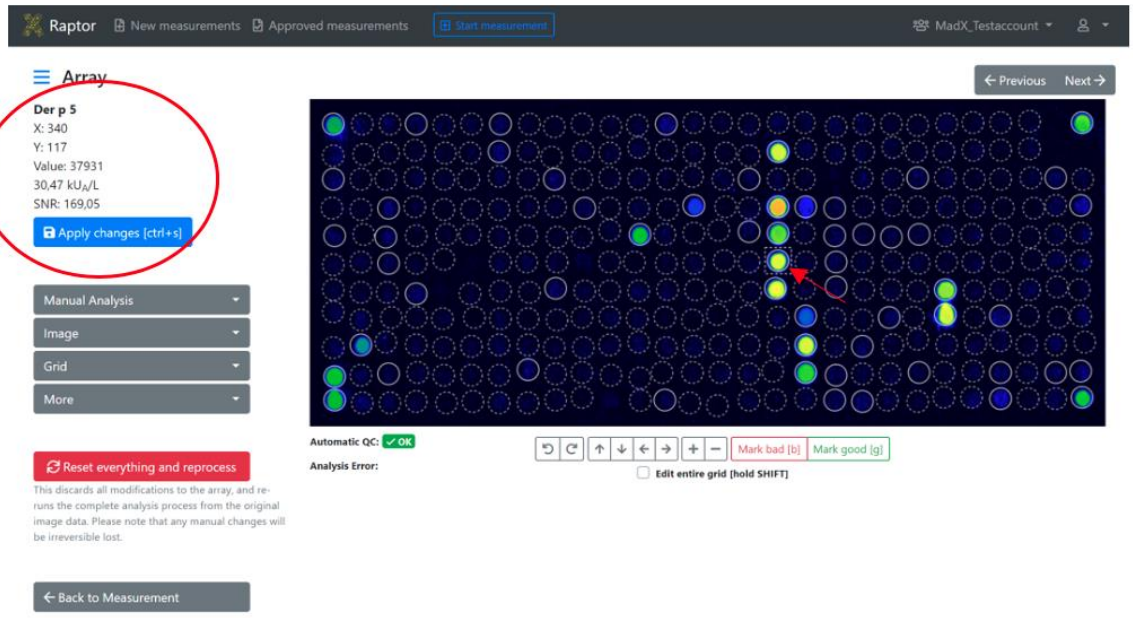
Click on this button to get information about the background, QC dot values and the applied reference values. This is especially useful if you need to find out why a measurement failed QC. For the QC to be OK, the background must be within a certain range and all guide dots must reach a certain threshold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

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).



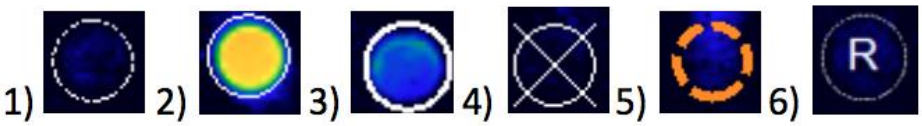
Pictures above from left to right: High color correction (default) - Medium color correction - Low color correction. By clicking inside one spot, name, x and y coordinates of the image, raw and result value of the spot and the signal-to-noise ratio (SNR) are displayed.



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

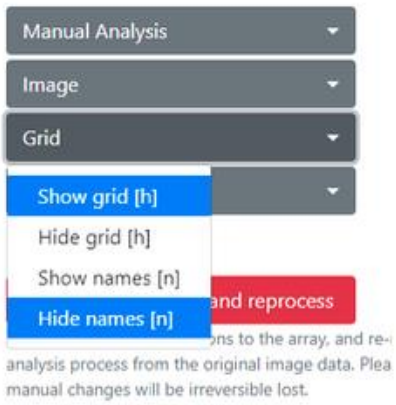
5. Circle with a thick dashed orange line: Spots to be inspected by the user with poor signal-to-noise ratio but a quantitative result above the system cut-off. Those spots should be set to “good” or “bad” by the user.
6. Research Use Only Spots (RUO) are marked with a “R” inside of the circle and will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

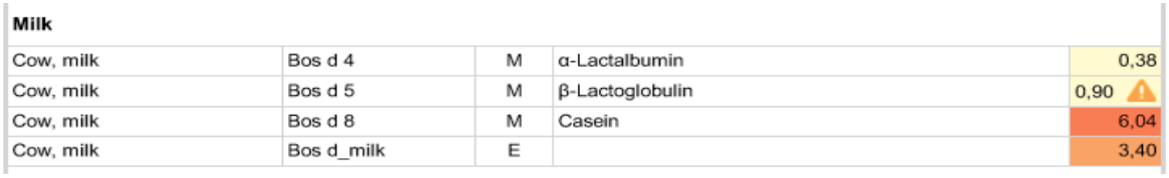
The last two features can also be used by selecting “Grid” --> “show or hide grid” and “show or hide names”.



VII.1.7.2 SHORTCUT SUMMARY

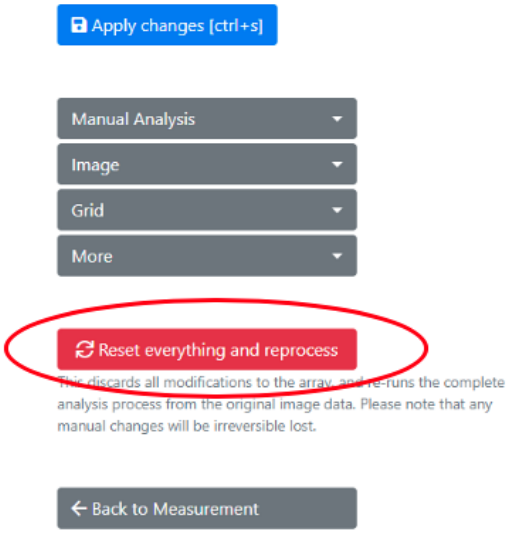
Short Cut	Execution
R	Reset analysis
W	Find grid
P	Process
G	Set feature to good
B	Set feature to bad
N	Annotate allergen features
H	Hide/unhide grid
SHIFT	Select all measurements

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.

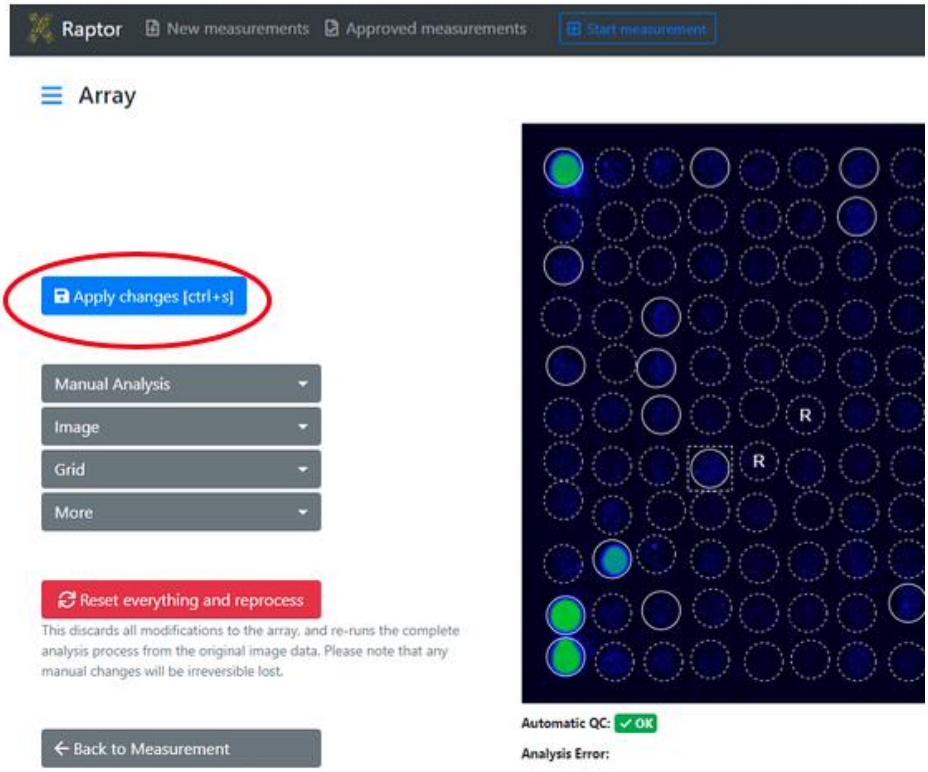


Milk				
Cow, milk	Bos d 4	M	α-Lactalbumin	0,38
Cow, milk	Bos d 5	M	β-Lactoglobulin	0,90
Cow, milk	Bos d 8	M	Casein	6,04
Cow, milk	Bos d_milk	E		3,40

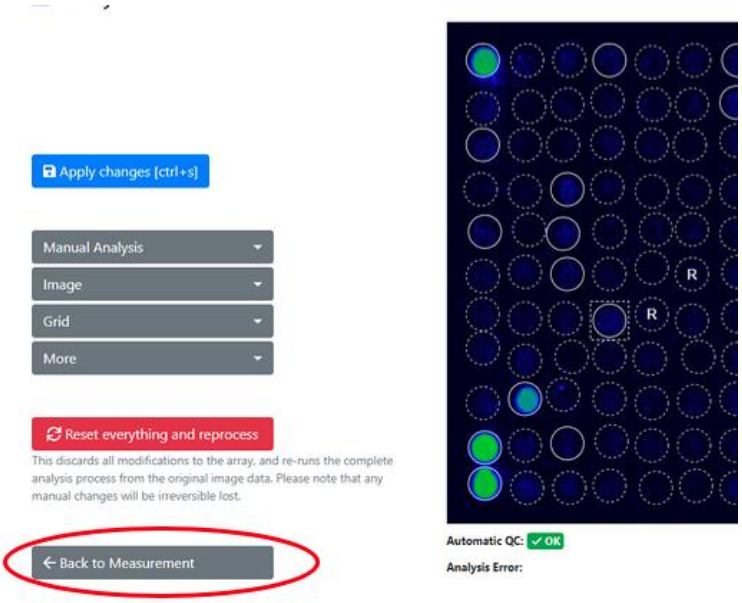
It is also possible to open an image of the QR-Code, an image of the unprocessed or the processed array. To do this, go to "More" and select the desired image. A complete reset is also possible by pressing the "Reset everything and reprocess" button.



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



To return to the detail page of the measurement from the image processing mode, press "Back to measurement". You can also click "Next/Previous" to go to the editing page of the following image.



VII.1.7.3 ANALYTICAL RESULTS

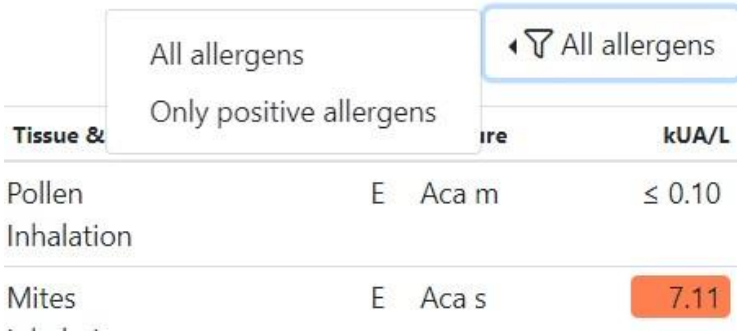
In the detailed results list, below the patient information and the analytic image, the results of the selected measurement will be displayed. The analytic result will display a list containing the following information:

- 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)

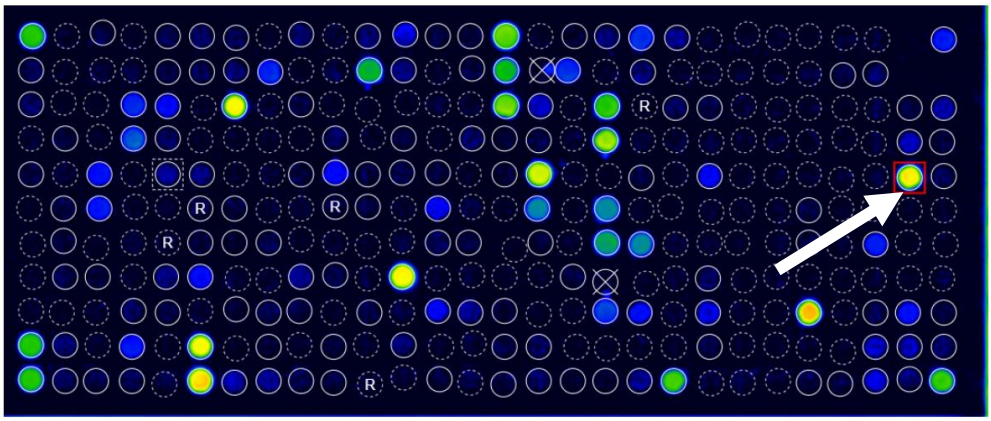
All allergens

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



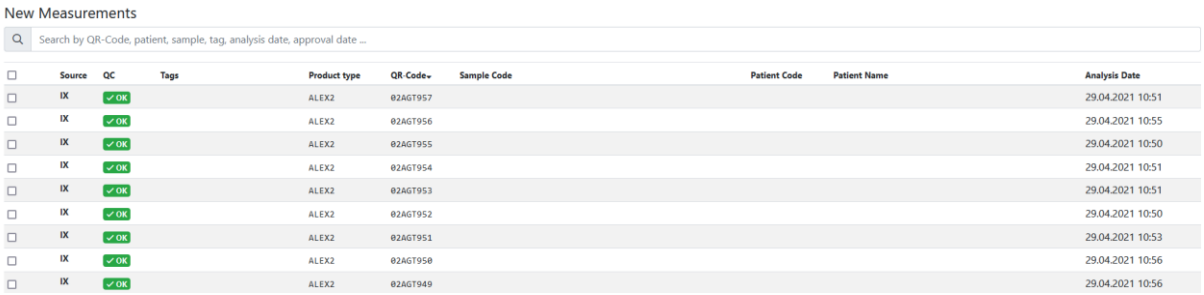
By clicking on the name of one or more allergens in the list of allergen results, the corresponding spots on the array image are highlighted by a red rectangular box.



