QlAreach® Software User Manual

For installation, setup, and use of QlAreach® Software version 1.3.0

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1 Introduction

This user manual contains all the information required to download and use the QIAreach® Software, version 1.3.0. The QIAreach Software is a PC-based program used to display and record QIAreach eStick results. The software is available for download in the applicable QIAreach product webpage at www.qiagen.com. Go to Product Resources > Operating Software to download the QIAreach Software.

This guide provides detailed step-by-step instructions on how to use the QlAreach Software. It is recommended that you read these instructions first to familiarize yourself with the software before use.

Table 1. Release information

Parameter	Version
QIAreach Software version	1.3.0

1.1 General information

1.1.1 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 QIAreach Software or QIAGEN products in general, 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.

1.1.2 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.

1.1.3 Version management

This document is the QIAreach Software (v1.3.0) User Manual.

QIAGEN will inform customers as new versions of the software becomes available.

1.1.4 Windows environmental settings

Windows text sizes are set to 100% by default (Windows ease of access). Text sizes above 100% may not display properly.

1.2 Intended use of QIAGEN QIAreach Software

QIAreach Software is for optional use with the QIAreach eHub and QIAreach tests. For information related to which QIAreach tests are supported by QIAreach Software version 1.3.0, please contact your local QIAGEN representative.

Refer to the applicable QIAreach test Instructions For Use for the intended use of specific tests.

1.3 Requirements for QIAreach Software

Connection of QIAreach eSticks to a QIAreach eHub is required to monitor tests and store results in the software database.

Ensure that the QIAreach eHub is connected to the computer through USB cable.

Note: You can only connect the QIAreach Software to one eHub at a time. We recommend not to share the computer with multiple eHubs.

System requirements are shown in Table 2.

Table 2. System requirements

Description	Minimum requirement
Operating system	Microsoft® Windows® 8.1 or 10
Processor	Intel® Pentium® processor, or equivalent 1.8-GHz processor or higher, depending on operating system
Main memory	2 GB RAM or higher
Hard disk space	2 GB available hard disk space
Monitor	1024 x 768 pixels (minimum screen resolution)

Important: Only install and run the software on computers that have adequate data access controls and protection (such as antivirus) for the intended use case and region of use.

1.3.1 Recommended cybersecurity actions

Refer to this list for the minimum set of recommendations for all use cases.

- Ensure that only authorized users have access to the computer in which the QIAreach Software is installed.
- Ensure that an antivirus software is installed on the computer in which the QIAreach Software is installed.
- Only connect trusted hardware and devices to the computer in which the software is installed.
- Only install QIAreach Software or QIAreach eHub software updates from the QIAreach product webpage at www.qiagen.com. Go to Product Resources > Operating Software to download the applicable software.
- Backup the database file regularly to ensure that hard-disk failure or ransomware impact is minimized. The database file is located at:
 - C:\ProgramData\Qiagen\QIAreachSoftware\Data\BlobCache
 - Note: You may have to enable the viewing of Hidden items to see this file.
- Ensure that any exported or printed data is stored appropriately.

Important: The software enables users to record identifiers and free text that could be regarded as electronically protected health information in some territories and requires appropriate controls to protect its confidentiality, integrity, and availability. Entities that use the software as part of a workflow that captures patient or private information must implement the appropriate controls for their use and follow applicable local regulations.

1.4 Software specifications

QlAreach Software, version 1.3.0

2 General Description

2.1 Software features

QIAreach Software is a PC-based program used to display and record QIAreach eStick results.

These features are available in QIAreach Software version 1.3.0:

- Record test-related information
- Display and filter test-related information
- Print test reports
- Export data and results to a comma separated value (.csv) file
- Automatically export data and result for LIMS collection
- Display and switch languages (English US, French, Spanish, Brazilian Portuguese)
- Update QIAreach eHub software

3 Installation Procedures

3.1 Software installation from website

The most recent version of the QIAreach Software is available for download at **www.qiagen.com**. Navigate to Infectious Disease > QIAreach Solutions to access the applicable QIAreach product webpage. Go to Product Resources > Operating Software to download the QIAreach Software.

