

# QIAstat-Dx<sup>®</sup> Remote Results Application User Guide

For use with the QIAstat-Dx Analyzer 2.0 and software version 1.6 and higher

REF

9002828 (QIAstat-Dx Analyzer 2.0, complete system)

REF

9002826 (QIAstat-Dx Operational Module PRO)



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R2

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# 1. Introduction

Thank you for choosing the QIAstat-Dx Remote Results Application software for the QIAstat-Dx Analyzer 2.0. We hope that the service will allow you to further expand the capabilities of your QIAstat-Dx device.

## 1.1. About this user guide

This user guide provides information about the QIAstat-Dx Remote Results Application for the QIAstat-Dx Analyzer 2.0 in the following sections:

- Introduction
- Safety and Data Security Information
- General Description
- Installation Procedures
- Signing Off a QIAstat-Dx Analyzer Test Report
- Viewing QIAstat-Dx Analyzer Test Reports
- Troubleshooting
- Glossary

The appendices contain the following information:

- Liability Clause

**Important:** QIAstat-Dx Analyzer 2.0 does not send any PHI (Personal Health Information) or PII (Personally Identifiable Information) information to QIASphere<sup>®</sup> by default. QIAstat-Dx test reports contain information such as patient ID, sample ID, and operator login; therefore to send a test report to QIASphere, the QIAstat-Dx Remote Results Application needs to be configured expressly beforehand by expert technical personnel with the correct credentials.

## 1.2. General information

### 1.2.1. Technical assistance

At QIAGEN<sup>®</sup>, we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the QIAstat-Dx Remote Results Application service, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact QIAGEN Technical Services at [support.qiagen.com](https://support.qiagen.com).

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- QIAstat-Dx Analyzer 2.0 serial number, type, software version, and installed Assay Definition Files
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- QIAstat-Dx Support package
- QIASphere Base support package

### 1.2.2. Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time.

To produce useful and appropriate documentation, we appreciate your comments about this user guide. Please contact QIAGEN Technical Services.

### 1.3. Intended use

The QIAstat-Dx Remote Results Application is a digital tool with no medical device function that supports remote review of results for tests in decentralized locations. It realizes the workflow and storage of reports and facilitates the network-based data management among the QIAGEN instruments, the QIASphere cloud, and the Electronic Signature and Storage Application. It requires the connection of the QIAGEN instrument to the QIASphere cloud, the upload of the report by a QIAGEN instrument, and access to the Electronic Signature and Storage Application by the customer.

When configured accordingly, reports are transferred from the devices via the QIASphere cloud connection to the Electronic Signature and Storage Application. The reports can be validated and approved without physical access to the single devices. Manipulation of the IVD results themselves is not possible at any time in the process and excluded by design.

### 1.4. Limitations of use

- The Remote Results Application for the QIAstat-Dx Analyzer 2.0 requires a MyQIAGEN account registered in the QIASphere platform.
- The Remote Results Application requires a configured and QIASphere-connected QIASphere Base.
- The QIAstat-Dx instrument that is to be used with the Remote Results Application has to be connected with the QIASphere-connected QIASphere Base.

## 2. Safety and Data Security Information

Before using the Remote Results Application for QIAstat-Dx Analyzer 2.0, it is essential that you read this user guide carefully and pay particular attention to the safety and data security information.

The following types of information appear throughout this user guide.

**Important** The term **Important** is used to highlight information that is critical for the completion of a task or optimal performance of the system.

**Note** The term **Note** is used for information that explains or clarifies a specific case or task.

The guidance provided in this manual is intended to supplement, not supersede, the data protection and cybersecurity policies of your organization.

### 2.1. Proper use

Use the Remote Results Application for QIAstat-Dx Analyzer 2.0 according to this user guide. It is highly recommended to carefully read and become acquainted with the instructions for use before using the Remote Results Application service. For the instructions for use of the QIAstat-Dx Analyzer 2.0, refer to the *QIAstat-Dx Analyzer 2.0 User Manual*.

- Follow all safety instructions printed on, or attached to, the QIAstat-Dx Analyzer 2.0 and QIASphere Base.
- Improper use of the QIAstat-Dx Analyzer 2.0 or QIASphere Base or failure to comply with their proper installation and maintenance may cause personal injuries or damage to the QIAstat-Dx Analyzer 2.0 or the QIASphere Base.

### 2.2. Data security

The Remote Results Application for the QIAstat-Dx Analyzer 2.0 has been designed with maximum security for the transferred data. All communication is done using encrypted connections. The data flowing among the QIAstat-Dx instrument, QIASphere Base, QIASphere Cloud, and Adobe Acrobat Sign are encrypted according to state-of-the-art guidelines.

The QIAstat-Dx Test Reports, which include sample ID, patient ID, and operator login name, are transferred and stored within the geographical region defined in the Pre-Installation Form of the Remote Results Application feature. No data are transferred outside of the selected region.

The Remote Results Application is purposely built to align with Privacy by Design principles compliant with data privacy regulations. By implementing technical and organizational measures into the design of the product, QIAGEN helps customers protect personal data, more specifically, special categories of personal data in the form of health data, being processed in the Remote Results Application. Each major release of Remote Results Application is subject to an internal privacy assessment to identify and appropriately mitigate any identified privacy risk. Additionally, QIAGEN enters contractual terms with customers and sub-processors to satisfy each party's data privacy regulations obligations.

## 2.3. Cybersecurity

It is highly recommended to follow the cybersecurity recommendations listed below when using the Remote Results Application for the QIAstat-Dx Analyzer 2.0:

- Follow the policy of your organization regarding setting-up complex passwords and the frequency when they are changed.
- Contact QIAGEN Technical Services in case you think your QIASphere account may have been compromised.

# 3. General Description

## 3.1. System description

The Remote Results Application for QIAstat-Dx Analyzer 2.0 is an extension service for the QIASphere-connected QIAstat-Dx Analyzer 2.0 that allows approving and viewing result reports using a web interface or the QIASphere mobile app.

The system defines two groups of users Approvers and Viewers that are respectively able to approve and view the approved QIAstat-Dx Analyzer 2.0 reports. Signing of reports is done using the Adobe Sign™ platform.