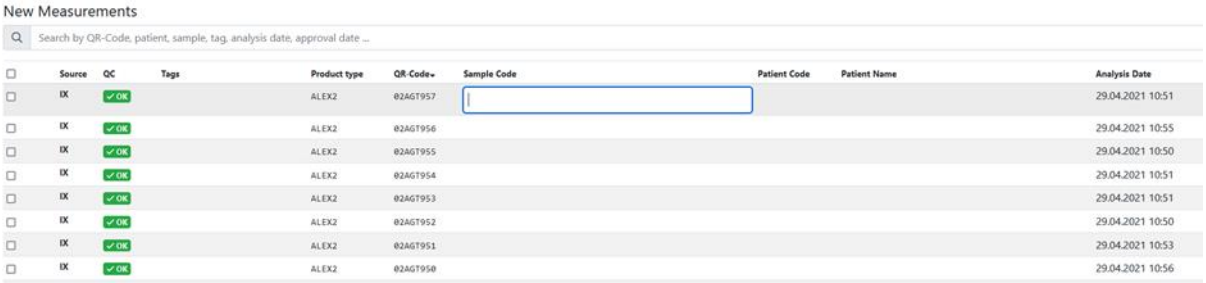
VII.1.8 OVERVIEW OF MEASUREMENTS

New and unapproved measurements can be displayed in the “New Measurements” overview, which also displays the following information for each measurement:

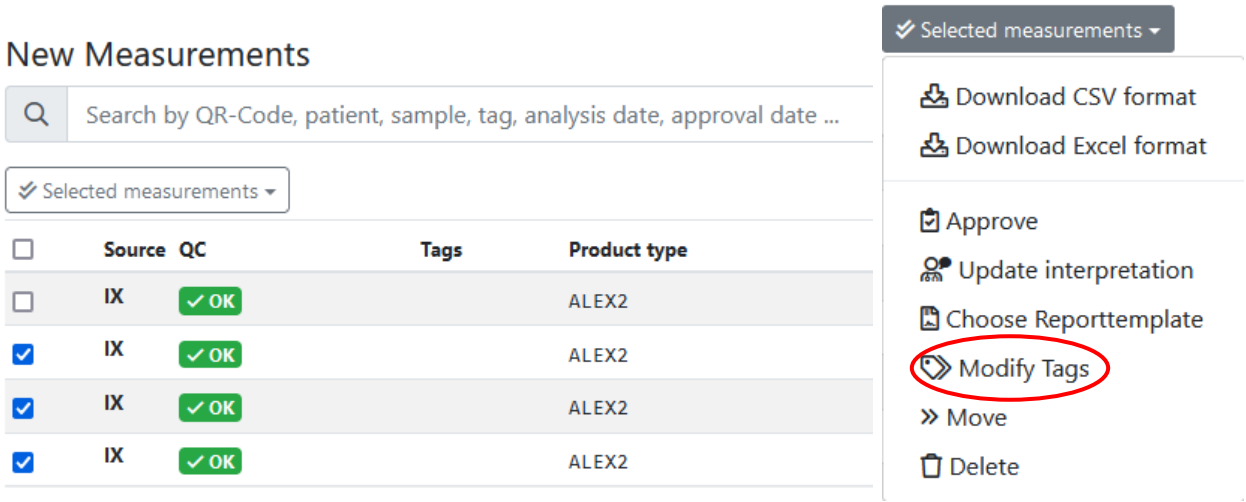
- Source of measurement
- QC status
- Tags
- Product Type
- QR-Code
- Sample Code
- Patient Code
- Patient Name
- Analysis Date



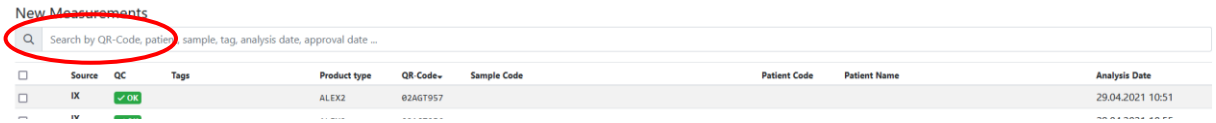
Clicking on the QR-Code or the analysis date takes you to the detail area of the measurement. Patient information, sample code and tags can also be entered in the overview page. To do this, simply click in the corresponding field of the measurement and insert it. Press the “Tab” button to automatically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



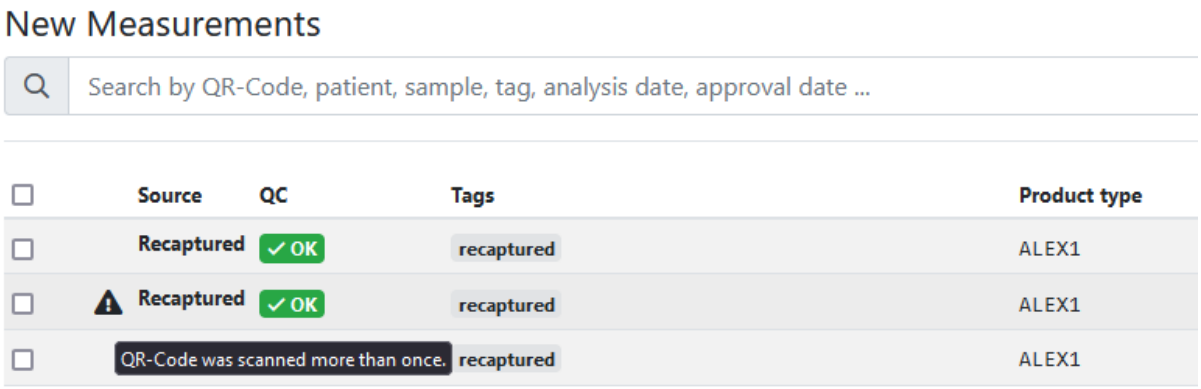
Tags can be added to or removed from multiple measurements at once using the drop down menu.



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.



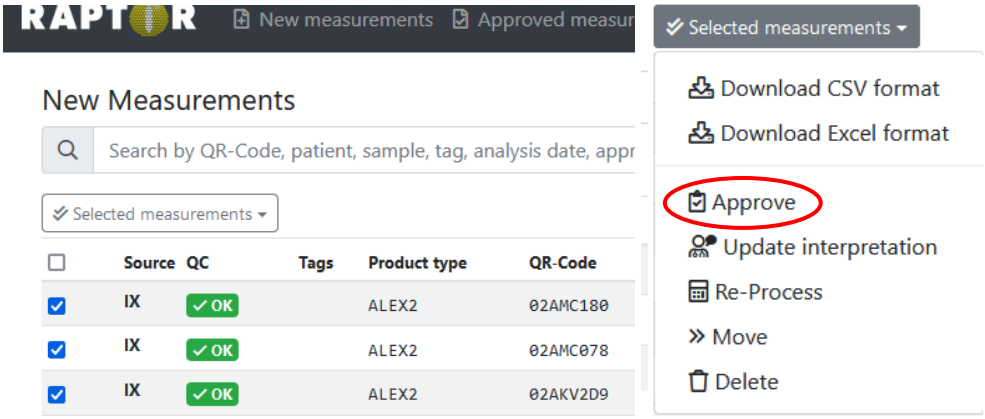
It is possible to duplicate the QR-Code and the measurement data in the data repository if cartridge is acquired several times. However, this is indicated by a triangle with an exclamation mark during measurement.



VII.1.9 APPROVING AND EXPORTING MEASUREMENTS

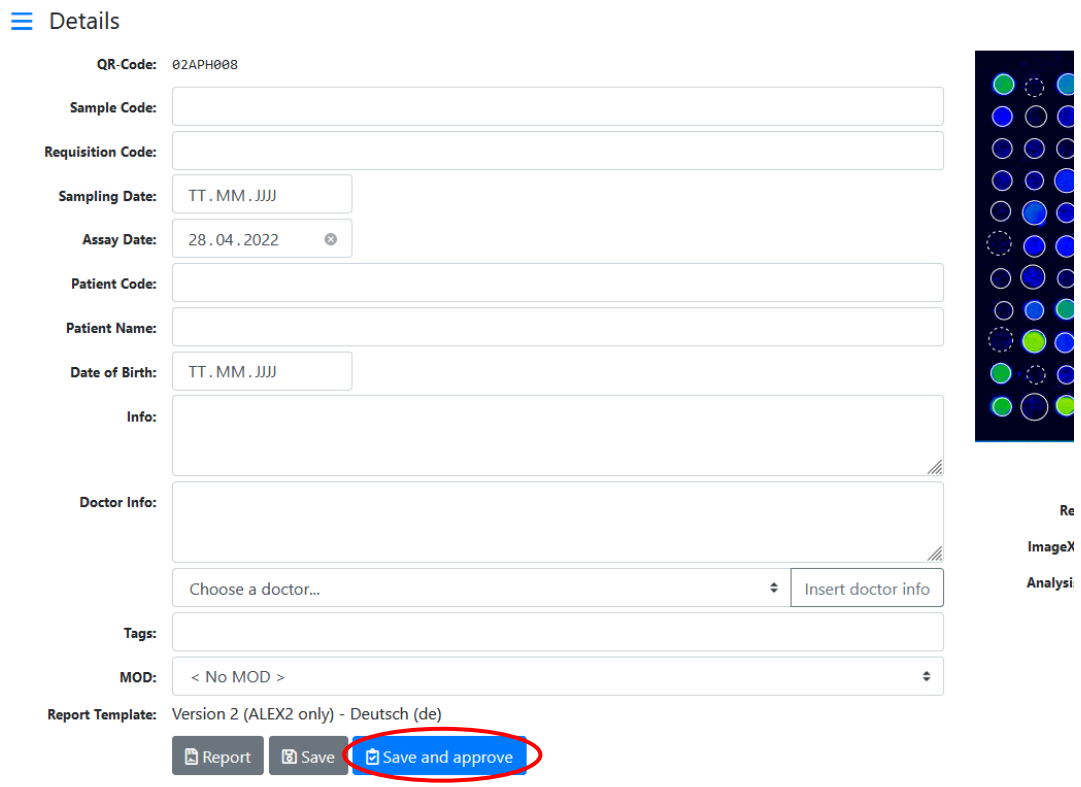
After analysis and careful revision of the results, the measurements can be approved by two ways:

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

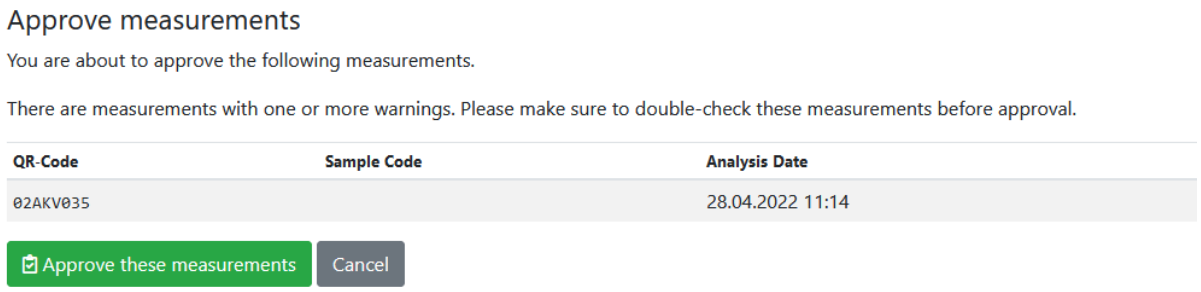


Unapproved measurements can also be downloaded as CSV or EXCEL.

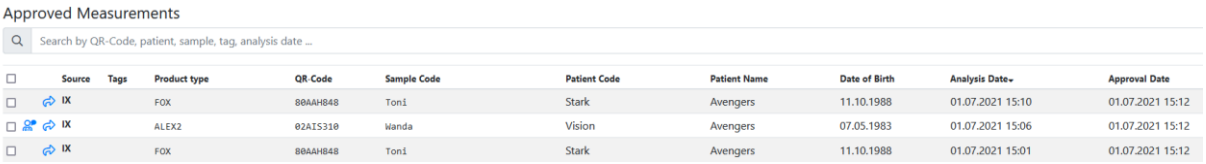
2. A measurement can also be approved on the detail page of a measurement. Simply click on "Save and approve".



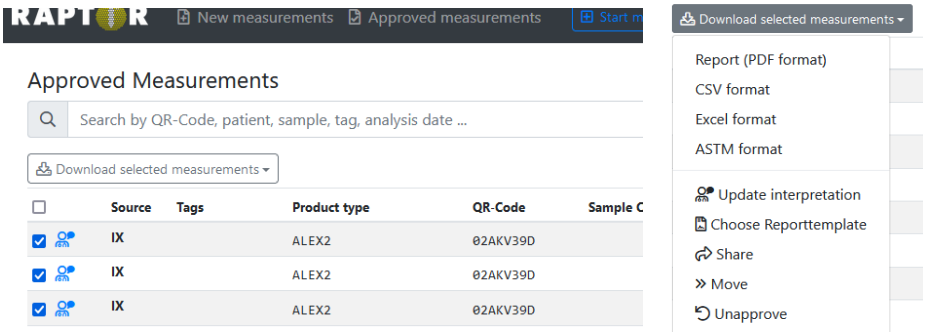
If the QC of a measurement is "OK", the measurement simply moves to the "Approved Measurements" tab upon approval. If the QC of a measurement is "Failed", the user will get a notification that the “Measurement QC is not OK”. In addition, it will also be stated on the report that the internal QC (plausibility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



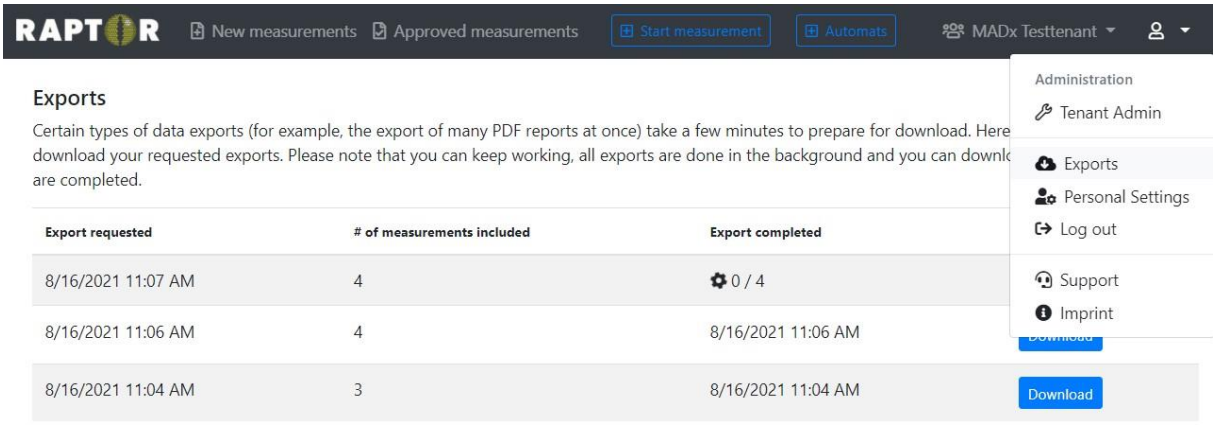
Approved measurements are stored in the section “Approved measurements”. No patient information can be changed or added here. The details/result of a measurement can be displayed by clicking on a measurement. The features of the image can also be displayed but cannot be adjusted anymore.