3.1.1 Downloading the QIAreach Software

Note: To download the software, ensure that you are logged in to your QIAGEN account.

To download the QIAreach Software:

- 1. In the applicable QIAreach product page, go to Product Resources > Operating Software to download the QIAreach Software.
- 2. Select your preferred language to use in the software.
 - O English US
 - O French
 - Spanish
 - O Brazilian Portuguese
- 3. Click Show Details.

You will be redirected to the download page of the software.

- 4. Click Download.
- 5. After the download is complete, save the downloaded zip file to an appropriate location within the computer.

3.1.2 Installing the QIAreach Software

To install the QIAreach Software:

- 1. Navigate to the folder where the zip file is located.
- 2. Extract the contents of the zip file in the same location.
- 3. To start the installation, double-click the applicable file based on the environment of your computer:
 - O 32-bit: QIAreach-Software-x86-1.3.0.msi
 - O 64-bit: QIAreach-Software-x64-1.3.0.msi

Note: A warning is displayed if you select the wrong version of the file.

- 4. Click Next in the Welcome to the QlAreach Software Setup Wizard window.
- In the End User License Agreement window, select I accept the terms in the License Agreement.
- In the Destination Folder window, click Next to install in the default location. If you want to
 install in a different location, click Change and navigate to the desired installation path. Click
 Install.
- After the installation is complete, click Finish to close the Completed the QIAreach Software Setup Wizard window.

The QIAreach Software icon is created and installed on your desktop.



Important: New installations of the QIAreach Software will overwrite the previously installed version.

3.2 Getting started

QIAreach tests may be run independently of the QIAreach Software. QIAreach Software may be used while running a QIAreach test as well as after a test has been completed. If you are using the QIAreach Software while running a test, the run test screen will display workflow prompts and test status (the same as in the IFU) to the user.

3.3 QIAreach eHub software upgrade

You may need to update the QIAreach eHub software in case a new version becomes available following the release of a new QIAreach product. Software updates for QIAreach eHub are available for download in the applicable QIAreach product webpage at **www.qiagen.com**. Go to Product Resources > Operating Software to download the latest QIAreach eHub software version. Save the downloaded software in your preferred location.

3.3.1 Settings

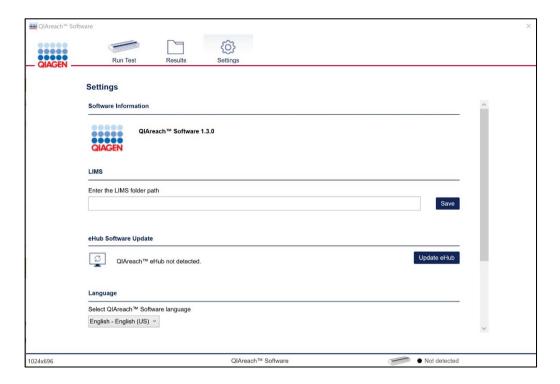


Figure 1. Configuration screen.

Note: The QIAreach Software version can be found in Settings. You can also view the serial number and software version of any connected eHub in this screen.

3.3.2 Upgrading the software

Important: Before you begin with the update, ensure that you have downloaded the latest version of the QIAreach Software from **www.qiagen.com**. This procedure requires an eHub software (firmware) file (*.hex). Do not attempt to use any other file type. For instructions on how to download the latest eHub software, see Software upgrade.

- 1. Go to Settings > eHub Software Update.
- 2. Click Update eHub.
- 3. Navigate to the folder where the downloaded eHub software file is located. Select the file, then click Open.
- 4. Wait for the update process to complete.

CAUTION



Disconnecting the eHub from the computer during the software (W2) update could result in damage to the eHub. If the update process is not completed within 90 seconds, do not disconnect the eHub. Click Update eHub again.

Note: Timing issues might occur between the USB port which is operated through the computer's operating system, and the bootloader application which uploads the new QIAreach eHub software to the QIAreach eHub microcontroller.

- 5. After the update is successfully completed, perform these steps:
 - 5a. Unplug the QIAreach eHub.
 - 5b. Press the Power button to turn on the QIAreach eHub.
 - 5c. Reconnect the QIAreach eHub to the computer.