After initial setup, the interaction of the QIAstat-Dx with Adobe Sign is fully automated. Users with Sign Test Report access rights are notified via e-mail that a report is waiting for them to be approved. Users with Sign and View Test Report access rights are notified via e-mail that a report is waiting for them to be viewed.

Note: The Remote Results Application service requires the QIAstat-Dx to be connected to QIASphere

Note: Integration and activation of the Remote Results Application is done by QIAGEN Technical Service.

## 3.2. Data flow diagram

Remote Results Application data flow diagram is presented in Figure 1. The Azure Region where the data is sent to and the data storage location for the Electronic Signature and Storage Application will be located in the same region (see QIASphere Cloud regional in the figure below) as noted in the Pre-Installation Form.

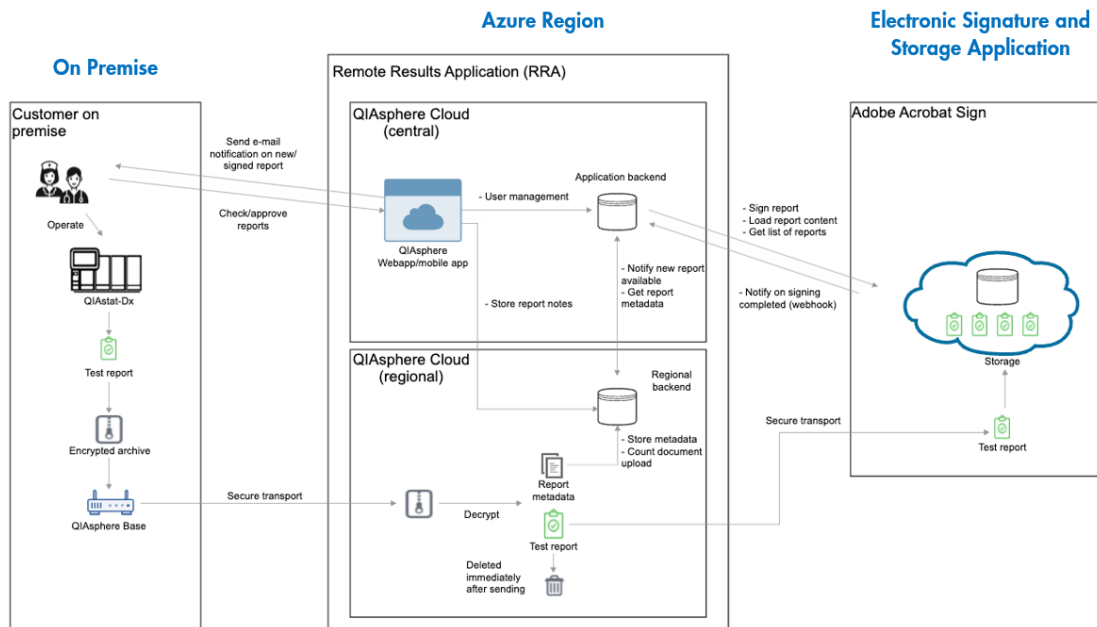


Figure 1. Data flow for the Remote Results Application.

# 4. Setup

**Note:** Activation of the Remote Results Application feature is done by QIAGEN Technical Service. After the initial step is completed the following setup can be carried out by the end user.

## 4.1. User access configuration

Granting access to Remote Results Application can be done by a user with a QIAsphere Administrator role.

- Navigate to [qiasphereadministration.qiagen.com](https://qiasphereadministration.qiagen.com).
- Select the **Users** tab.

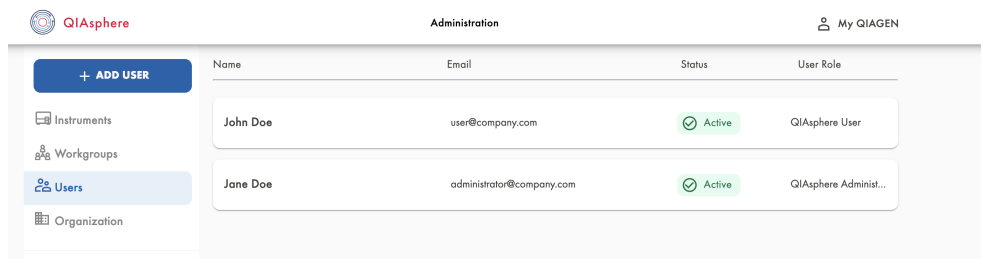


Figure 2. User list.

- Select a user that you would like to grant Remote Results Application access.
- User details view will be presented.

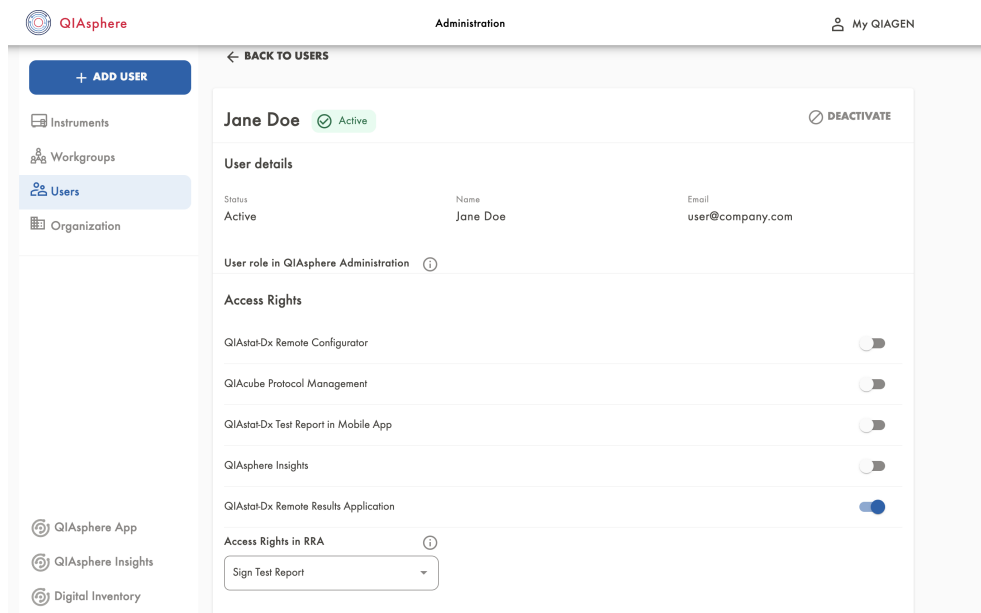


Figure 3. User details view with Access Rights.

