

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

For use with the QIAstat-Dx Analyzer 2.0

For use with software version 1.6.0

**REF**

9002828 (QIAstat-Dx Analyzer 2.0, complete system)

**REF**

9002826 (QIAstat-Dx Operational Module PRO)



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A printed version of this manual is available upon request.

# 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 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 or PII information to QIASphere® by default. To send a test report to QIASphere, 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®, 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 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 which 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.

<b>Important</b>	The term <b>Important</b> is used to highlight information that is critical for data security.
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<b>Note</b>	The term <b>Note</b> is used for information that explains or clarifies a specific case or task.
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The guidance provided in this manual is intended to supplement, not supersede, the data protection and cyber security 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.
- The Remote Results Application and related Adobe Acrobat Sign account should only be used for the purpose related to operating the QIAstat-Dx 2.0 instrument.

## 2.2 Data security

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

The QIAstat-Dx reports 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.

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 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:

- Do not share links to your QIAstat-Dx generated reports stored in Adobe Acrobat Sign.
- Do not share your Adobe Acrobat Sign passwords with unauthorized users.
- 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 Adobe Acrobat Sign account may have been compromised.

# 3 General Description

## 3.1 System description

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

The system defines two groups of users, Approvers and Viewers, which are respectively able to approve and view approved QIAstat-Dx 2.0 reports. Signing and viewing of reports are done using the Adobe Acrobat Sign platform.

After initial setup, the interaction of the QIAstat-Dx with Adobe Acrobat Sign is fully automated. Users assigned to the Approvers and Viewers groups are notified via email that a report is waiting for them to be approved or 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 are sent to and the data storage location for the electronic signature and storage application will be located in the same region as noted in the Pre-Installation Form.

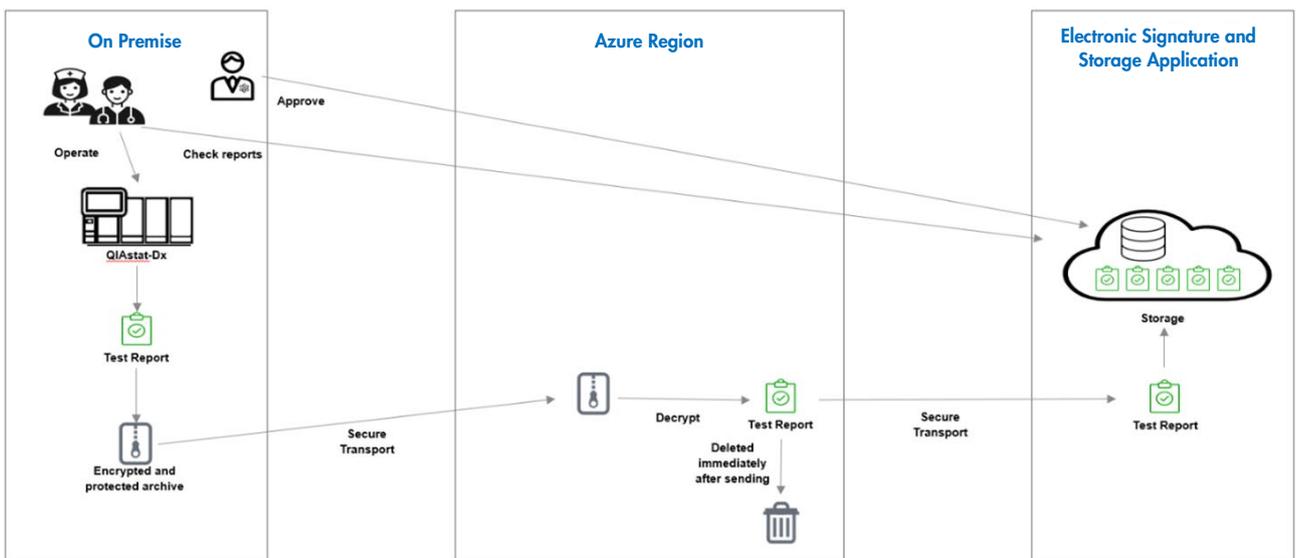


Figure 1. Data flow for the Remote Results Application.