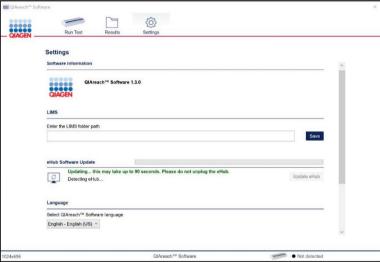


Figure 2. Settings screen.

4 Operating Procedures

4.1 Starting the QIAGEN QIAreach Software

From your Home screen, locate QIAreach or double-click the icon on the desktop to open the QIAreach Software. The program will open to the main Run Test window that provides a menu to access each of the three screens:

Run Test

- O View the status of the test, QIAreach eHub, and the estimated time to completion.
- Enter general test details such as Sample Type, Sample ID, Test Site ID, Operator ID,
 Collection Site ID, Sample Collection Date, Kit Lot Number, and Notes.
- Additional test sample information such as DOB, Gender, and Symptoms can be entered depending on the surveillance needs and the test (eStick) being performed.
- O View and print results for tests as they become available.
- If properly setup, the QIAreach Software can automatically send test results and Test Information (test record) to a LIMS collection folder.

Results

- O View test results for each sample.
- O Filter test results.
- O Print and export results data.

Settings

- O Define LIMS data collection path.
- O Define the QIAreach Software language.
- View the installed QIAreach Software version and connected QIAreach eHub software version and update the software on the connected QIAreach eHub.

For more information about these screens, see Screens in the QIAGEN QIAreach Software.

4.2 Screens in the QIAGEN QIAreach Software

4.2.1 Startup screen

The software requires a powered-on QIAreach eHub to be connected via USB to use the Run Test screen. The main startup screen will prompt the user to power on the QIAreach eHub and connect to the PC if not already connected (Figure 1).

Note: The Results and Settings screens can still be accessed if the QIAreach eHub is not connected to the software.

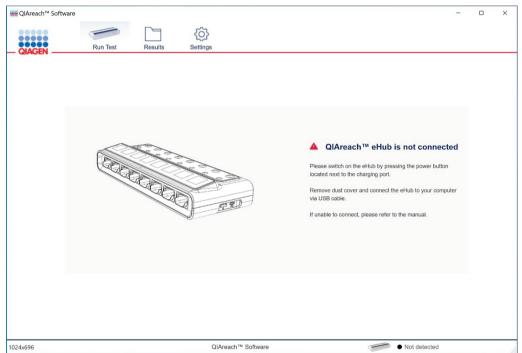


Figure 3. eHub disconnected warning.

CAUTION



Disconnecting the QIAreach eHub from the computer during a test (W1) could result in the QIAreach Software not receiving the result from currently processing tests. Similarly, the QIAreach Software will not receive results from a connected QIAreach eHub when the computer is turned off, entered into Sleep mode, or logged out while tests are being processed.



Figure 4. QlAreach eHub connected screen.

4.2.2 Run Test screen

The Run Test screen features a virtual eHub console that displays the real time status and OLED port displays for the QIAreach eHub that is connected to the QIAreach Software. Clicking on any one of the virtual eHub ports will open the run test screen for that specific port. After an eStick is inserted into the QIAreach eHub port, the eStick test type will be displayed in the Run Test screen and the sample information can be specified on the window that appears on the screen. If the QIAreach test is yet to be performed, the Ready for Sample screen will appear (Figure 3). If a used eStick is inserted into the QIAreach eHub port, the test result will appear.

Run Test - Ready for Sample screen

Select the sample type from the Sample Type list and specify the sample ID* in the Sample ID field. Optional fields are also available for the test site ID, operator ID, collection site ID, sample collection date, kit lot number and notes or comments related to the test. A selection of surveillance related fields are also available in which the fields are dependent on the eStick being used. All information entered is automatically saved to the results database.

^{*} Sample type and Sample ID are mandatory fields needed for the test result to be transmitted to any specified LIMS collection folder. See Run Test – Test Result screen and Settings screen.