- Scroll to the **Access Rights** section.
- Enable the QIAsphere Remote Results Application toggle.



- Select an access right from the **Access Rights in RRA** drop-down. There are two possible values that can be chosen from:
  - View Test Report
  - Sign Test Report

**Table 1. Remote Results Application access rights**

RRA access right	Allowed actions
View Test Report	View reports Add notes to unsigned reports Remove added notes
Sign Test Report	All from View test Report plus <ul style="list-style-type: none"> <li>• Sign unsigned reports</li> </ul>

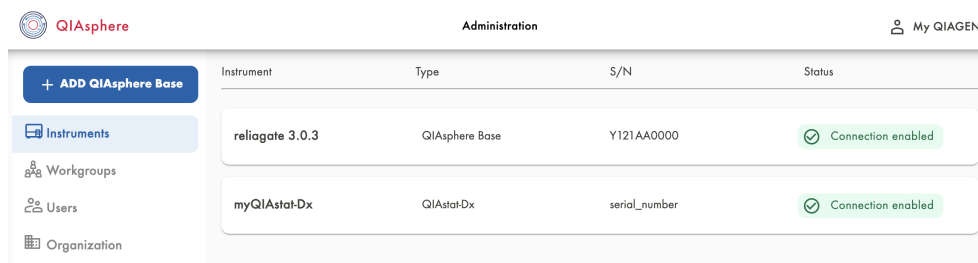
**Note:** There must be at least one user with the RRA access right “Sign Test Report” for the QIAstat-Dx reports to be visible in Remote Results Application.

**Note:** There should be at least two users with the granted RRA access, that is, one user with “Sign Test Report” and one with “View Test Report” access.

## 4.2. Activating the feature on a QIASphere connected instrument

Activating the Remote Results Application feature for a QIASphere-connected instrument can be done by a user with a QIASphere Administrator role.

- Navigate to [qiasphereadministration.qiagen.com](https://qiasphereadministration.qiagen.com)
- Select the **Instruments** tab.



**Figure 4. QIASphere Administration instrument list view.**

- Select a QIAstat-Dx 1.6.0 instrument.

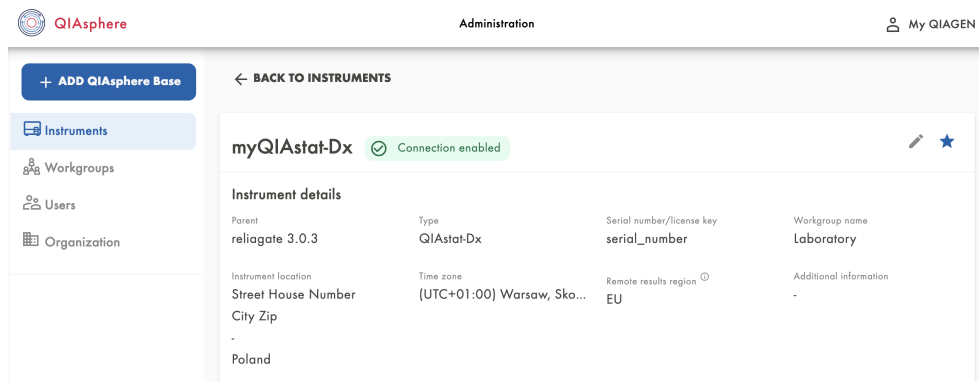


Figure 5. QIASphere Administration instrument details view.

- Press the pencil icon to edit the instrument settings.
- Locate the Remote Results Application (RRA) section and set the toggle to on.

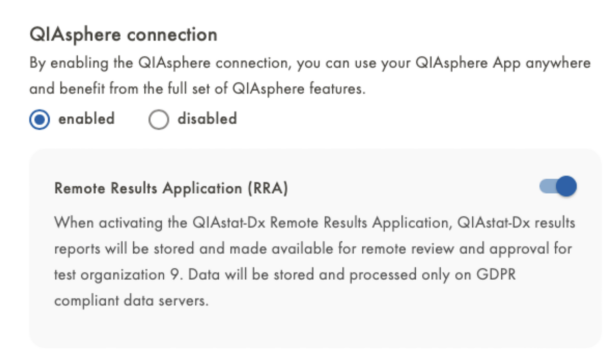


Figure 6. QIASphere Administration - Edit instrument details view.

# 5. QIAstat-Dx Analyzer Test Reports in QIASphere Application

QIAstat-Dx Analyzer test reports can be viewed in the QIASphere Application.

- Open [qiasphere.qiagen.com](https://qiasphere.qiagen.com).
- Login using your MyQIAGEN account.
  - In case you do not have a MyQIAGEN account, use the register account functionality.
- Click on the **Reports** tab.

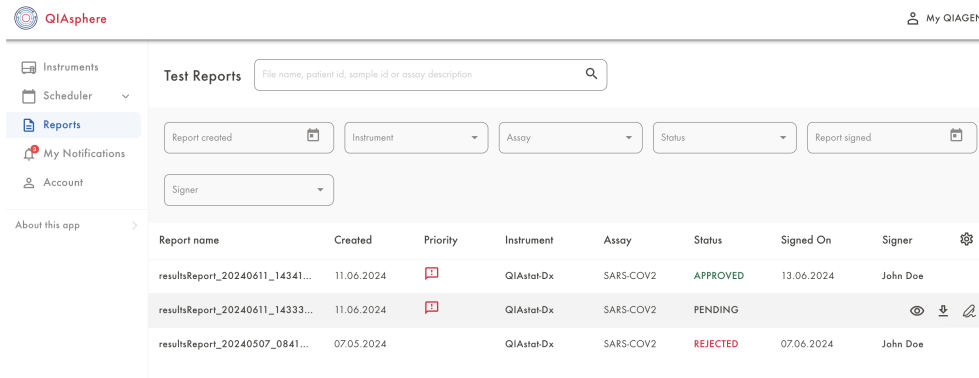


Figure 7. QIASphere Administration - Test Reports view.