## 4 Installation Procedures

### 4.1 Configuration of Adobe Acrobat Sign

#### 4.1.1 Adobe Acrobat Sign – first login

1. During the Remote Results Application setup procedure, an invitation email will be sent (Figure 2).

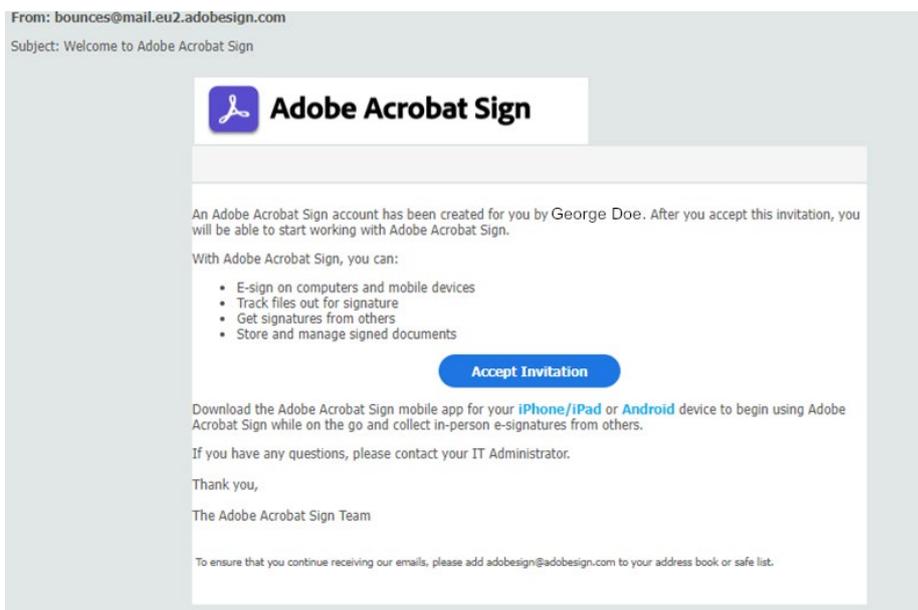


Figure 2. Adobe Acrobat Sign invitation email.

2. Click the **Accept Invitation** button.
3. Adobe Acrobat Sign account creation screen will be opened in the default web browser (Figure 3).

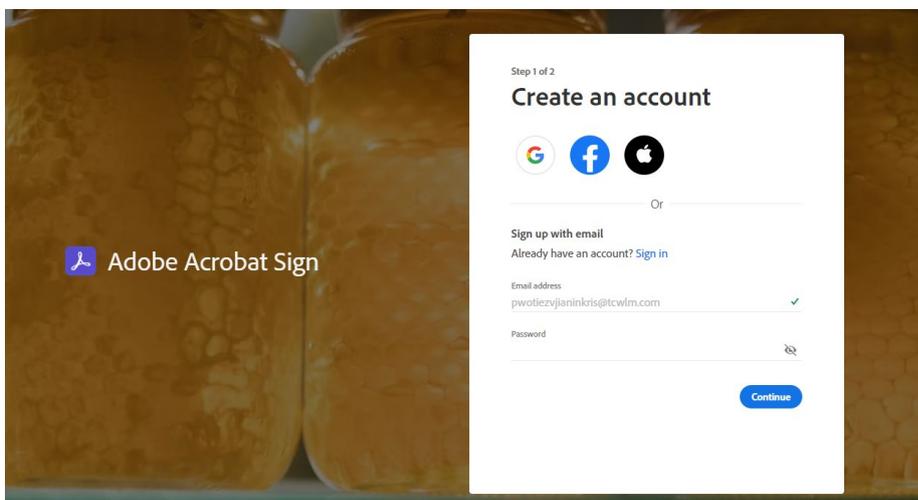


Figure 3. Adobe Acrobat Sign account creation screen.

4. Set a password according to your company standards, and click **Continue**.
5. Second step screen will appear (Figure 4).

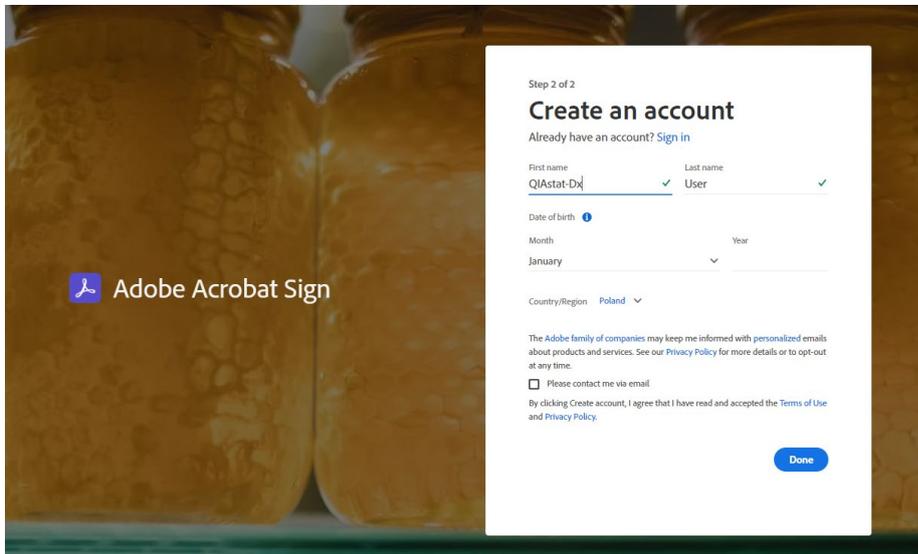


Figure 4. Adobe Acrobat Sign account creation screen – step 2.