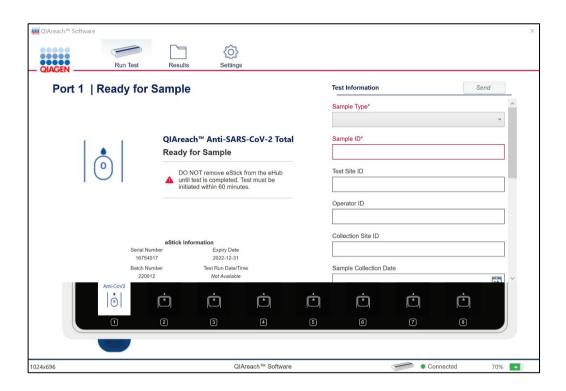


Figure 5. Ready for Sample screen. For information related to which QIAreach tests are supported by QIAreach Software version 1.3.0, please contact your local QIAGEN representative.

4.2.3 Run Test – Analysis screen

Workflow prompts will be displayed on the Run Test screen until the sample is added to the eStick. The sample must be added within 60 minutes or an error code will be displayed and the eStick is invalid. Once the eStick detects the sample, sample processing begins and a test countdown timer is displayed on the screen (Figure 4). Do not remove the eStick from the QIAreach eHub until a result is displayed. Other QIAreach eHub ports may be used and samples may be run simultaneously for all available QIAreach eHub ports.

Note: eStick sample detection can take up to one minute.

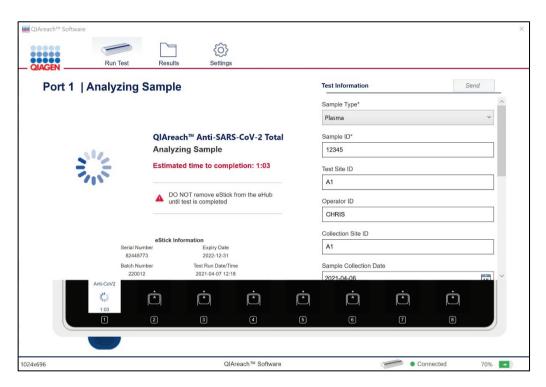


Figure 6. Analyzing Sample screen. For information related to which QIAreach tests are supported by QIAreach Software version 1.3.0, please contact your local QIAGEN representative.

4.2.4 Run Test – Test Result screen

After the test has been completed, the result is automatically saved to the Results folder and shown on both the QIAreach eHub display as well as the test run window screen of the QIAreach Software (Figures 5 and 6). If mandatory fields are populated, the Send button will be enabled and test results can be sent to the specified LIMS collection folder (Figure 5).

To view the individual test report, click Print Result.

Important: After a test is sent to the LIMS collection folder, the result is locked and can no longer be edited. A message appears to inform users that the result is locked. This message can be disabled for subsequent test results. You can re-enable the message in the Settings screen.

If the QIAreach test has been previously run without the use of the QIAreach Software, test information can still be added to the eStick by connecting the used eStick to the QIAreach eHub. The Test Result screen is automatically displayed and you can specify the applicable sample and run, and surveillance information.

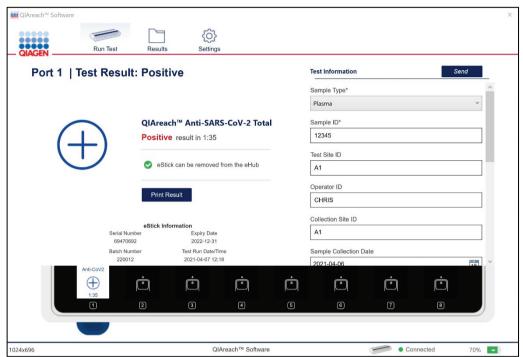


Figure 7. Positive Test Result screen. For information related to which QIAreach tests are supported by QIAreach Software version 1.3.0, please contact your local QIAGEN representative.



Figure 8. Individual Test Report. For information related to which QlAreach tests are supported by QlAreach Software version 1.3.0, please contact your local QlAGEN representative.

4.2.5 Results screen

The Results screen is accessible even without a connected QIAreach eHub. The results database displays test results for all completed QIAreach test eSticks that are connected to a QIAreach eHub while the software is in use. Click Results to access the results database. The results can be filtered using the filter options on top of the database header row. This screen also shows tests that failed to complete and their associated error codes.