## 5.1. Test report list


Each report that is generated by a Remote Results Application-enabled QIAstat-Dx instrument is presented in the report list.

Every list entry consists of the following:

- The report name
- Date when the report was created by the instrument
- Priority badge indicating that the report should be analyzed with priority due to the results
- Type of instrument that generated the results
- Assay used
- Status of the report

Reports can be in three statuses:

- Pending – The report is waiting for review and declaration whether it is approved or rejected
- Approved – The report is reviewed, electronically signed, and marked as approved
- Rejected – The report is reviewed, electronically signed, and marked as rejected
- Date of signing
- Name of the signer

Columns in the test report list can be customized by clicking the  button on far upper right of the list. This opens the column configuration panel.

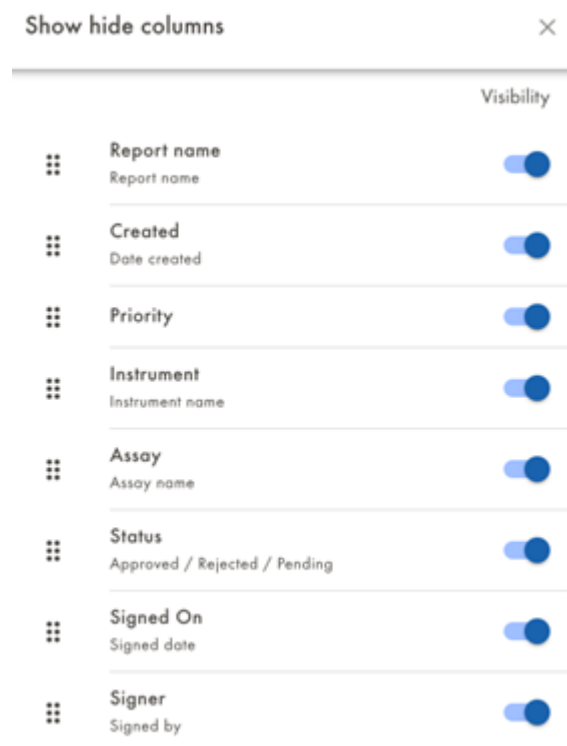


Figure 8. Test report list view column configuration panel.

The panel allows the user to show/hide particular columns in the table as well as reorder them using a drag and drop mechanism.

## 5.2. Test report list – filtering

The test report list can be filtered basing on different criteria. Filtering can be performed using the filter and search bar at the top of the report list.

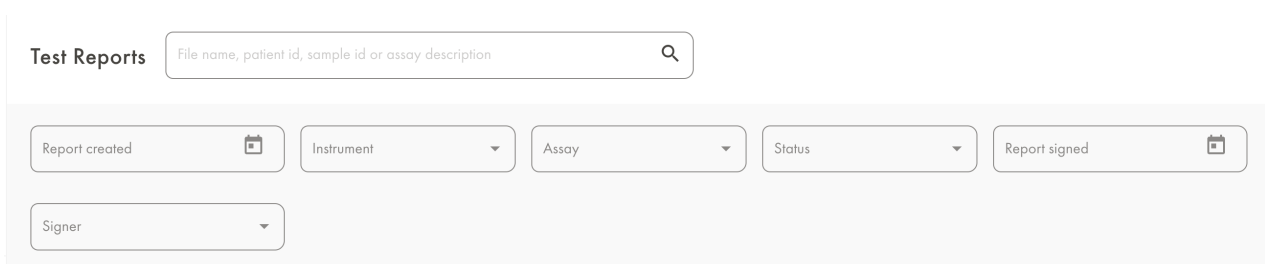


Figure 9. Report list view filter bar.

Reports can be filtered with the created date:

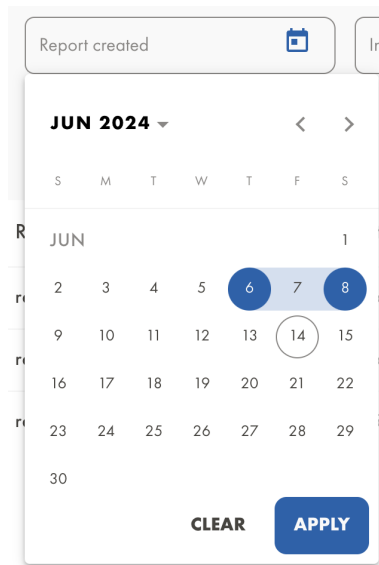


Figure 10. Report list view filter bar – date range selector.

As well as instrument type, assay type used in the report, status, and date that it was signed.

Reports can also be searched using the free text search field (loupe) at the top.

### 5.3. Test report list – report actions

The user can initiate actions on a particular report directly from the report list. Hovering over a particular report shows action buttons on the far right.

Report name	Created	Priority	Instrument	Assay	Status	Signed On	Signer	
resultsReport_20240611_14341...	11.06.2024		QIAstat-Dx	SARS-COV2	APPROVED	13.06.2024	Jol	
resultsReport_20240611_14333...	11.06.2024		QIAstat-Dx	SARS-COV2	PENDING			

Figure 11. Report list view – list item actions.

- View the selected report.
- Download it locally to his computer.
- Sign the report in case it is in Pending state.

## 6. Viewing Test Reports

Test reports can be viewed by clicking the eye icon on a list item. After clicking the button, the report preview is shown in the main area of the page.