6. Set your date of birth and region, and click **Done**.
7. The final confirmation screen will be shown (Figure 5).

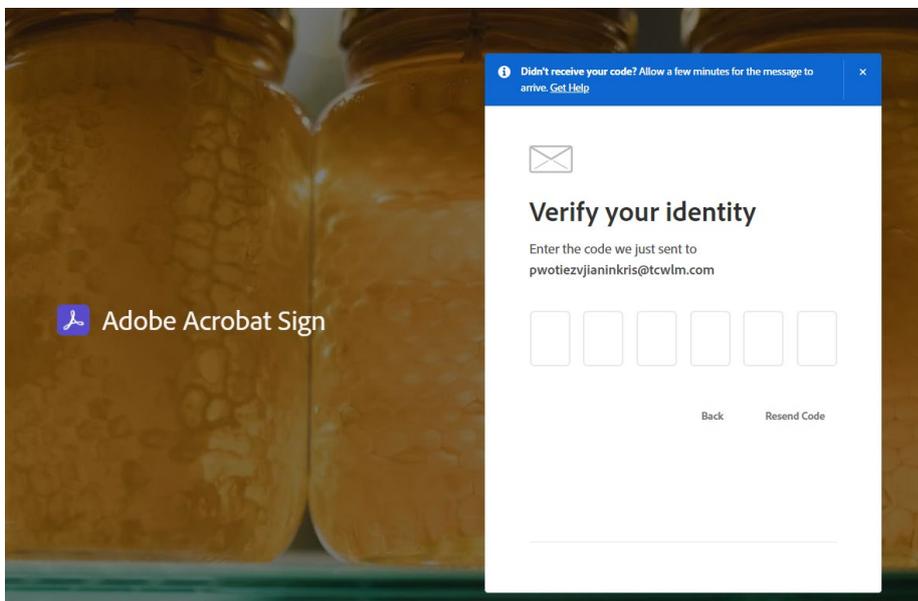


Figure 5. Adobe Acrobat Sign account creation screen – verification step.

8. Please check your mailbox for a confirmation code.
9. Enter the confirmation code in the form from Figure 5.

## 4.1.2 Change password for installation account

During setup of the Remote Results Application service, the QIAGEN Technical Service will be using a special technical account. This account is only used for the purpose of the installation. One of the steps of the installation procedure requires the end user to change the password of the technical account.

This step is necessary to secure the Adobe Acrobat Sign account and mandatory before activating the Remote Results Application service.

**Important:** The Adobe Acrobat Sign account password has to be changed as part of the installation procedure. The password change request will be communicated by QIAGEN Technical Service.

**Important:** After the password is changed, it should not be shared with unauthorized users.

## 4.1.3 Adding additional users to the Adobe Acrobat Sign platform

After the installation, the Adobe Acrobat Sign platform will have two accounts created:

- The technical account used for the integration with QIAsphere
- The Administrator account for the end user]

Adding additional users to Adobe Acrobat Sign can be done in the user management view (Figure 6) The view can be reached by navigating to: [https://qgsig.eu1.echosign.com/account/accountSettingsPage#pagelid::USER\\_LIST](https://qgsig.eu1.echosign.com/account/accountSettingsPage#pagelid::USER_LIST)

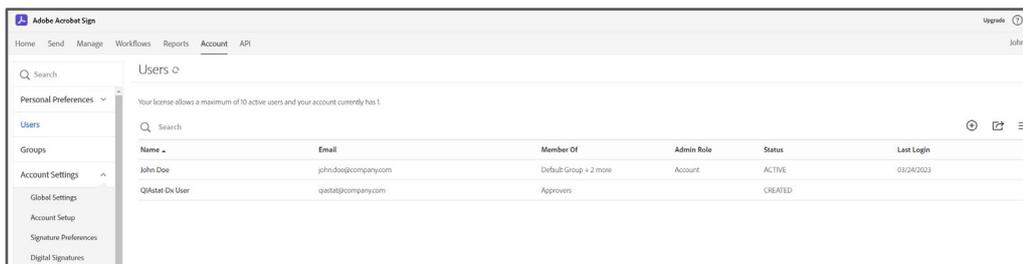


Figure 6. Adobe Acrobat Sign user management view.

1. Go to **Account**, and click **Users** in the left-hand side menu.
2. The user management view (Figure 6) will appear.
3. Press the **+** button.

4. Create user form (Figure 7) will be shown.

The image shows a 'Create' dialog box with a close button (X) in the top right corner. Below the title bar, there are two tabs: 'Create a user' and 'Create/update users in bulk'. The 'Create a user' tab is active. The form contains the following fields and controls:

- Email Address:** A text input field with a pink background highlight.
- First Name:** A text input field.
- Last Name:** A text input field.
- Primary Group:** A dropdown menu with 'Default Group' selected.
- New Group Name:** A text input field.
- View Their Agreements:** A checkbox.
- Buttons:** 'Cancel' and 'Save' buttons at the bottom right.

Figure 7. Adobe Acrobat Sign create user form.