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.



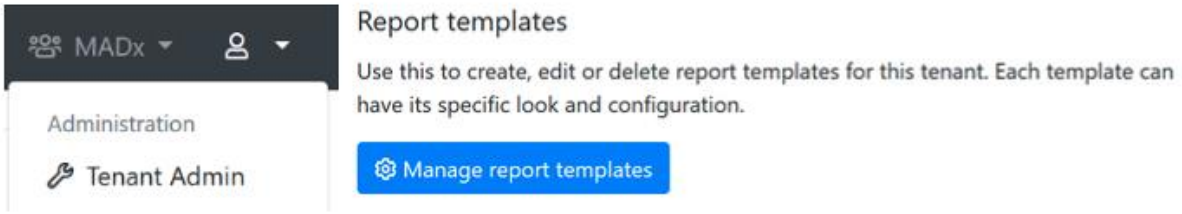
If a larger amount of data is requested for export, for example multiple .pdf reports, an export download link will be generated in a separate window. The export process then runs in the background and can be viewed by clicking on the menu in the upper right corner. A finished export can be downloaded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



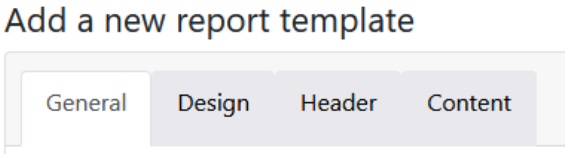
VII.2 REPORT

VII.2.1 CREATING A CUSTOM REPORT TEMPLATE

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



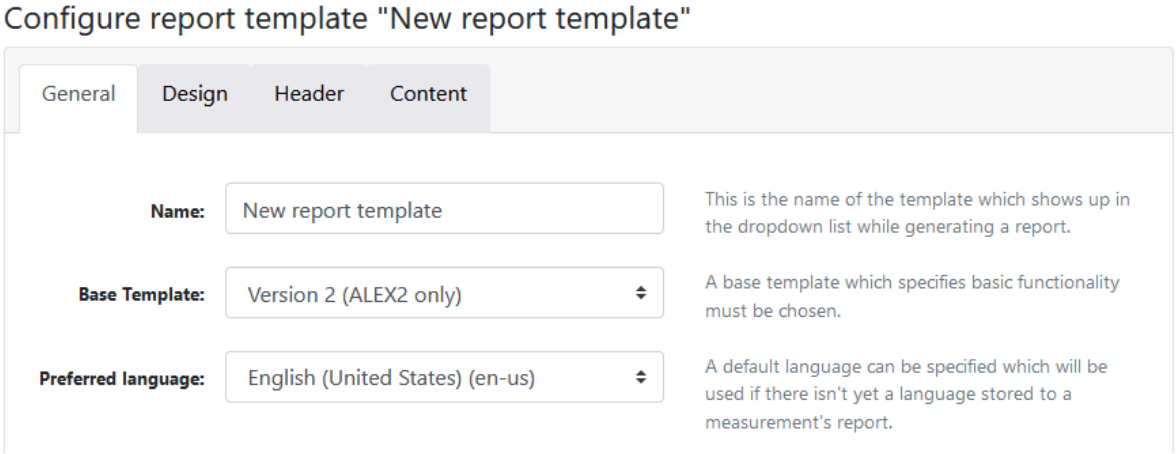
The Report Template Configurator consists of four tabs, which can be used to customize a report template: General, Design, Header and Content.



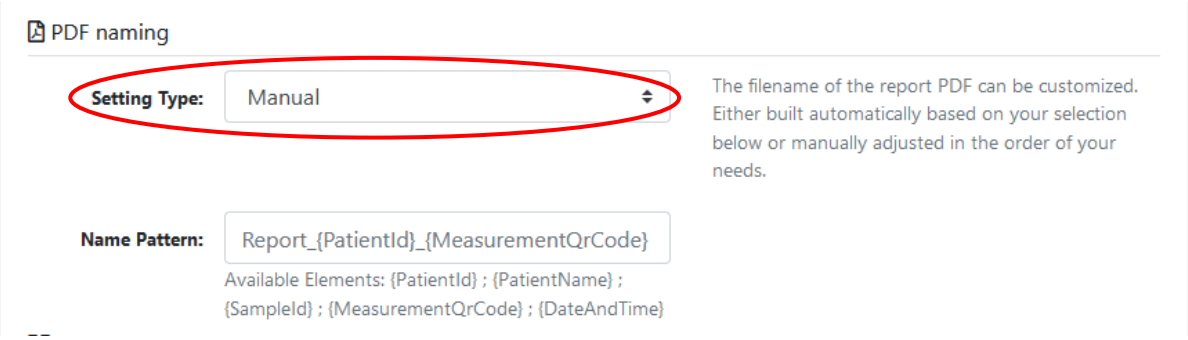
VII.2.1.1 GENERAL SETTINGS FOR CUSTOM REPORT TEMPLATE

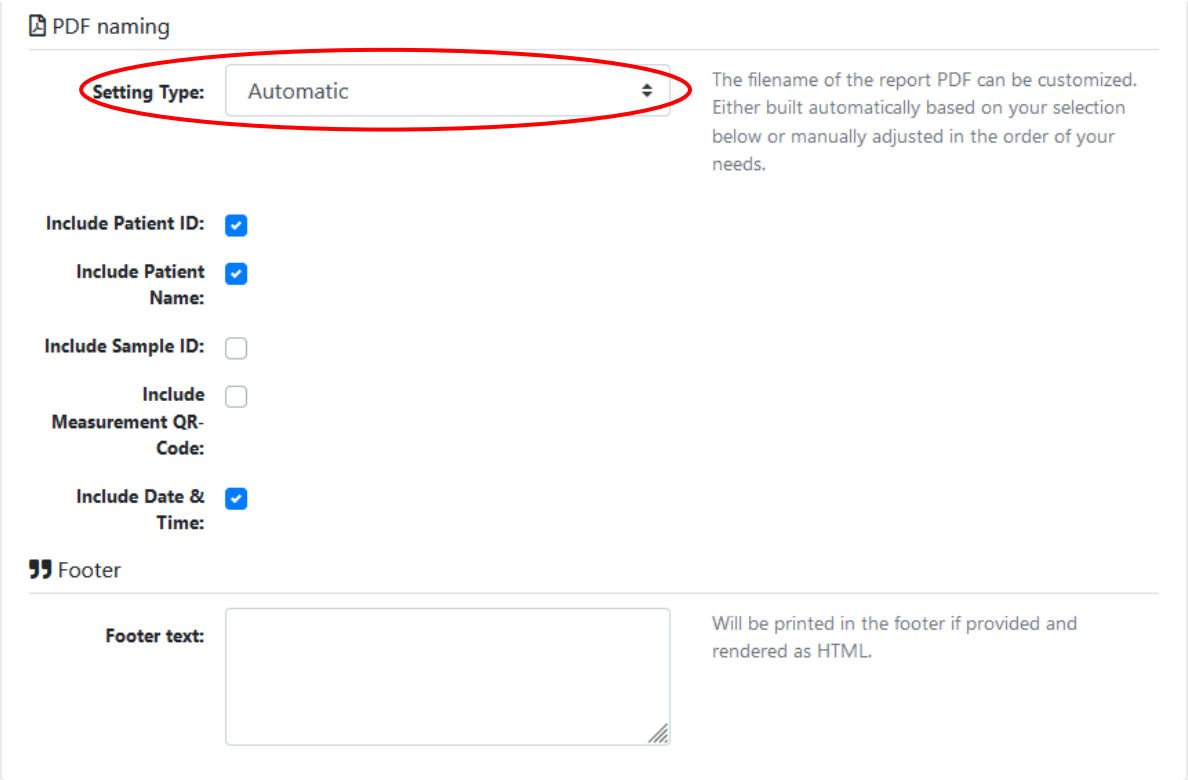
In the tab “General” the following settings can be selected:

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



- 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

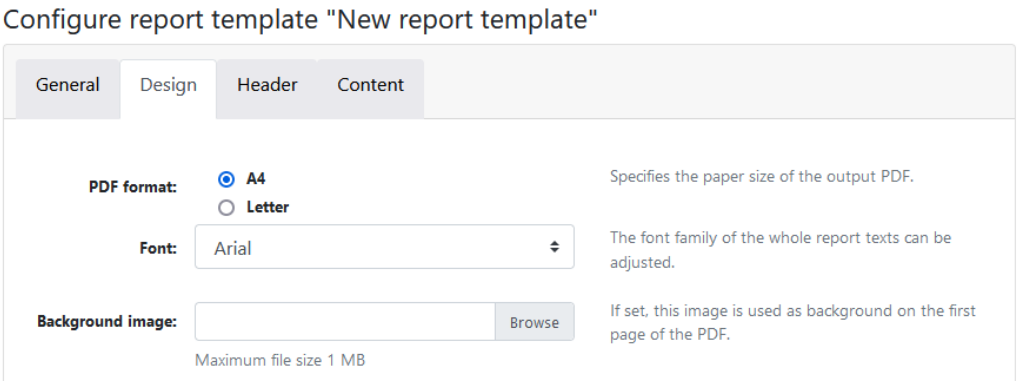




VII.2.1.2 DESIGN SETTINGS FOR CUSTOM REPORT TEMPLATE

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.



- 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): Browse

Maximum file size 1 MB

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

Text (center):

This text will appear in the **top middle** of the first page of the report.

Logo (right): Browse

Maximum file size 1 MB

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

Small logo: Browse

Maximum file size 1 MB

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

Signatures

Left: Browse

Maximum file size 1 MB

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

Center: Browse

Maximum file size 1 MB

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

Right: Browse

Maximum file size 1 MB

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

Indicators

Custom intensity indicator:

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

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

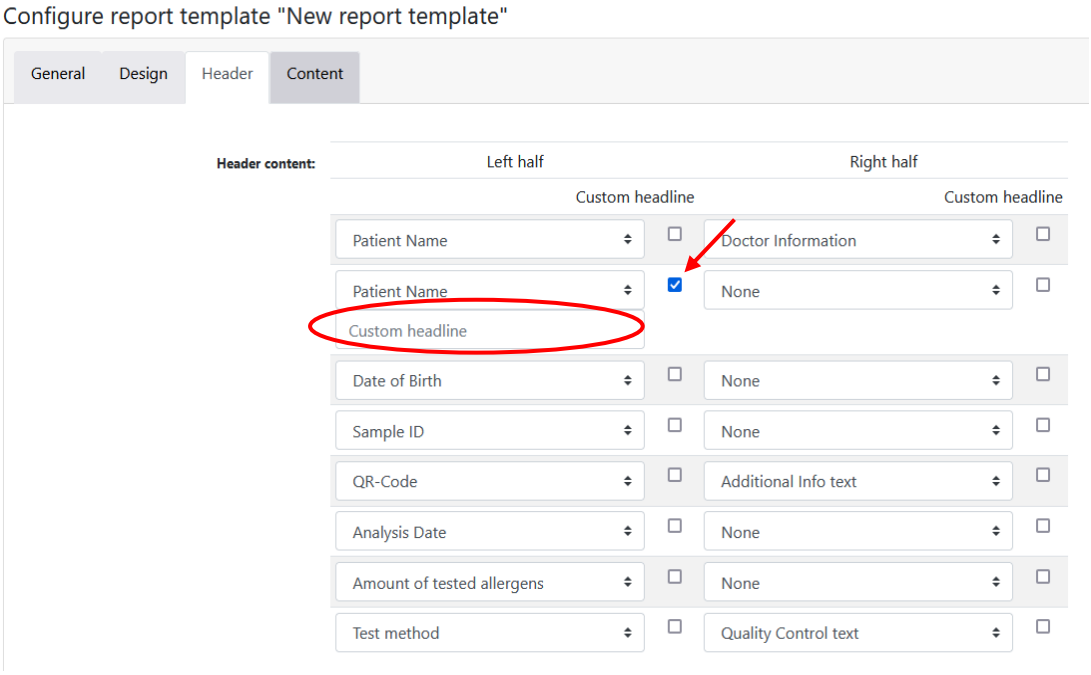
SVGs paths which should be colored must require the **colorize** class as well as a fill defined in the `defs` segment of the SVG.