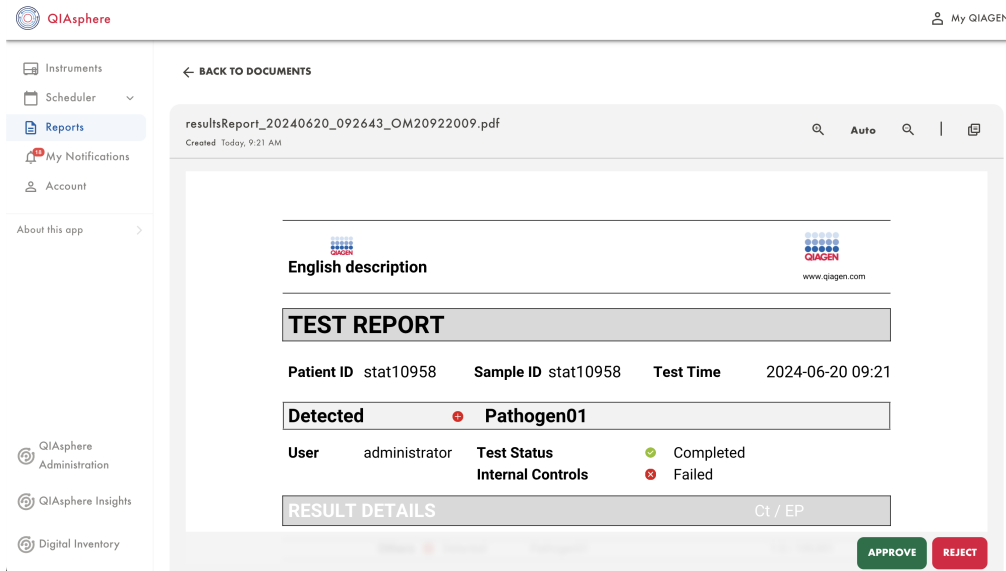


Figure 12. Test Report view.

The preview contains the following:

- Report name
- **Zoom-in/Zoom-out** buttons (replaced with pinch-to-zoom in case of the QIASphere mobile application)
- **Report Notes** button
- **APPROVE/REJECT** buttons

Please note that in case the user does not have an electronic signature created, the **APPROVE/REJECT** buttons will not be shown. The user will be presented with an information that he needs to create a signature password first.

The **APPROVE/REJECT** buttons will not be visible for users with View Test Report access rights. Users with View Test Report rights will not be prompted in any way to create a signature password.



Figure 13. Test report view — create signature banner.

## 7. Test Report Notes

The Remote Results Application allows the user to add notes to the reports.

**Note:** Notes can be added by all users who have access to the Remote Results Application as long as the report is not signed. An unsigned report is in status Pending. In case a report has been signed and is in the status Approved or Rejected, no new notes can be added.

**Important:** Please do not input notes containing patient-related information.

Please be aware that notes are not part of the test report. This means that they are not visible or uploaded with the report to the regional storage. The notes have a pure informational function and are viewable only in the QIAsphere web or mobile application.

Test report notes panel can be opened by clicking on the **Notepad** (  ) button in the view report panel. Once clicked the notes panel is opened.



Figure 14. Report notes panel.

The report notes panel contains the following:

- Name of the user that added the note
- Note content
- Delete icon in case the note was created by the current user – only if the report is not signed
- Input field to add a comment
- Submit comment button. The enter button can also be used to add a note.



# 8. Electronic Signature

**Note:** The sections below are applicable only to users with Sign Test Report access rights. If users have View Test Report access rights only, the described functionality is not visible.

The electronic signature is a passkey enabling to sign documents in the Remote Results Application. The electronic signature has to be created before attempting to sign any reports. The user is prompted to create an electronic signature in case he does not have one when viewing the report list as well as in the report preview.

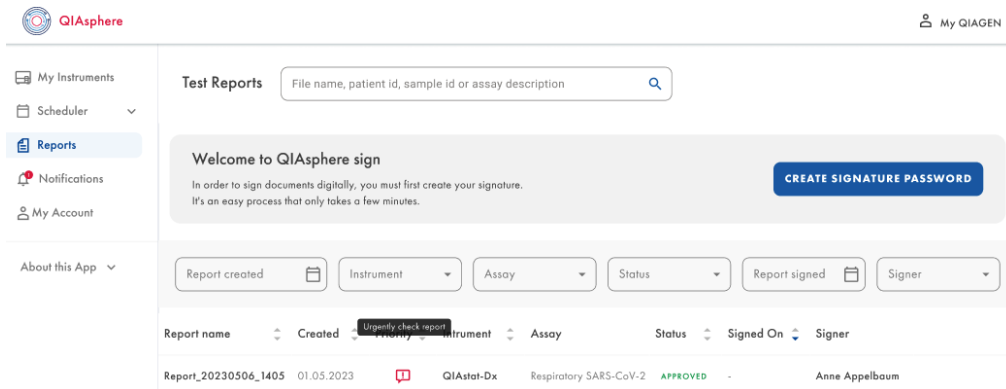


Figure 15. Test report list view with create signature password banner.

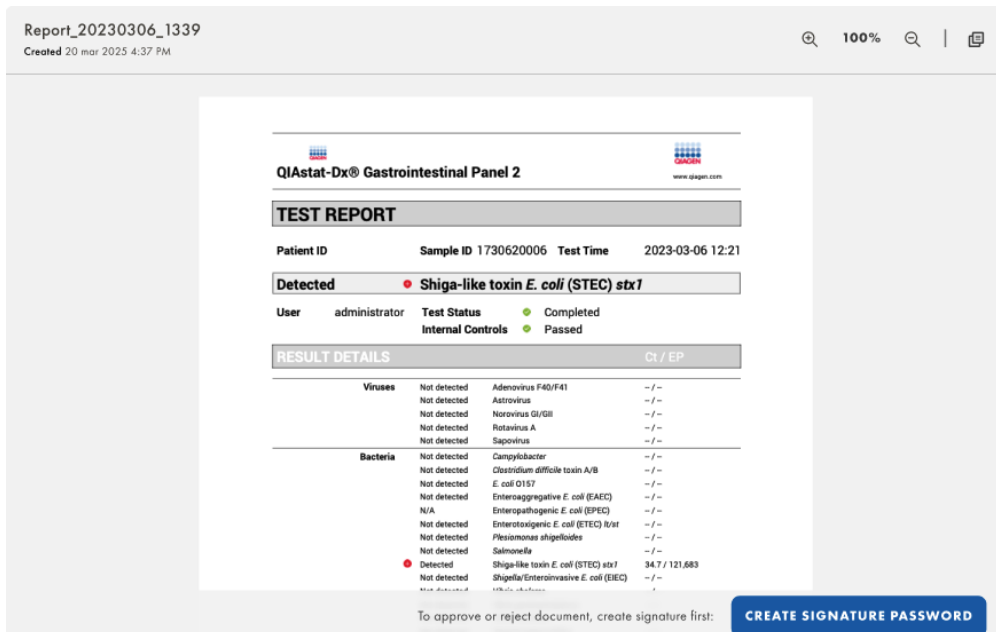


Figure 16. Test report view with signature banner at the bottom.