5. Provide the email address of the user that should be created (the created user should already have access to this mailbox).
6. Fill out the First Name and Last Name fields.
7. Primary Group can be left to default or can be assigned to Viewers or Approvers in case this decision can be made at this point.
8. Press **Save**.
9. The user will receive an email and will have to create an Adobe Acrobat Sign account as described in Section 4.1.1.

#### 4.1.4 Adding users to Approver group

1. Go to **Account**, and click **Groups** in the left-hand side menu.
2. The following view will be shown (Figure 8).



Figure 8. Adobe Acrobat Sign group management view.

3. Click the **Approvers** list entry.
4. Click **Group Settings** as noted in Figure 9.



Figure 9. Approvers group selected.

5. Select **Users in Group** from the left-hand side menu (Figure 10).



Figure 10. Adobe Acrobat Sign approvers user group settings.

6. Click the **Assign Users to Group** button (  ).

7. Assign Users to this Group view will be shown (Figure 11). The list will contain all users that have the Adobe Acrobat Sign account.

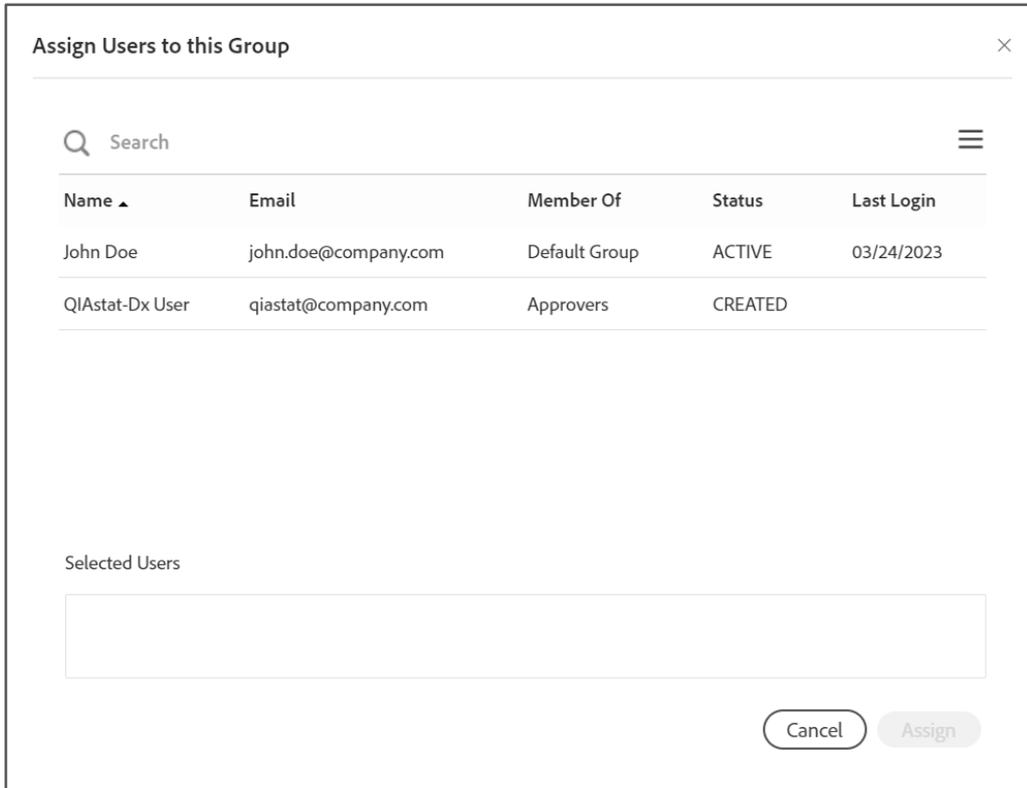


Figure 11. Adobe Acrobat Sign assign user to this group view.

- 8. Select the account you would like to assign to the group.
- 9. Click **Select User** button.