VII.2.1.3 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

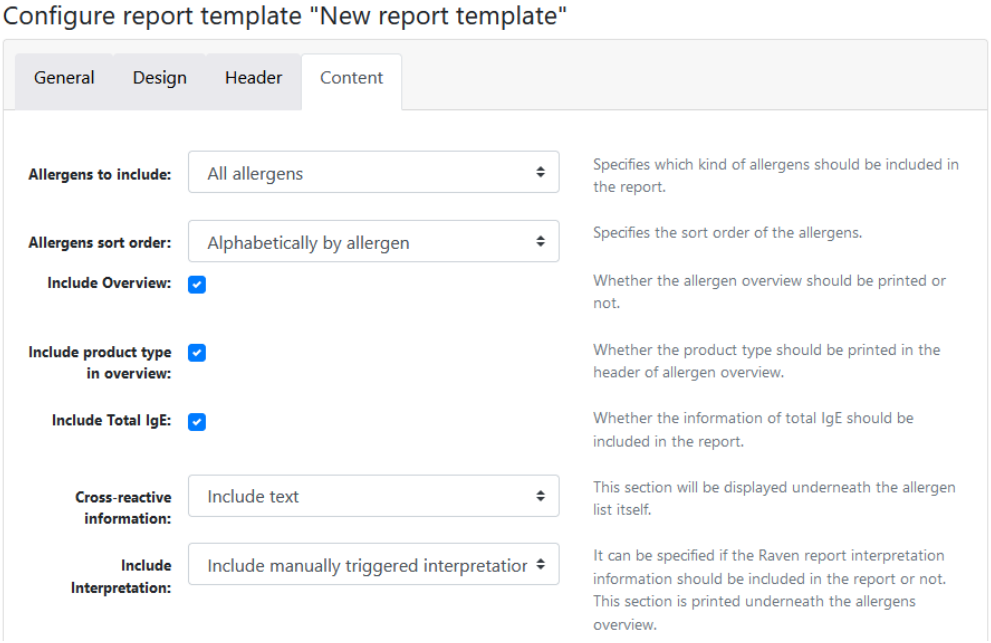
If the dropdown is left at “None”, no text will be displayed at that position. Furthermore, a custom headline can be added if desired by ticking the checkbox next to the textbox that should be customized.

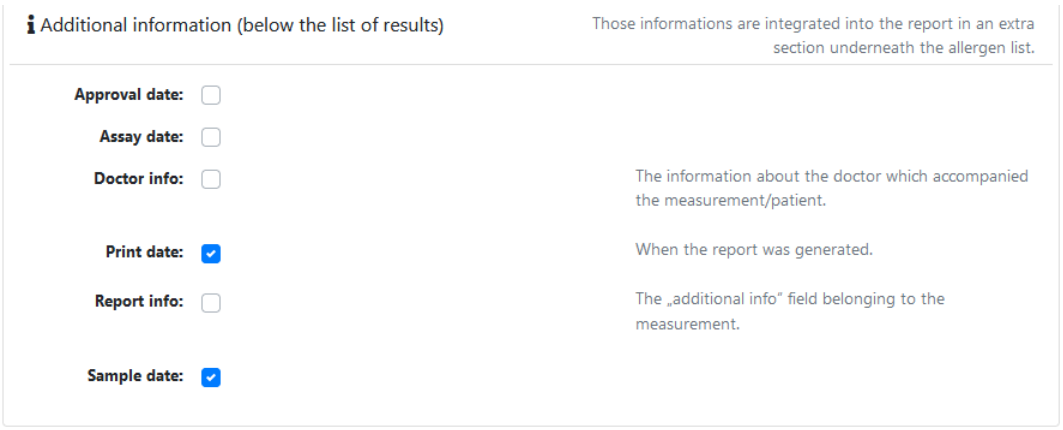


VII.2.1.4 CONTENT SETTINGS FOR CUSTOM REPORT TEMPLATES

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
- 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





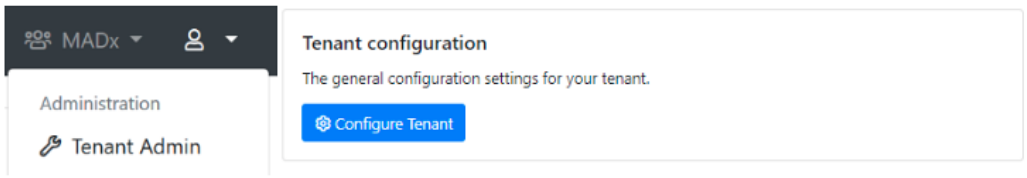
After the change, the report template can be saved by clicking the “Save” Button.

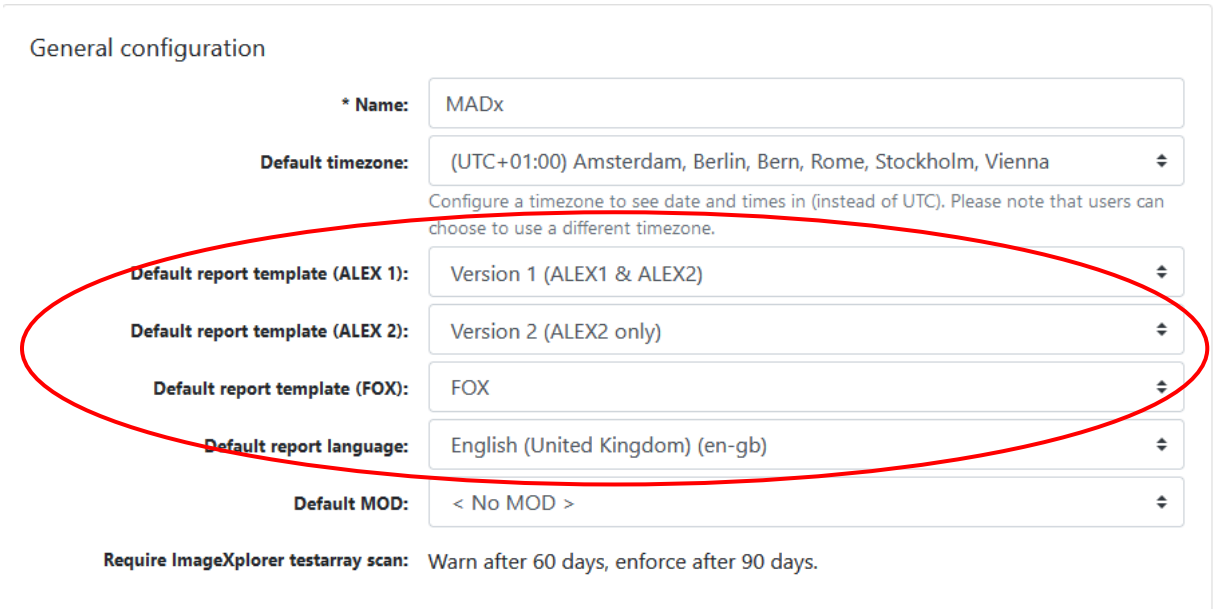
The following languages are available:

- 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

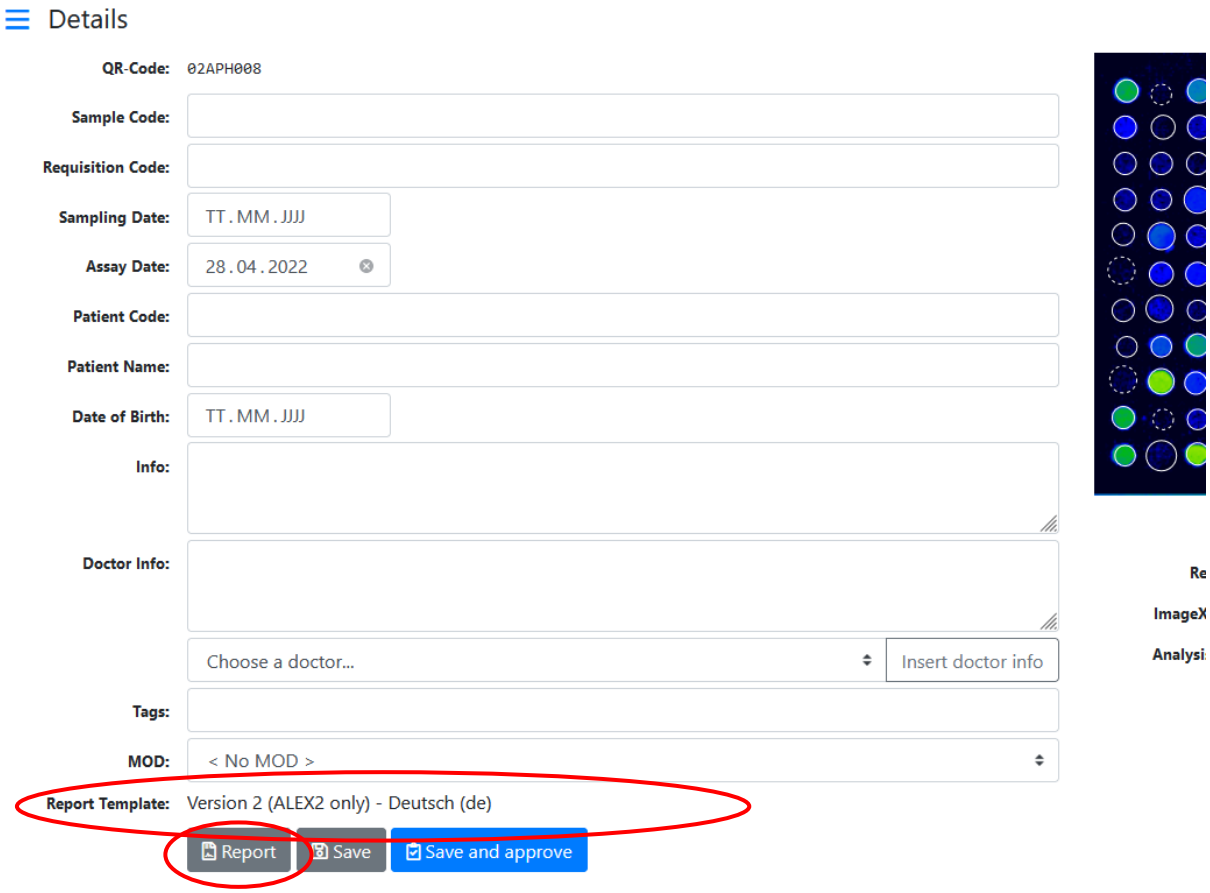
- Portuguese
- Portuguese (Brasil)
- Romanian
- Russian
- Slovak
- Slovenian
- Spanish
- Spanish (Mexico)
- Swedish
- Thai
- Turkish
- Ukrainian

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 ALEX^2 and FOX.

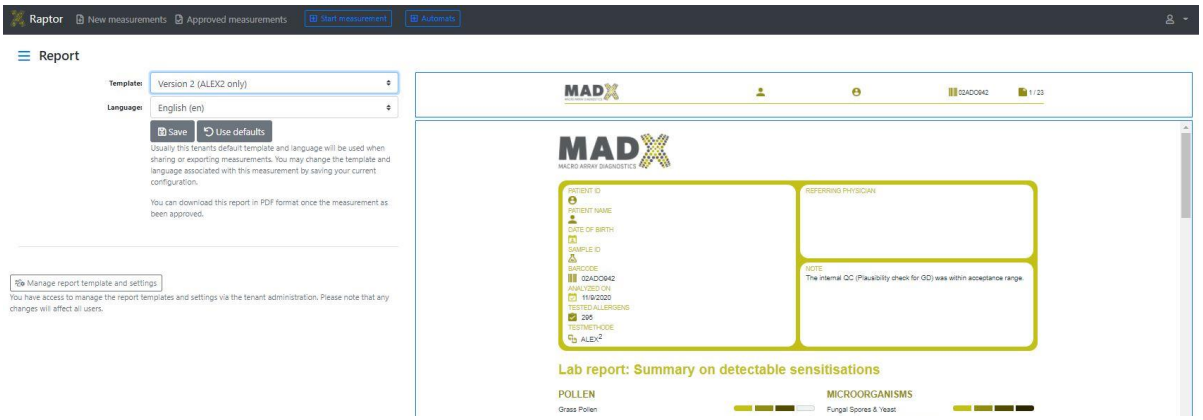




A report of an unapproved measurement can be viewed by clicking on the measurement QR-Code under in the “New measurements” tab; Select the desired report template and click “Report”.

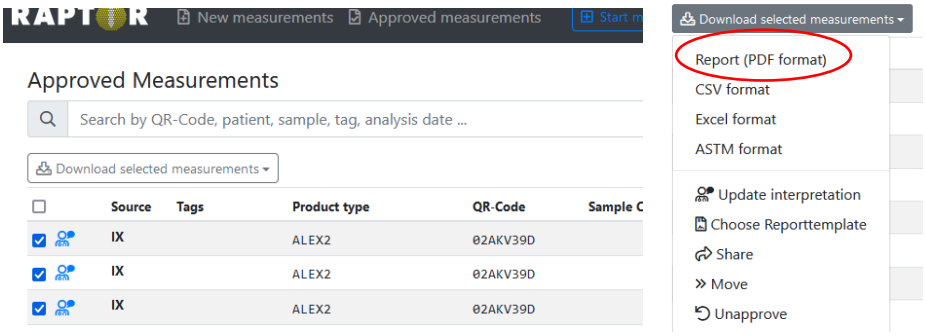


Then you see a preview of the report, where you can select a report template (default or customized) and set the default language. However, it is not possible to download this PDF report. For this purpose, it is necessary to approve the measurement first.