## 8.1. Electronic signature creation

The electronic signature creation can be initiated by clicking the **Create signature** banners on the report list view as well as in the report preview view. After clicking the **Create Signature Password** button, the create signature password panel appears.

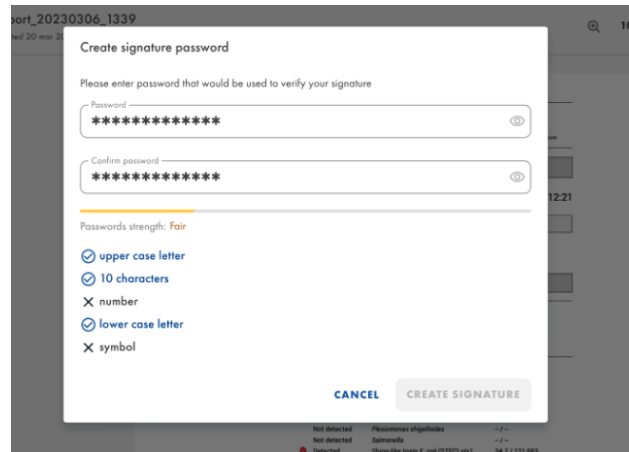


Figure 17. Create electronic signature panel.

The electronic signature password needs to fulfill complexity requirements as below:

- Has to contain at least one upper case letter
- Has to have minimum 10 characters
- Has to contain at least one number
- Has to contain at least one lower case letter
- Has to contain at least one symbol

Once all requirements are fulfilled the create signature button will become active and the electronic signature can be created.

## 8.2. Electronic signature changing

The electronic signature can be changed by navigating to the **Account** tab in the QIAsphere Application and clicking the **Change Signature Password** link.

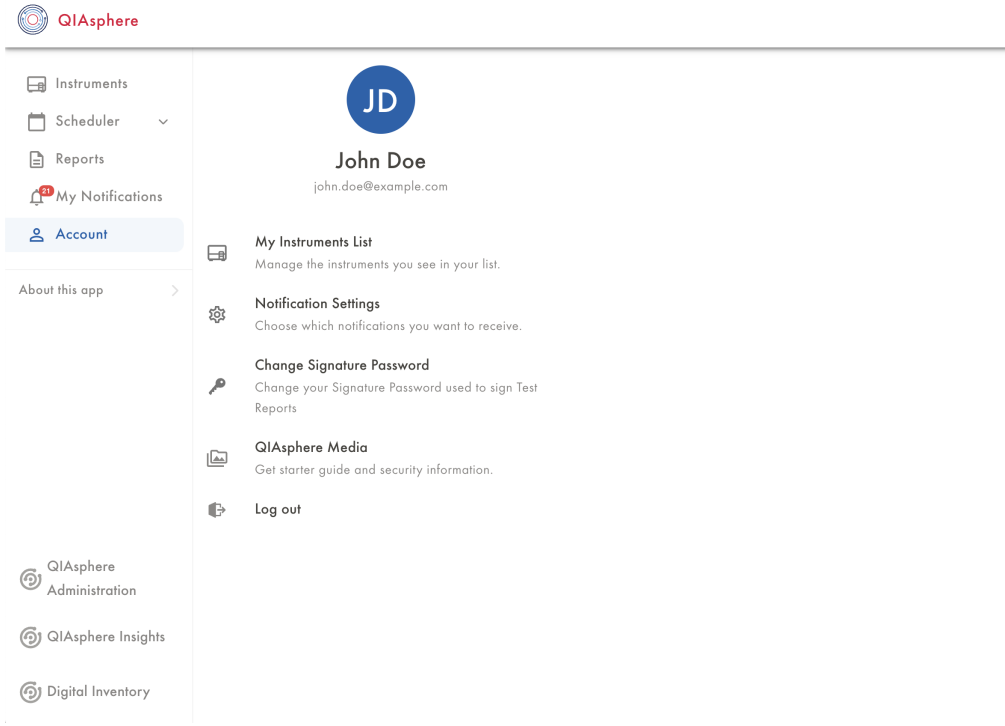


Figure 18. QIAsphere Application Account settings view.

Once clicked, the Change Signature password panel opens.