10. The selected user will be shown in the "Selected Users" area (Figure 12).

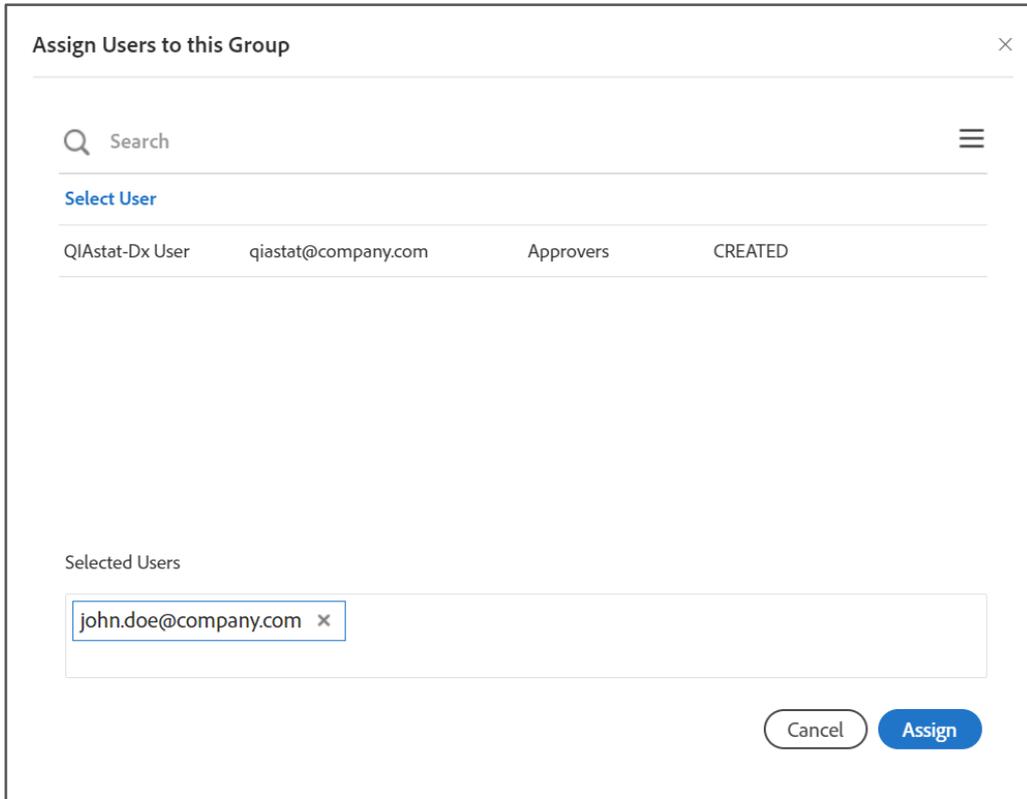


Figure 12. Adobe Acrobat Sign user to group assignment.

11. Once all users are selected, click **Assign**.

12. The selected user(s) will appear in the "Users in Groups" view (Figure 13).



Figure 13. Adobe Acrobat Sign Approvers user group settings with added users.

## 4.1.5 Adding users to Viewer group

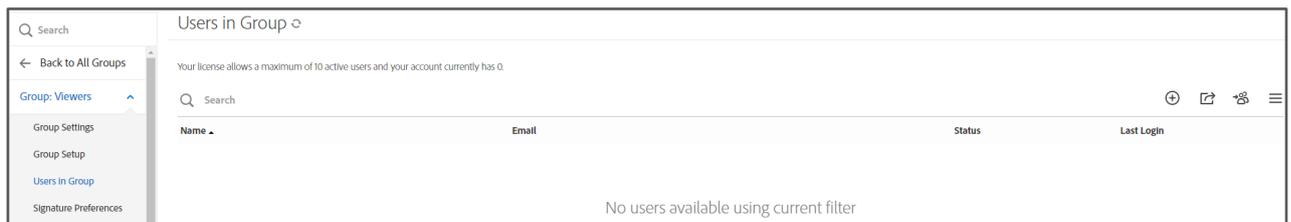
1. Go to **Account**, and click **Groups** in the left-hand side menu.
2. The view on Figure 8 will be shown.
3. Click the Viewers list entry.
4. Click **Group Settings** as noted in (Figure 14).



Name	# of Users	Administrator(s)	Status	Last Modification
Approvers	2		ACTIVE	02/16/2023
Default Group	1	john.doe@company.com	ACTIVE	03/24/2023
Viewers	0		ACTIVE	02/16/2023

Figure 14. Viewers group selected.

5. Select **Users in Group** from the left-hand side menu (Figure 15).



Name	Email	Status	Last Login
No users available using current filter			

Figure 15. Adobe Acrobat Sign Viewers user group settings.

6. Click the **Assign Users to Group** button (  ).
7. Assign Users to this Group view will be shown (Figure 11 – Section 4.1.5). The list contains all users who have the Adobe Acrobat Sign account.
8. Select the account you would like to assign to the group.
9. Click **Select User** button.
10. The selected user will be shown in the “Selected Users” area (Figure 12 – Section 4.1.5).
11. Once all users are selected, click **Assign**.
12. The selected user(s) will appear in the Users in Groups view (Figure 16).



Name	Email	Status	Last Login
John Doe	john.doe@company.com	ACTIVE	03/24/2023

Figure 16. Adobe Acrobat Sign Viewers user group settings with added users.

## 5 Signing Off a QIAstat-Dx Analyzer Test Report

Whenever a report is ready to be signed by a user assigned to the Approver group, the user will be notified by an email message (Figure 17).

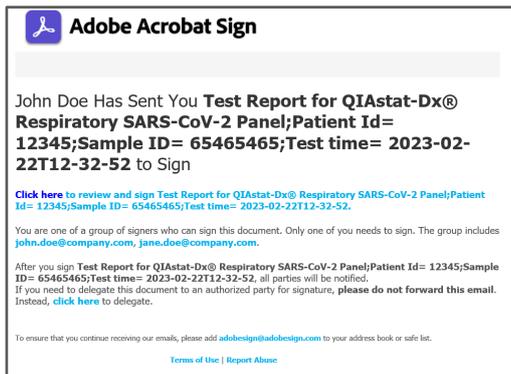


Figure 17. Report sign request.