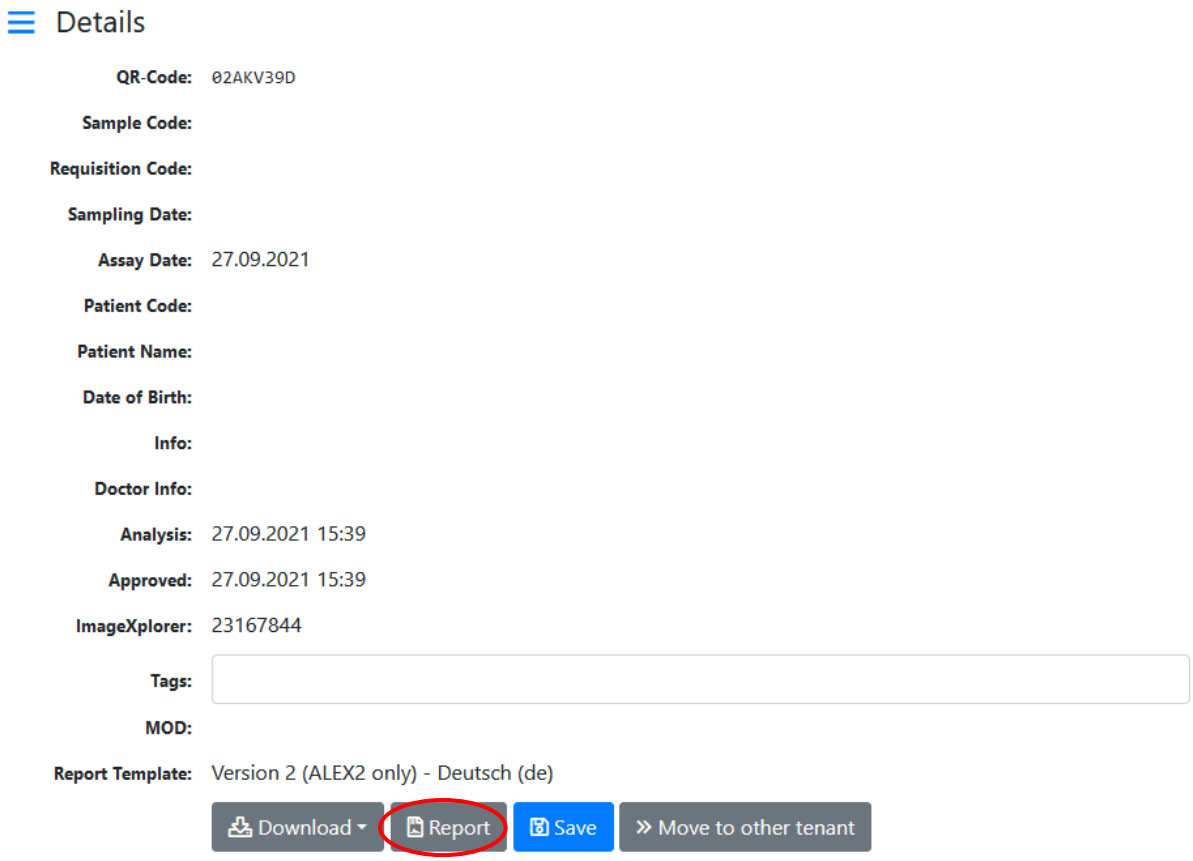


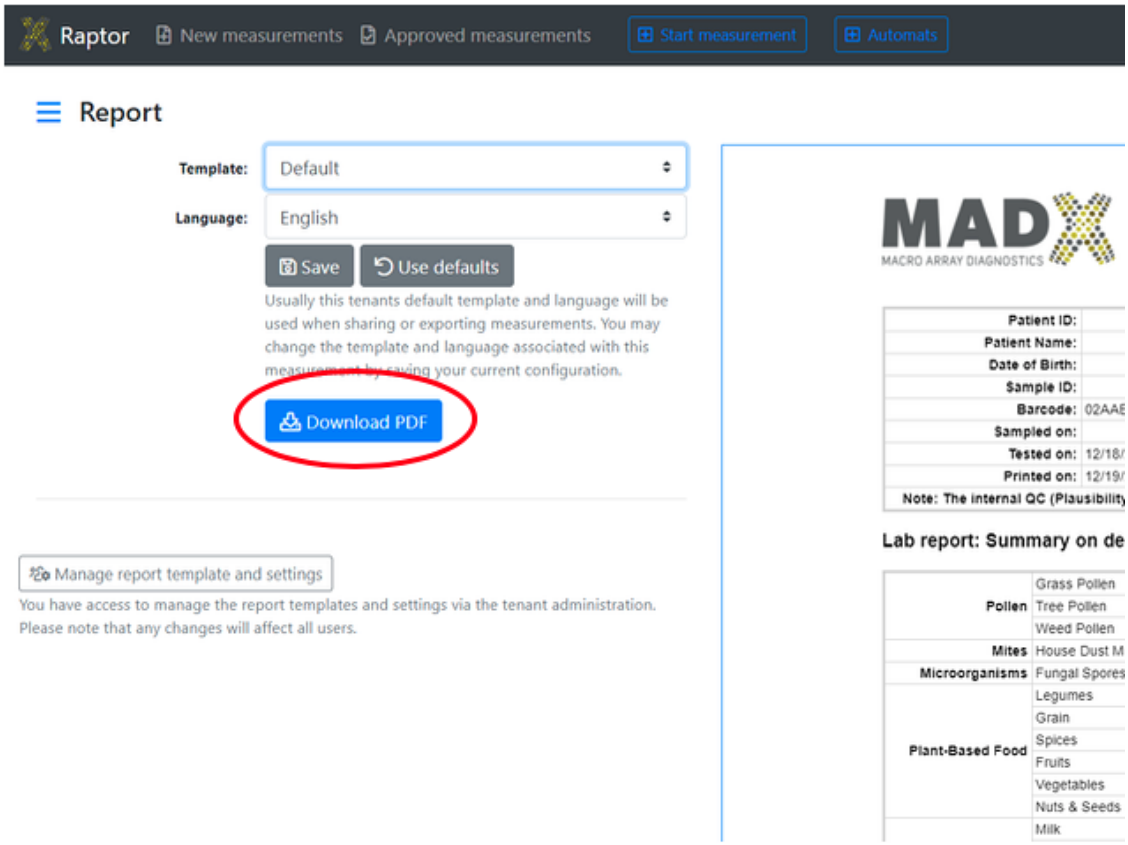
Approved measurements can either be downloaded together or individually. To download measurements together, first go to the "Approved measurements" tab and select the

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.



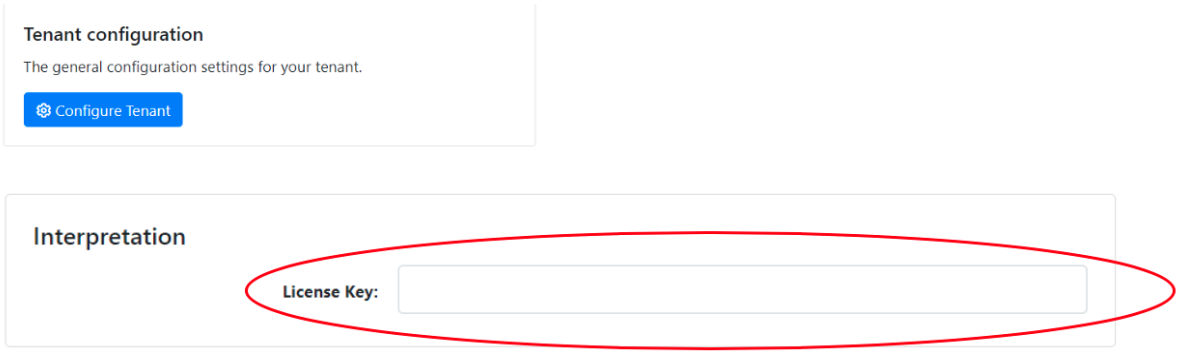


VII.2.2 REQUESTING INTERPRETATION GUIDANCE

A special software module has been implemented to support the interpretation of ALEX^2 results: RAVEN interpretation guidance.

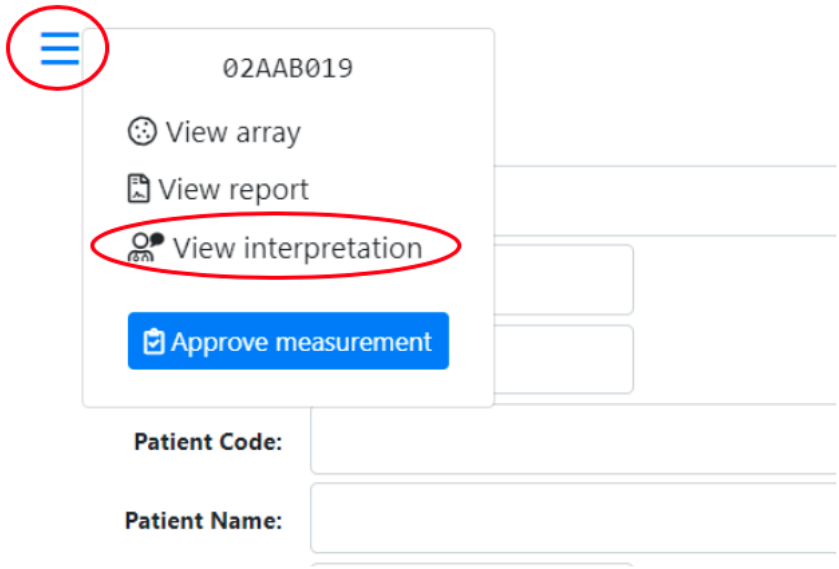
For using this service, a license key must be requested from your local distributor.

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.**

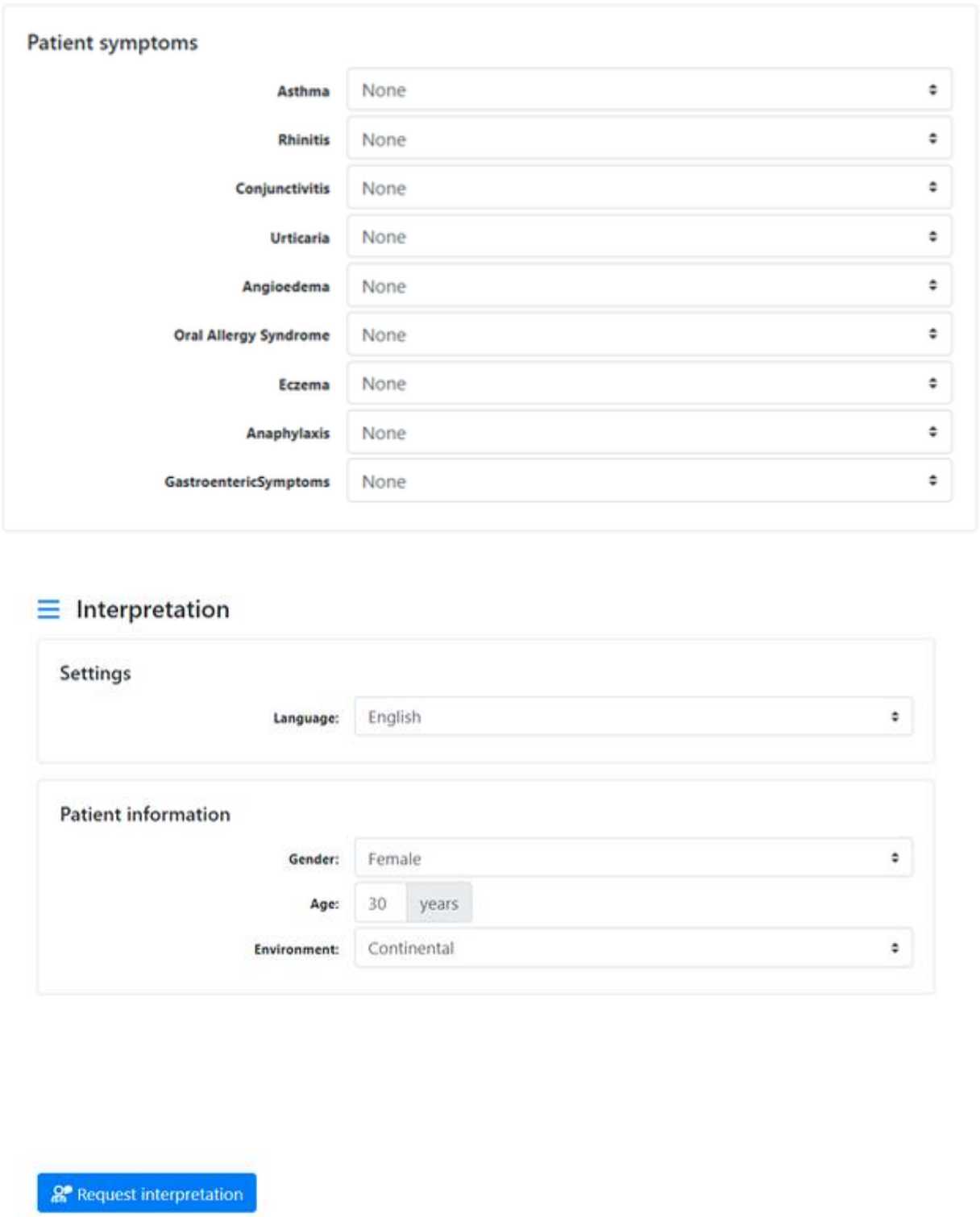


An interpretation query with RAVEN is possible for both - approved and unapproved - measurements. The report can only be downloaded for approved measurements. The interpretation is added automatically to the report, if a report template is chosen for which the option “Automatically include interpretation”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

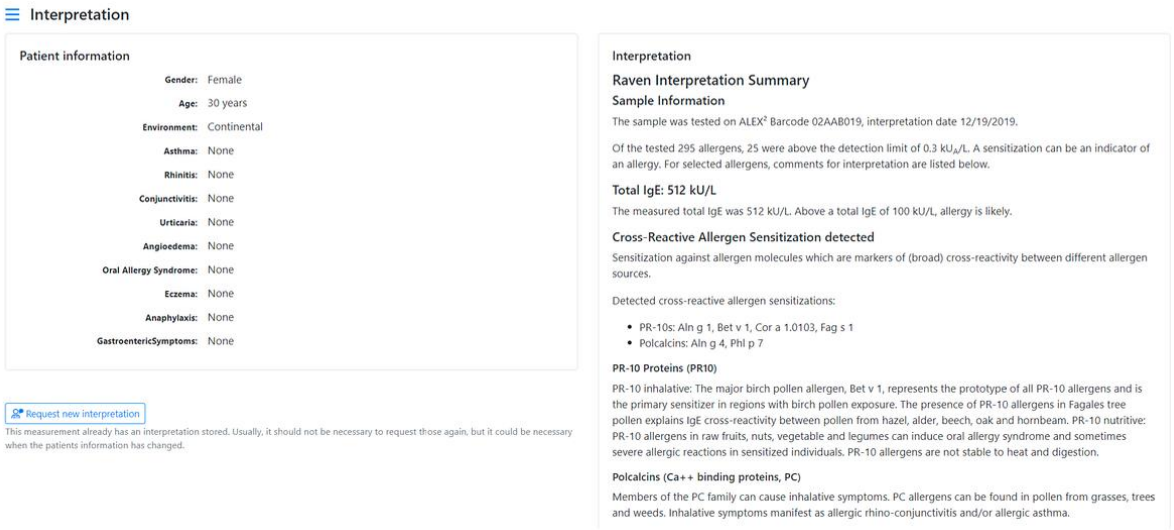
In case for your report template the Interpretation option “Include manually triggered interpretation” was selected, you must trigger the interpretation manually for a measurement by getting to the detail page of a measurement, then clicking on the menu icon and selecting "View interpretation".