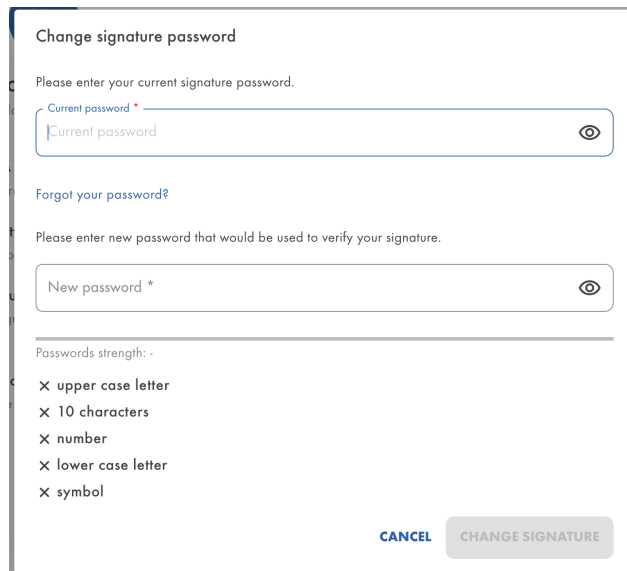
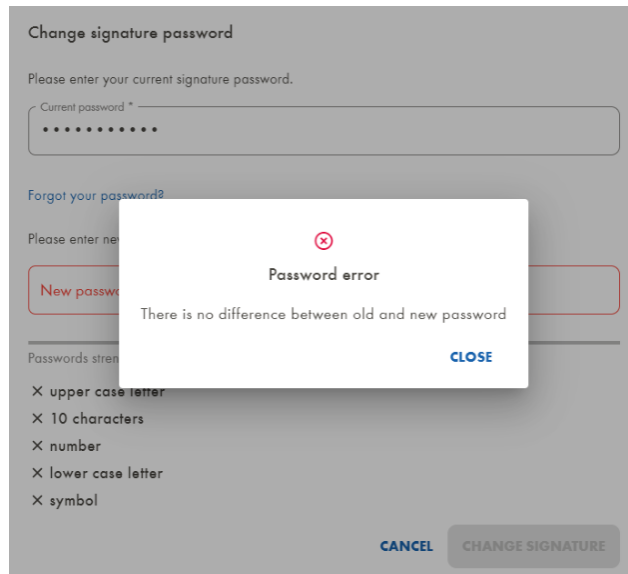
The panel is titled "Change signature password". It contains two password input fields. The first is labeled "Current password \*" and the second is "New password \*". Below the fields is a "Forgot your password?" link. A "Passwords strength:" section lists requirements: upper case letter, 10 characters, number, lower case letter, and symbol, each with an "X" indicating it is met. At the bottom are "CANCEL" and "CHANGE SIGNATURE" buttons.

Figure 19. Change signature password panel.

To change the electronic signature password, the user has to input the old signature password and the new signature password that will meet the complexity requirements.

**Note:** The current signature password and the new signature password have to be different.

In case the old signature password and new signature password are the same, the following pop-up will be displayed.



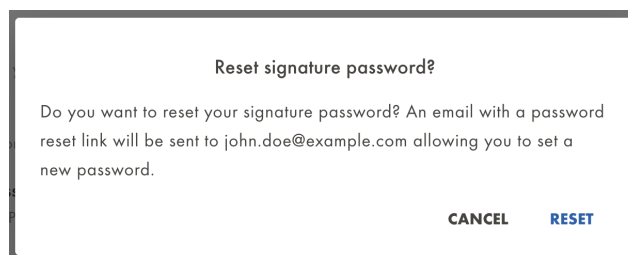
**Figure 20. Change electronic signature panel – not matching password error pop-up.**

In case the current password is correct and the new password meets the complexity requirement, the **Change Signature** button will become active. Once the user clicks the **Change Signature** button, the password will be changed.

In case the user does not remember his current password, he can click the **Forgot your password?** link.

### 8.3. Forgotten electronic signature

In case the user wants to change his electronic signature password as mentioned in Section 8.2 he has the possibility of using the **Forgot your password?** link. Once clicked the below panel will be shown.



**Figure 21. Reset electronic password confirmation pop-up.**

In case the user confirms that he wants to reset his password, he will get a confirmation pop-up that the password reset link has been sent to his email address.

**Note:** The password reset link is valid only for 24 hours. After that time, the user will have to reset the password again to receive a new link.

The user will receive an email like below.

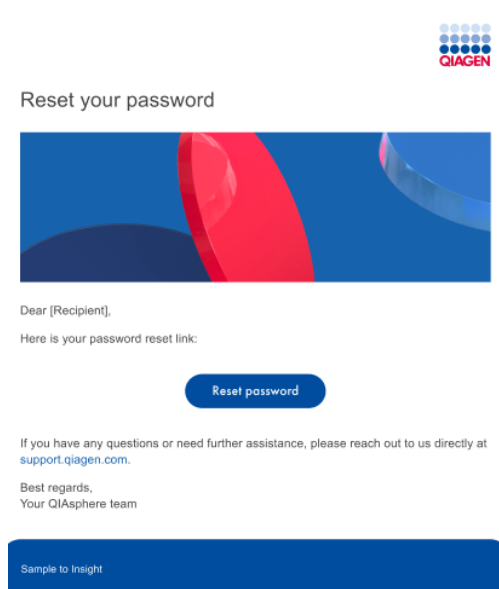


Figure 22. Reset electronic password email with Reset password button.

Clicking the **Reset password** button in the email will redirect the user to the QIASphere Application. The following panel will be displayed afterwards.

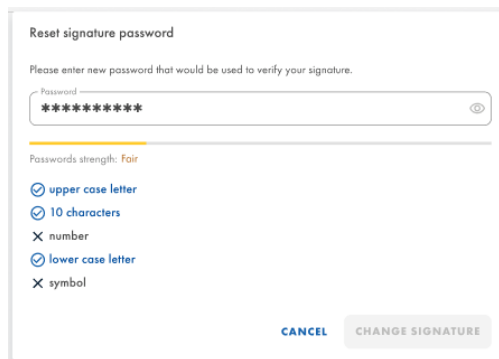


Figure 23. Reset electronic signature password panel.

The new electronic signature password has to match the complexity criteria:

- Has to contain at least one upper case letter
- Has to have minimum 10 characters
- Has to contain at least one number
- Has to contain at least one lower case letter
- Has to contain at least one symbol
- The current signature password and new signature password have to be different

Once the criteria are met, the Change signature button will become enabled.

Reset signature password

Please enter new password that would be used to verify your signature.

Password  
\*\*\*\*\*

Passwords strength: Strong

- upper case letter
- 10 characters
- number
- lower case letter
- symbol

CANCEL CHANGE SIGNATURE

**Figure 24. Reset electronic signature password – change signature button active.**

Clicking the **Change signature** button will change the signature password to the one entered in the Password input field.

## 9. Signing a QIAstat-Dx Analyzer Test Report

Report signing can be initiated from two places:

- Report list view – pencil icon (see Section 5.3)
- **APPROVE/REJECT** buttons when previewing the report (see point 6)

Clicking any of the above options opens the following panel:

Sign the document

THE REPORT  
resultsReport\_20240620\_113442\_OMpre0505.pdf  
Created Yesterday, 11:34 AM

Approved Rejected

Comment

Enter password to sign document

Password

CANCEL SIGN DOCUMENT

Figure 25. Sign test report pop-up with “approved” option selected.