To sign the report:

1. Click the **Click here to review and sign...** text.
2. Identity Verification view will be shown (Figure 17).

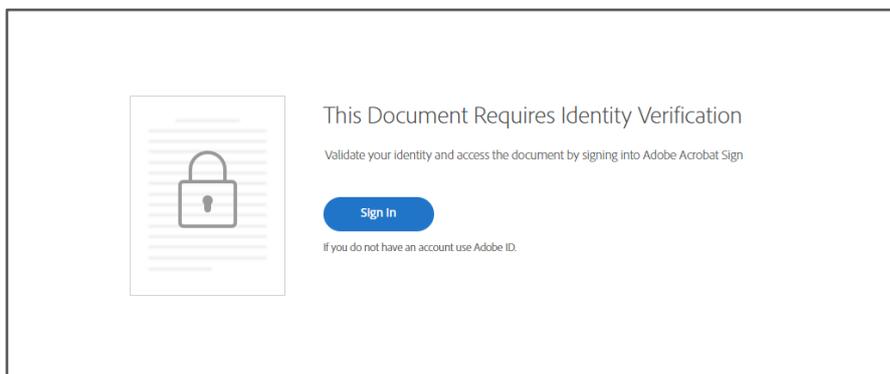


Figure 18. Sign report identity verification.

3. The user will be redirected to the Adobe Acrobat Sign login screen (Figure 19).

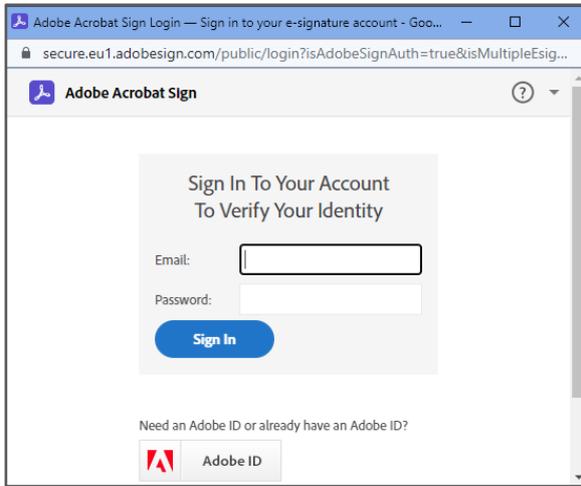


Figure 19. Sign report login screen.

4. Log in to Adobe Acrobat Sign.

5. The test report preview will be displayed (Figure 20).

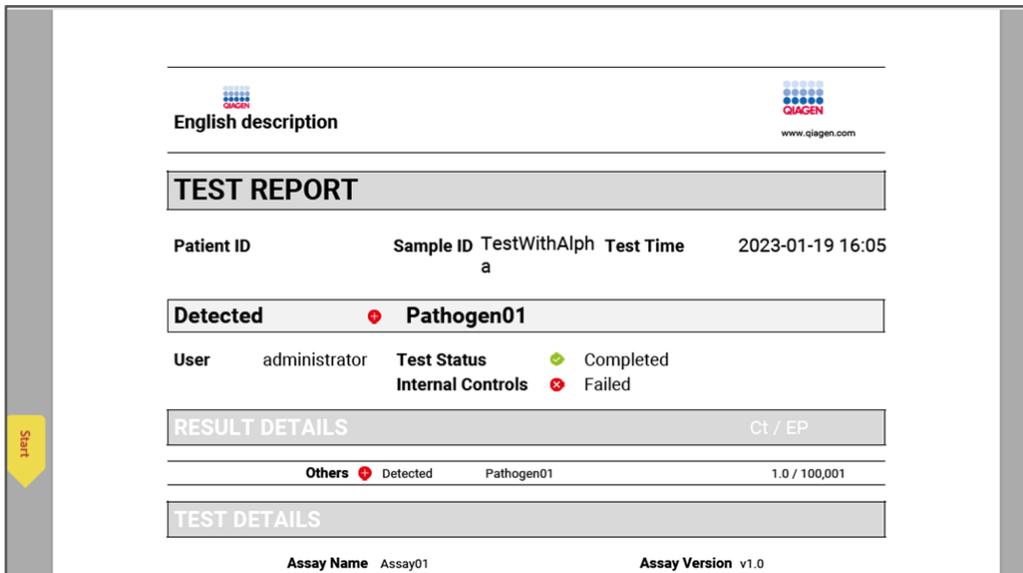


Figure 20. Test report preview.