To display a test report, double-click an individual test result in the results database. If the eStick is still inserted, the screen is redirected to the Run Test screen. If the eStick is removed, the individual test report print page will be displayed.

Status icons indicate the transmission status of results to the LIMS collection folder. Only successful test results will be sent to the LIMS collection folder. Tests that failed to complete and show an error code will not be transmitted.

Table 3. Transmission status icons

Icon	Status	Description
	Draft saved	New results record are created and saved but still editable to add test information.
	Pending Transmission	Result is no longer editable and waiting for transmission to LIMS folder.
	Sent	Result is successfully sent to LIMS folder.
×	Sending failed	An error occurred in the transmission of the results file.

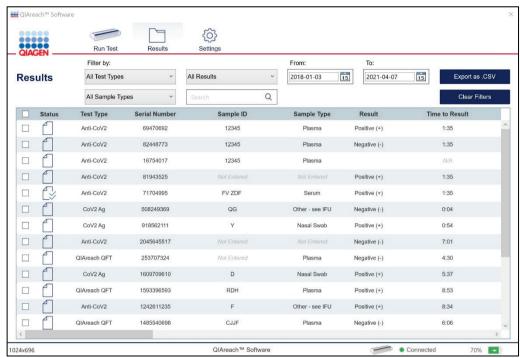


Figure 9. Results Database screen. For information related to which QIAreach tests are supported by QIAreach Software version 1.3.0, please contact your local QIAGEN representative.

The user can export results which can then be imported into an external spreadsheet application such as Microsoft Excel®.

To export results, select Export as.csv as seen in the Results screen (Figure 7).

All results in the database will be exported as a default setting. If a filter or selection is applied, only the results that are selected by the filter and/or selection checkboxes will be exported.

Note: The optional step of exporting data is not required to obtain QlAreach results. It can be employed by the user for pooling and trending data. Take care when pasting data into spreadsheet programs, due to the possibility of the spreadsheet's default formatting affecting the presentation of the data.

4.2.6 Settings screen

The Settings screen show the existing QIAreach Software and QIAreach eHub software versions.

The LIMS collection folder path is where transmitted results are sent for collection by the LIMS. To define the LIMS collection folder, specify the path, then click Save.

Note: If the path entered is invalid or inaccessible, an error message is indicated.

The following options are available in the Settings screen:

- Enable or disable the warning message when sending result files
- Change the software language

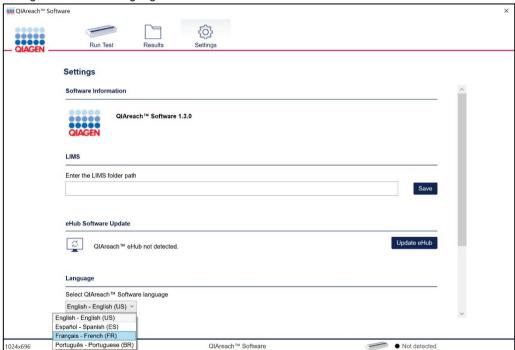


Figure 10. Settings screen.

The Settings screen also provides an option to update the eHub software when a newer version becomes available. Software updates are available in the QIAreach product webpage at **www.qiagen.com**. For more information about eHub software updates, see QIAreach eHub software upgrade.

5 Troubleshooting

5.1 Contacting QIAGEN Technical Services

Whenever you encountered a QIAreach Software error, ensure that you have the following information at hand:

- Software version
- Sample input material
- Detailed description of the error situation

This information will help you and your QIAGEN Technical Service Specialist to deal most efficiently with your issue.

Note: Information about the latest software and protocol versions can be found at www.qiagen.com. In some cases, updates may be available for addressing specific problems.

5.2 Sending log files to QIAGEN Technical Services

To send log files to QIAGEN Technical Services:

- 1. On your computer, open Windows File Explorer.
- 2. Click the View tab.
- 3. In the Show/hide section, ensure that the Hidden items box is checked.
- 4. Navigate to this folder path:
 - C:\ProgramData\Qiagen\QIAreachSoftware\Logs
- 5. Attach the log files to your email and send to QIAGEN Technical Services.