The user can decide to approve or reject the report and add an optional comment.

The input comment will be visible in the test report on the last page in the comments field (see Figure 27). The comment will become an integral part of the test report document.

**Note:** Optional comment is different from report notes (mentioned in Section 7). Report notes are not an integral part of the report and are not visible in the document.

To sign the document, the user has to input the electronic signature password and press the **Sign Document** button. In case the password is correct the user will be redirected to the Adobe Sign report page as below:

Adobe Acrobat Sign

Acrobat Sign

Options Sample test report Next required field

English description

**TEST REPORT**

Patient ID stat10958 Sample ID stat10958 Test Time 2024-06-20 09:21

**Detected** Pathogen01

User administrator Test Status Completed Internal Controls Failed

RESULT DETAILS Ct / EP

Others Detected Pathogen01 1.0 / 100,001

TEST DETAILS

Sign

Figure 26. Adobe Acrobat Sign report signing step.

To sign the document, please scroll to the last page.



The screenshot shows a form for signing a document. It includes a 'Status' field with the value 'Approved', a 'Comment' field, and an 'Electronic Signature' section. The 'Electronic Signature' section contains fields for 'Date', 'Place', 'Name', and 'Job title', all of which are pre-filled. The 'Signature' field is highlighted in yellow and contains the text 'Click here to sign'.

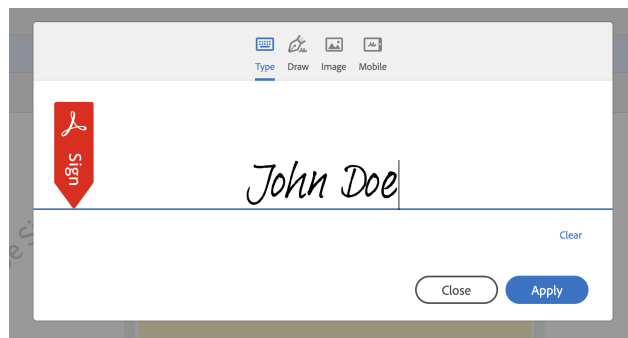
**Figure 27. Adobe Acrobat Sign – report signing step, signature field.**

Values of the Date, Place, Name and Job title will be pre-filled based on the following information:

- Date – today's date
- Place – city taken from organization address, workgroup name
- Name – user name
- Job title – job title as stated during QIAsphere user creation

Place, Name, and Job title fields are editable and can be updated if needed.

Click on the Signature field.

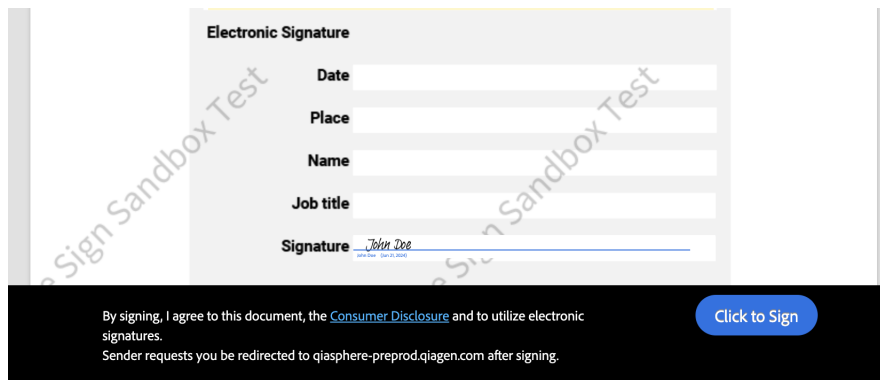


**Figure 28. Adobe Acrobat Sign signature input.**

Type your name, draw a signature, or upload an image in order to sign. Press **Apply** once done.



The **Click to Sign** button will appear. After pressing, the button the document will be considered as signed.



The screenshot displays the Adobe Acrobat Sign interface. At the top, there is a section titled "Electronic Signature" with a light gray background. Below this title, there are five input fields: "Date", "Place", "Name", "Job title", and "Signature". The "Signature" field contains a blue scribble representing a signature and the name "John Doe" in a small font. Below the signature fields, there is a black bar containing white text: "By signing, I agree to this document, the [Consumer Disclosure](#) and to utilize electronic signatures. Sender requests you be redirected to [qiasphere-preprod.qiagen.com](#) after signing." To the right of this text is a blue button with white text that says "Click to Sign".

**Figure 29. Adobe Acrobat Sign – Click to Sign button.**

In 5 seconds after pressing **Click to Sign**, you will be redirected to the QIASphere Application and the report will be marked as signed with status Approved or Rejected depending on the chosen option.

# 10. Troubleshooting

This section provides information on some issues that may occur with the Remote Results Application for the QIAstat-Dx Analyzer 2.0.

If further assistance is required, contact QIAGEN Technical Services using the contact information below:

**Website:** [support.qiagen.com](https://support.qiagen.com)

When contacting QIAGEN Technical Services about an error with Remote Results Application for the QIAstat-Dx Analyzer 2.0, note the steps leading up to the error and any information appearing in any dialog boxes. This information will help the QIAGEN Technical Services solve the problem.

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- QIAstat-Dx Analyzer 2.0 serial number, type, software version, and installed Assay Definition Files
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- QIAstat-Dx Support package
- QIASphere Base support package

# 11. Glossary

Glossary terms are listed in alphabetical order.

<b>Term</b>	<b>Description</b>
Adobe Acrobat Sign	Electronic signature backend system provided by Adobe Systems. Used as a signature and storage service provider.
IVD	In Vitro Diagnostic
QIASphere	Proprietary QIAGEN platform for instrument connectivity. It allows monitoring and managing of QIAGEN instruments deployed in the workspace setting.
QIASphere Base	Internet of Things hardware gateway that enables cloud connectivity for QIAGEN instruments.

# Appendix A – Technical Data

## Liability Clause

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# Document Revision History

Revision	Changes
R1, January 2024	Initial release
R2, August 2024	Updated with Remote Results Application version 2.0

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