6. Scroll to the last page of the report.

7. Set the report to “Approved” or “Rejected” using the dropdown (Figure 21).

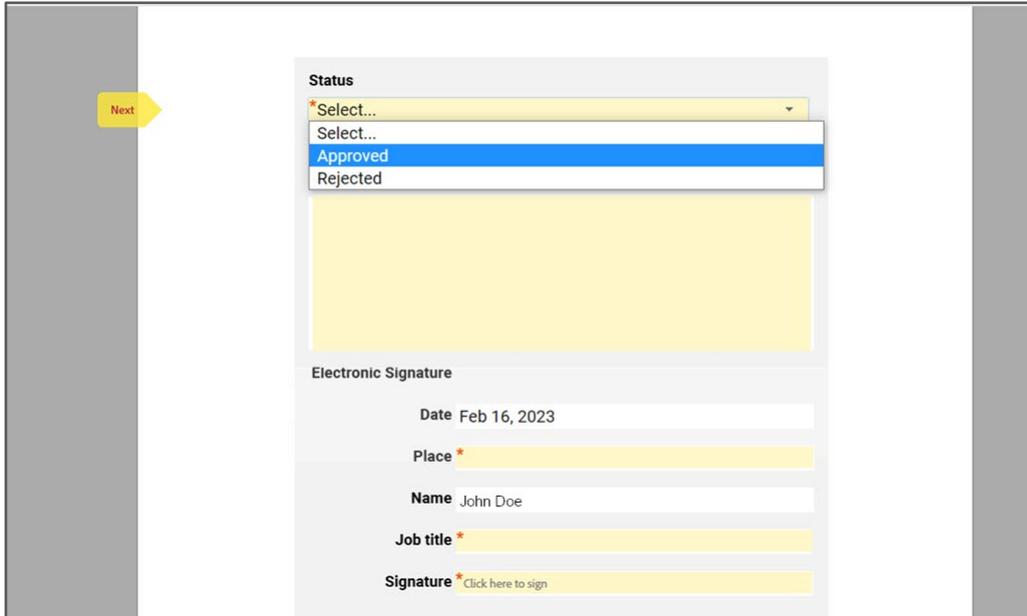


Figure 21. Report preview view — last page. Approve/Reject dropdown.

8. Fill out the Place and Job title fields.

9. Click on the Signature field. The signature popup will appear (Figure 22).

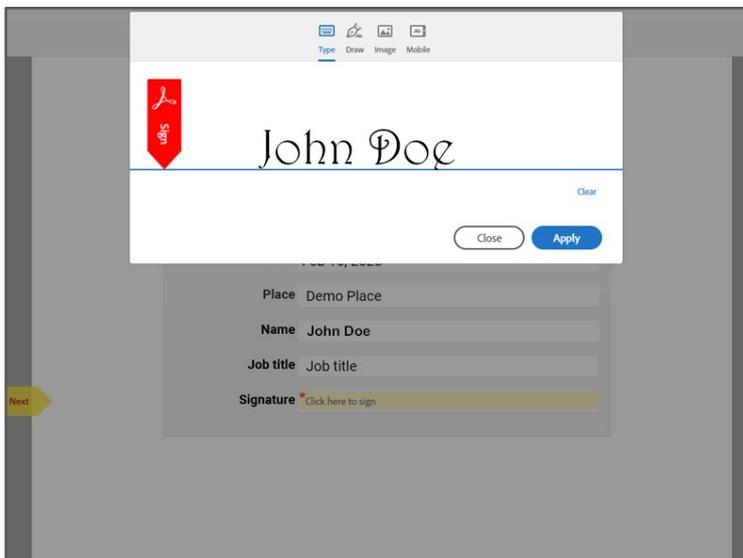


Figure 22. Adobe Acrobat Sign signature popup.

10. Add signature using the typing, drawing, or attaching an image.

11. Click **Apply**.

12. The **Click to Sign** button will be shown (Figure 23).



Figure 23. Sign report final confirmation required.

13. The document is signed, and the confirmation screen is shown (Figure 24).

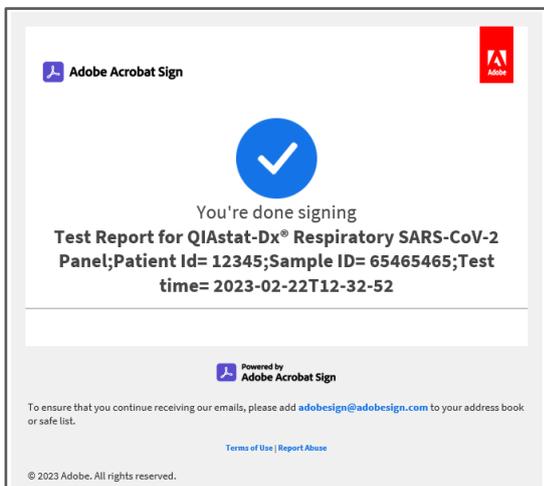
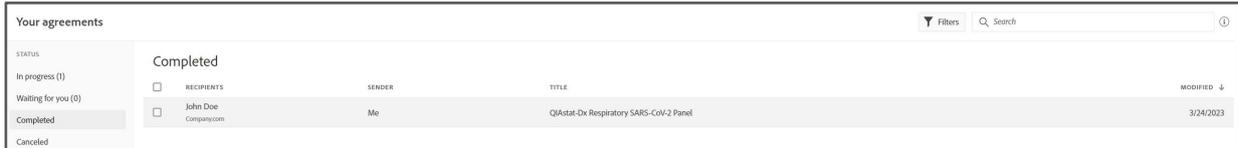


Figure 24. Sign report final confirmation screen.