6 Technical Specifications

6.1 Common tasks in QIAreach Software

Refer to this table for the steps on how to perform the common tasks in QIAreach Software:

Table 4. Common tasks in QIAreach Software

Tasks	Steps	
Data Annotation	1. Ensure that test is started.	
	2. Specify the data in Test Information section.	
Barcode Data Entry	1. Ensure that test is started.	
	2. Connect the barcode scanner to a computer's USB port.	
	3. Select the corresponding data entry field in Test Information section.	
	4. Scan barcode.	
Data Transfer	 Ensure that the LIMS folder path is specified and saved in the Settings window. 	
	2. Ensure that all required data annotation is specified.	
	3. Ensure that test is completed.	
	4. Click Send.	
Data Annotation for used eStick	1. Insert used eStick.	
	2. Navigate to the Results page.	
	3. Select the test result for the corresponding eStick serial number.	
	4. Double-click the result to open and start annotation.	
Create a backup of the database	5. On your computer, open Windows File Explorer.	
	6. Click the View tab.	
	7. In the Show/hide section, ensure that the Hidden items box is checked.	
	8. Navigate to this folder path:	
	$C: \label{local-condition} C: \label{local-condition} C: \label{local-condition} O: \label{local-condition} C: \label{local-condition} C: \label{local-condition} O: \label{local-condition} C: local-con$	
	9. Create a copy of the Blobs database file to a secure location.	

Table continued on next page

Table continued from previous page Table 4. Common features in QIAreach Software (cont'd)

Tasks	Steps	
Restore software data from database backup	1. On your computer, open Windows File Explorer.	
Баскор	2. Click the View tab.	
	3. In the Show/hide section, ensure that the Hidden items box is checked.	
	4. Navigate to this folder path:	
	C: lem:lem:lem:lem:lem:lem:lem:lem:lem:lem:	
	5. If you have previously created a backup of the database file, navigate	
	to the location where you saved the backup file.	
	Note: To create a backup of the Blobs file, refer to the Create a	
	backup of the database row in this table.	
	6. Delete or rename the Blobs.db file. For example, rename the file to	
	Blob.db.old.	
	7. Copy and paste the backup file you created to this folder:	
	$C: \label{lem:condition} C: lem:condi$	
	8. Restart the software.	
Create shared folder on LAN	Refer to Host Interface Specification available at www.qiagen.com	
Create LIMS parser	Refer to Host Interface Specification available at www.qiagen.com	

7 Ordering Information

Product	Contents	Cat. no.
QIAreach Software	N/A	1118894
Related Products		

For related product availability in your region, please contact local QIAGEN representative.

For up-to-date licensing and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Services or your local distributor.

8 Document Revision History

Date	Changes
R1, September 2020	Initial release
R2, November 2020	Product brand name change to QIAreach Software
	Updated screenshots throughout this document
	Software version update from 1.01.0 to 1.2.0
	Updated Intended Use section to include list of QIAreach tests supported by the software
	Added information about LIMS data collection throughout this document
	Updated Results screen section to add a table for Transmission status icons
	Added Technical Data section for information about the common tasks performed in QIAreach Software
	Updated the Troubleshooting section to add instructions on how to send log files to QIAGEN Technical Services
	Layout changes
R3, May 2021	QlAreach Software version upgrade from 1.2.0 to 1.3.0
	Added Section 1.1.4 for Windows environmental settings
	Updated System Requirements (Table 2) to change monitor settings
	New feature to add option to select software languages
	Updated screen images

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Limited License Agreement for QIAreach^T Software

Use of this product signifies the agreement of any purchaser or user of the product to the following terms:

- 1. The product may be used solely in accordance with the protocols provided with the product and this handbook and for use with components contained in the kit only. QIAGEN grants no license under any of its intellectual property to use or incorporate the enclosed components of this kit with any components not included within this kit except as described in the protocols provided with the product, this handbook, and additional protocols available at www.qiagen.com. Some of these additional protocols have been provided by QIAGEN users for QIAGEN users. These protocols have not been thoroughly tested or optimized by QIAGEN. QIAGEN neither guarantees them nor warrants that they do not infringe the rights of third-parties.
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