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

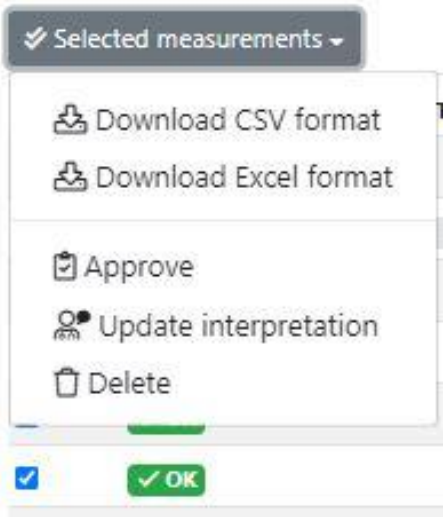


After entering these, the query can be started with the button "Request interpretation".



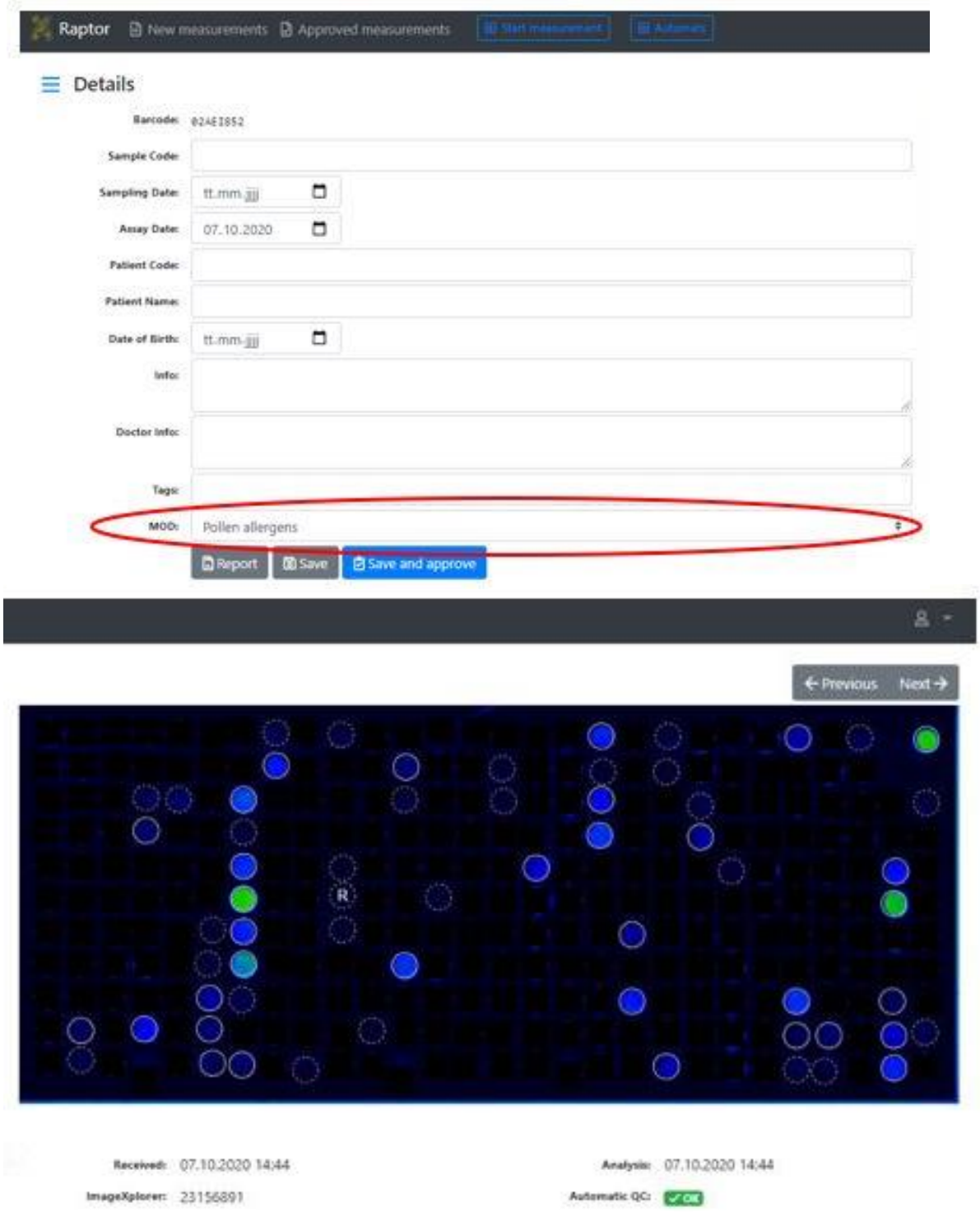
The interpretation will be then inserted at the end of the report and is also displayed in a preview window. Measurements which have already received an interpretation are indicated by the following symbol: . After clicking on the symbol, the interpretation can be reviewed as above, with the possibility 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.



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".

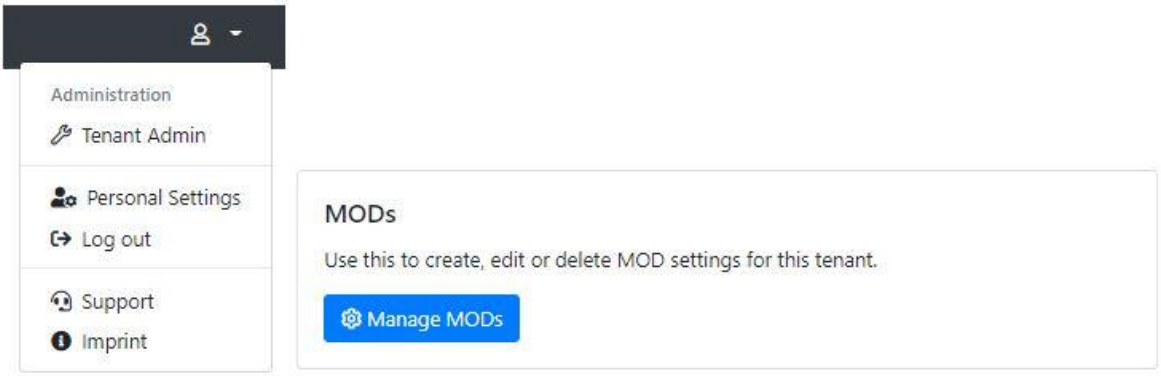


CAUTION! After approval of the measurement, the allergen results, which were not included in the MOD, will be deleted from both image and data. The unselected allergens are then listed in the report as "-".

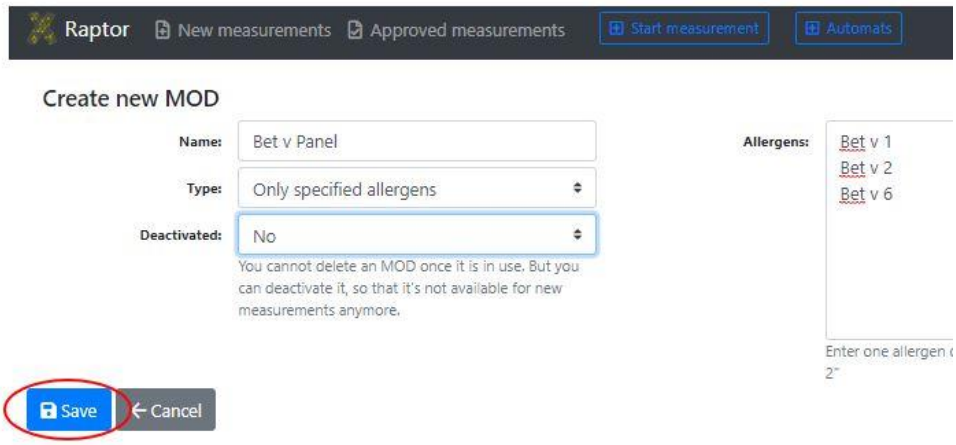
The following allergen panels can be selected as the predefined MODs:

- AIT relevant
- ALEX^2 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.



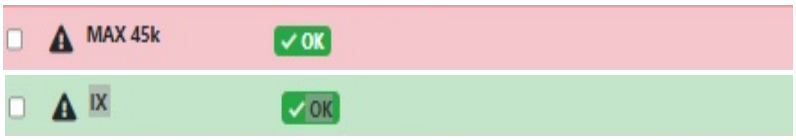
Enter the name of the panel, the product type, the MOD type (only specified allergens, or all allergens except the specified ones), and the allergens (by their code) you would like to include in the panel.



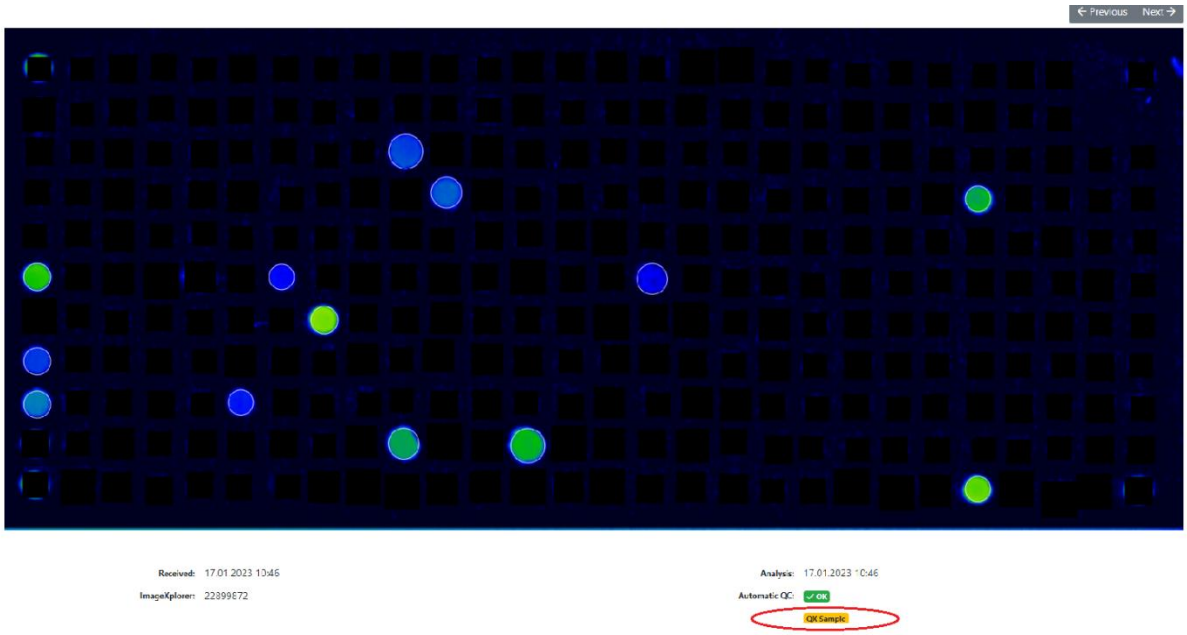
VII.3 MEASUREMENTS OF QUALITYXPLORER SAMPLES

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 QualtiyXplorer 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).

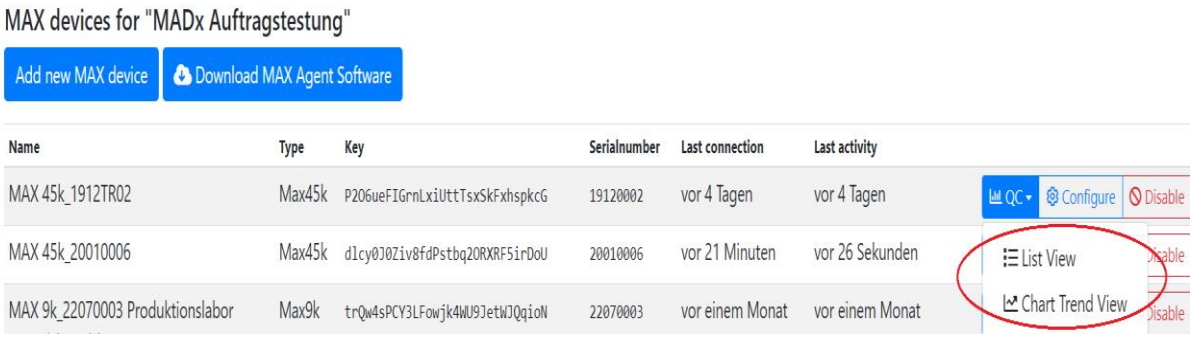
New QX measurements are displayed in the “New Measurements” overview. If the measurement is highlighted in red, the measured values of individual antibodies are outside the defined acceptance intervals. If the measurement is marked as green, all acceptance criteria have been met.



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).



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).

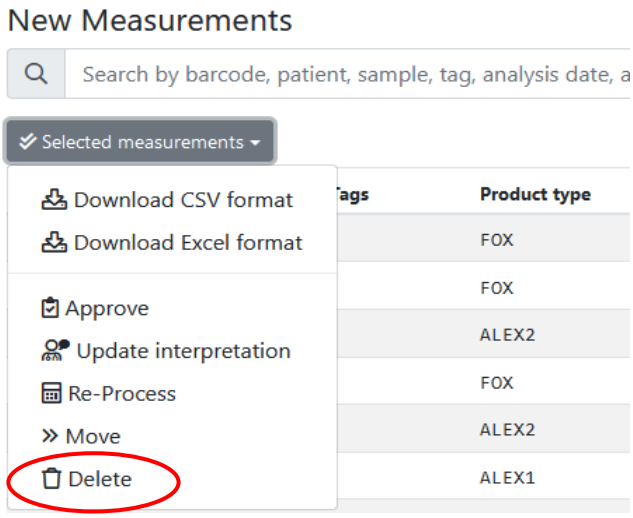
After a min. number of measurements (e.g.: 20 measurements), device-specific intervals (2 and 3 standard deviations) can be monitored. In this way, the laboratory-specific intervals for each QualityXplorer allergen can be determined precisely.