14. Clicking on the **Manage** button will open the list of reports that are still waiting to be signed.

## 6 Viewing QIAstat-Dx Analyzer Test Reports

1. Click on the **Manage** tab in Adobe Acrobat Sign.
2. Select **Completed** from the left-hand side menu.
3. List of signed reports will be displayed as “Completed” (Figure 25).



STATUS	RECIPIENTS	SENDER	TITLE	MODIFIED
Completed	<input type="checkbox"/> John Doe Company.com	Me	QIAstat-Dx Respiratory SARS-CoV-2 Panel	3/24/2023

Figure 25. Adobe Acrobat Sign signed report list.

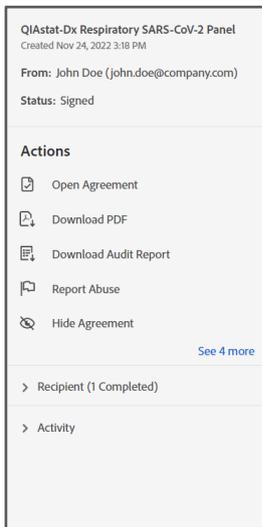
Reports that are waiting to be signed can be reached by selecting the “In progress” from the left-hand side menu (Figure 26).



STATUS	RECIPIENTS	TITLE	STATUS	MODIFIED
In progress	<input type="checkbox"/> john.doe@example.com 1 of 2 completed	QIAstat-Dx Respiratory SARS-CoV-2 Panel	Out for signature	3/24/2023

Figure 26. Adobe Acrobat Sign unsigned report list.

4. Select one of the reports.
5. The menu will be shown on the right-hand side (Figure 27).



QIAstat-Dx Respiratory SARS-CoV-2 Panel  
Created Nov 24, 2022 3:18 PM

From: John Doe (john.doe@company.com)

Status: Signed

**Actions**

- Open Agreement
- Download PDF
- Download Audit Report
- Report Abuse
- Hide Agreement

[See 4 more](#)

> Recipient (1 Completed)

> Activity

Figure 27. Signed report right-hand side menu.

6. To open the report preview, click **Open Agreement**.
7. To download the report, click **Download PDF**.
8. Pressing **See 2 more** will show additionally the **Share** and **Add Notes** options.

**Important:** When sharing the report, please make sure that the link to the report is not shared with unauthorized users. Sharing links does not require a user to authenticate in Adobe Acrobat Sign to view the report.

## 7 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

## 8 Glossary

Glossary terms are listed in alphabetical order.

<b>Term</b>	<b>Description</b>
Adobe Acrobat Sign	Electronic signature platform provided by Adobe Systems allowing to sign, store and view documents.
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

QIAGEN and its suppliers provide the QIASphere-based services provided in connection herewith “as is” and make no warranty, express, implied, statutory, or arising from course of performance, dealing, usage or trade, with respect to services delivered hereunder or any part thereof, including without limitation any implied warranty of title, availability, reliability, usefulness, data accuracy, completeness, merchantability, fitness for a particular purpose or non-infringement. Neither QIAGEN nor any of its suppliers warrants that the QIASphere services or any part thereof or services delivered hereunder will meet your requirements or be uninterrupted, timely, available, secure or error-free, or that any errors will be corrected.

# Document Revision History

Revision	Description
R1, January 2024	Initial release

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Trademarks: QIAGEN<sup>®</sup>, Sample to Insight<sup>®</sup>, QIASphere<sup>®</sup>, QIAstat-Dx<sup>®</sup> (QIAGEN Group); Acrobat<sup>®</sup>, Adobe<sup>®</sup> (Adobe); ACGIH<sup>®</sup> (American Conference of Government Industrial Hygienists, Inc.); Brother<sup>®</sup> (Brother Industries, Ltd); Clinical and Laboratory Standards Institute<sup>®</sup> (Clinical Laboratory and Standards Institute, Inc.); Windows<sup>®</sup> (Microsoft Corporation); OSHA<sup>®</sup> (Occupational Safety and Health Administration, U.S. Dept. of Labor); PostScript<sup>®</sup> (Adobe, Inc.); HP<sup>®</sup>, LaserJet<sup>®</sup>, OfficeJet<sup>®</sup> (Hewlett-Packard Development Company). Registered names, trademarks, etc. used in this document, even when not specifically marked as such, are not to be considered unprotected by law.  
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