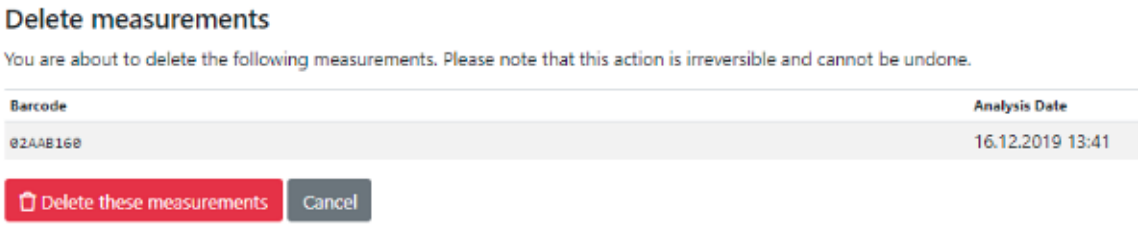
It is also possible to use “Lyphochek Allergen IgE, Panel A” from Bio-Rad Laboratories as a quality sample. Acceptance criteria for selected allergens of the respective Lyphochek lot (lot

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

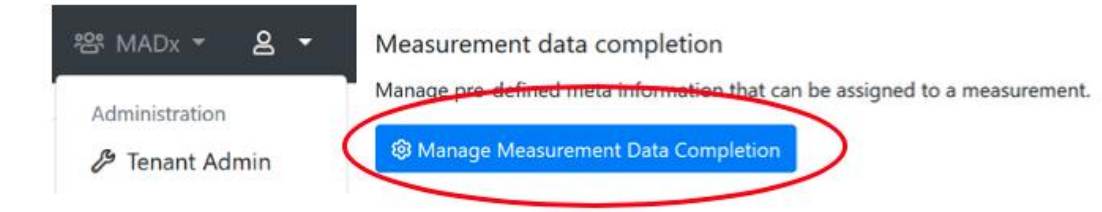
Non-approved (new) measurements can be deleted by selecting the desired measurements and choosing “delete” in the drop-down menu. Before a measurement is permanently deleted, a warning appears that is to be approved. Deleted measurements will be permanently erased and cannot be restored.

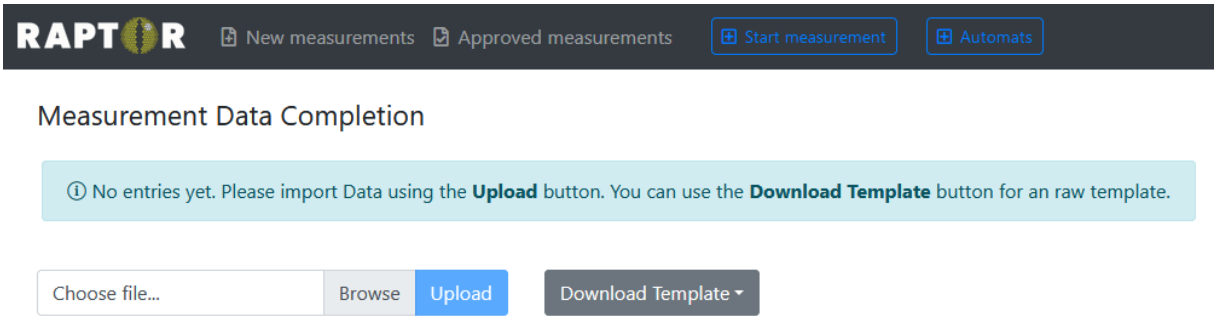




VII.5 IMPORTING THE PATIENT INFORMATION FROM A FILE

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).

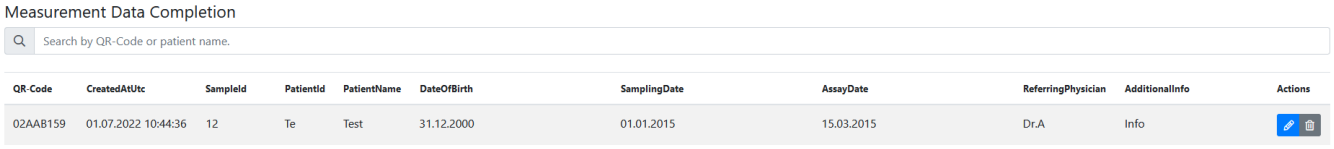




After downloading the Template file, you can type in patient information for the corresponding QR-Code, save it on your computer, upload the document again and click “Apply Changes”.

	A	B	C	D	E	F	G	H	I
1	QR-Code	Sample ID	Patient ID	Patient Name	Date Of Birth	Sampling Date	Assay Date	Referring Physician	Additional Info
2	02AAB159	12	Te	Test	31.12.2000	01.01.2015	15.03.2015	Dr.A	Info

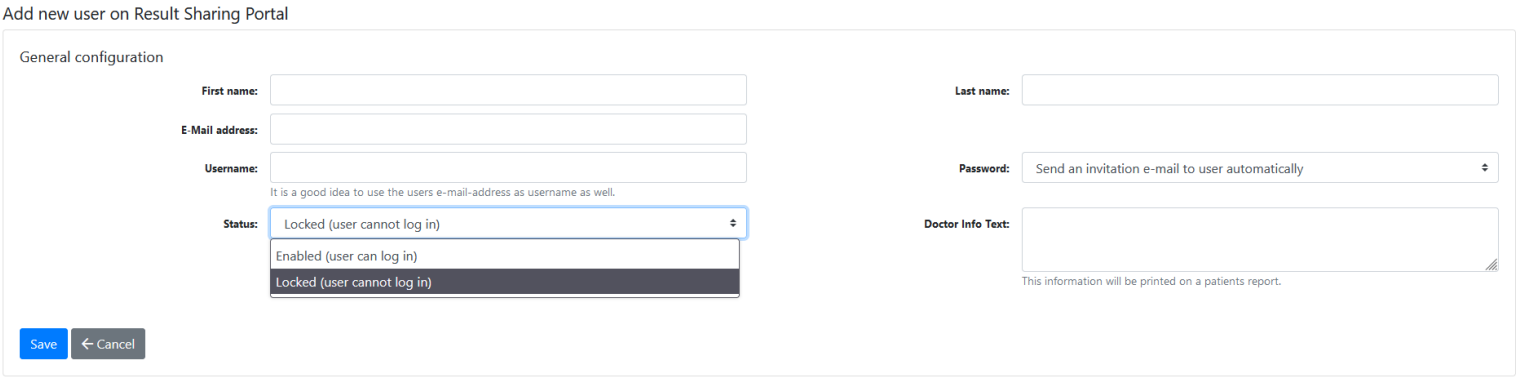
After uploading this file, the entered information will be displayed. This information can be further edited, and changes can be applied.



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.

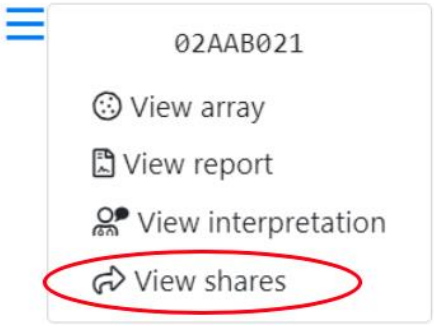
VII.6 RESULT SHARING PORTAL

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.

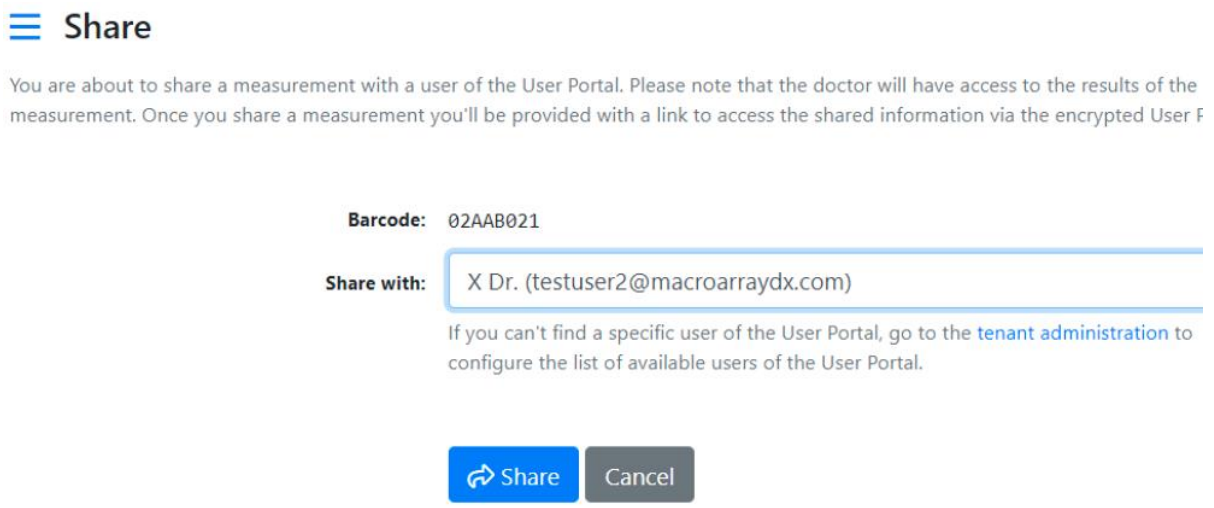


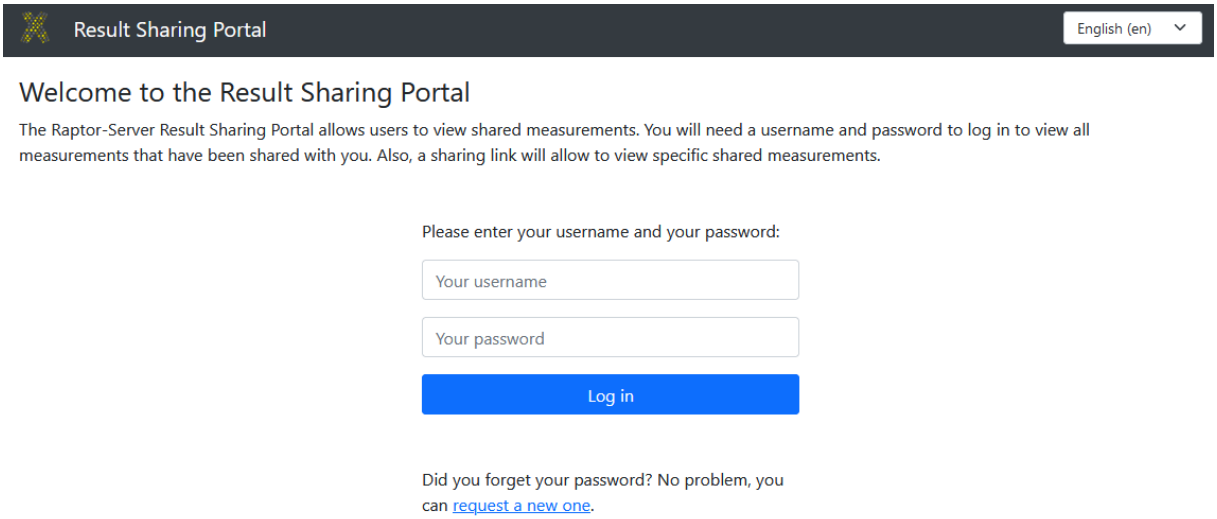
Enter the user information and send an E-mail for password creation. Alternatively, you can predefine the password for the user. Make sure you change the status of the user to “enabled”.

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".

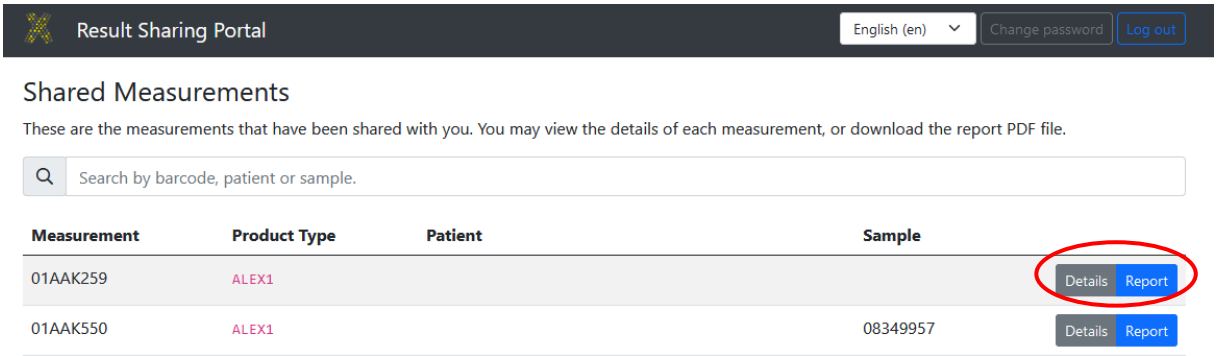


Then select the user with whom you want to share the measurement and click “Share”. After that you can either send a link by E-mail, with which the user can access this measurement. Alternatively, the user can log in to their account on the following website (https://resultshare.raptor-server.com) and see the measurement shared with him.

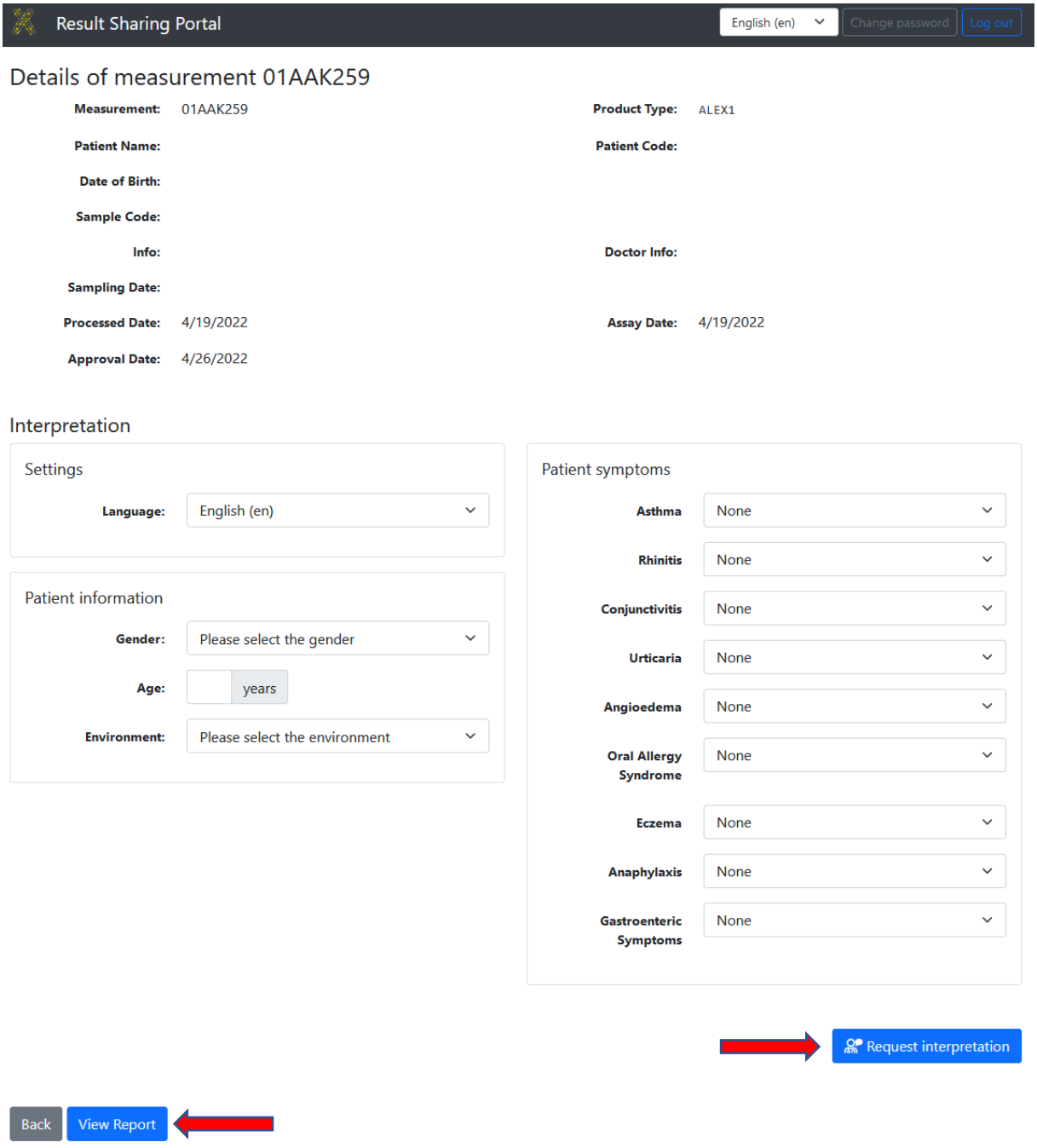




After logging in, the user can view the patient details of the measurements which have been shared with them and open the report. However, the user cannot change anything. The user can also change their password if desired by clicking on “Change password”.

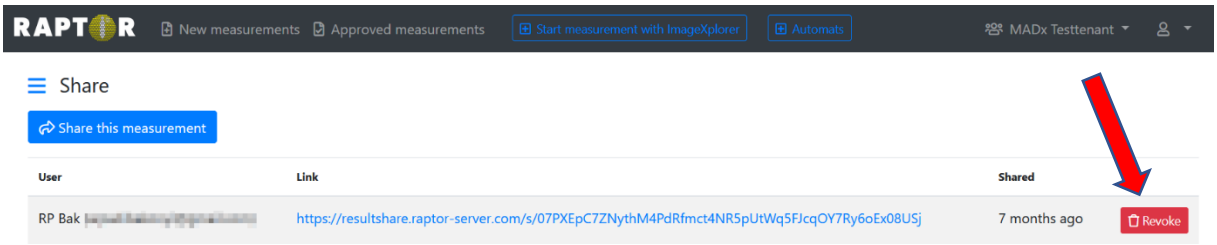


It is possible to request a RAVEN interpretation guidance for shared measurements too. For this purpose, fill out the patient data accordingly and click on “Request interpretation”. Then, to view the patient report, click on “View Report”.



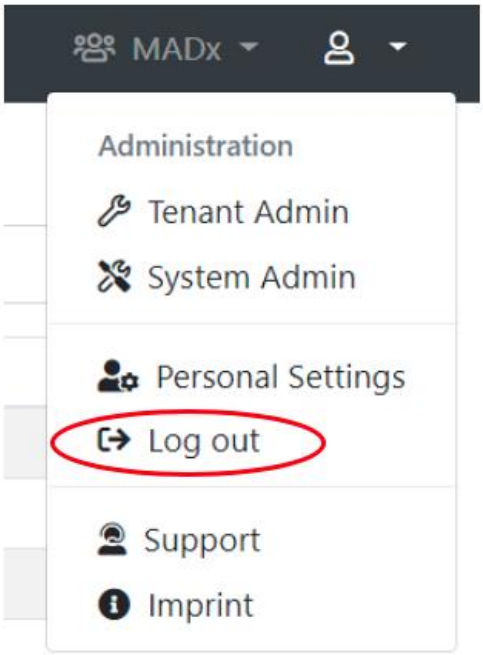
Measurements that have been shared are marked with the following symbol in the list of approved measurements:

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



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

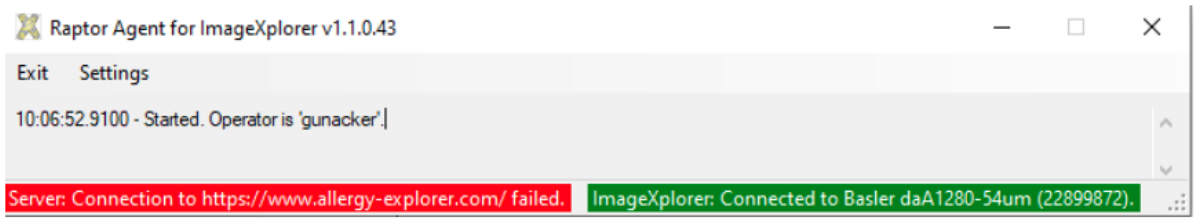
The GUI of RAPTOR SERVER can be accessed in a single web-browser. The application is optimized for Google Chrome on Windows 10. Following access rights must be enabled for the use, at least on the outgoing port 443:

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

VII.10 TROUBLESHOOTING

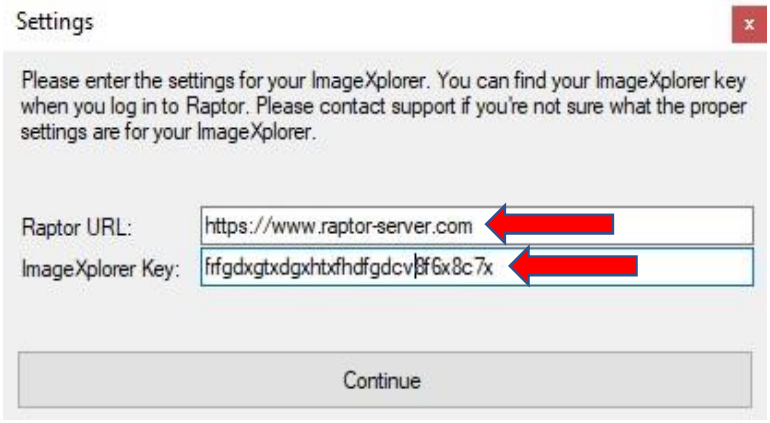
The following errors are the most common ones and therefore explained here in more detail.

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



Possible Solutions:

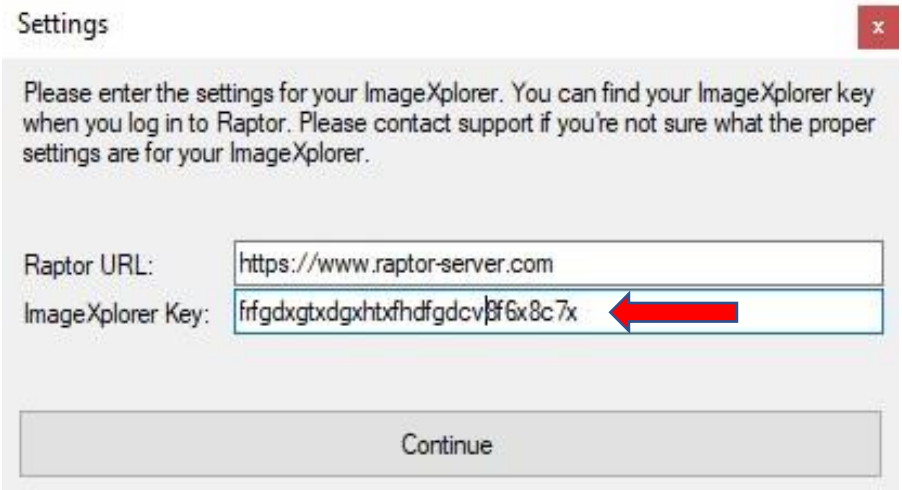
- Check internet connection
- Click settings and check if RAPTOR SERVER URL (www.raptor-server.com) is correct
- Click settings and check if ImageXplorer key is correct and corresponds to the one specified for the Tenant on RAPTOR SERVER



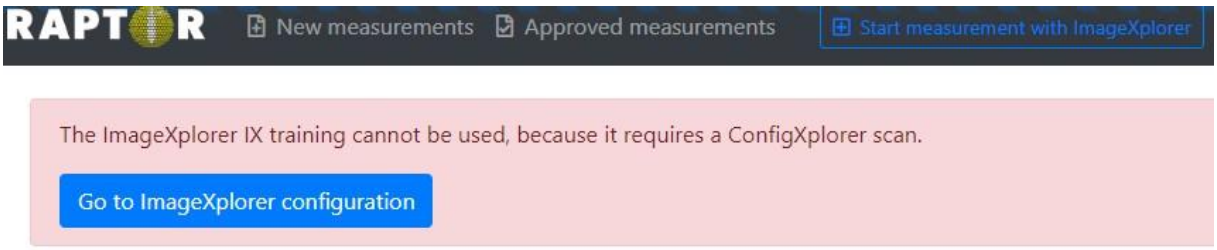
ImageXplorer Connection failed (Agent flags connection in red color):

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

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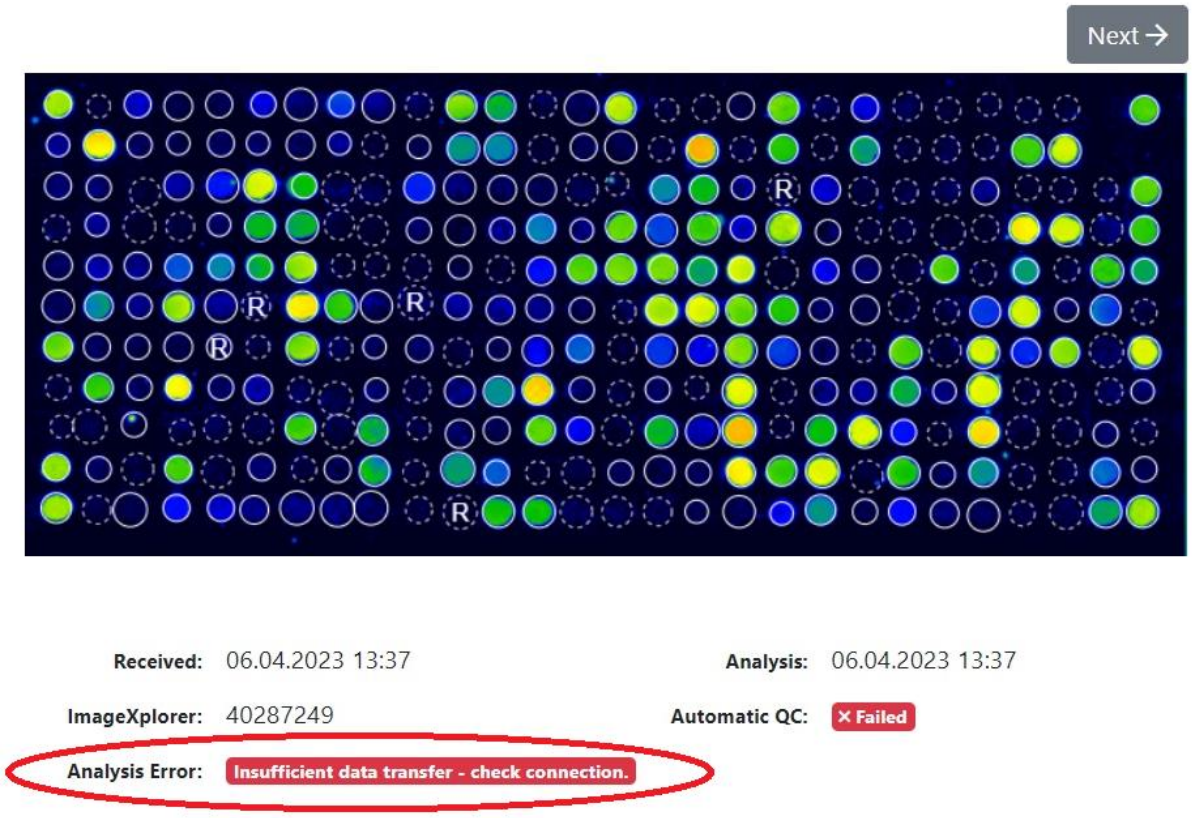
Failed transmission of the measurements to the RAPTOR-SERVER:

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.



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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