August 2021

QIAreach® eHub User Manual

For *in vitro* diagnostic use
For Emergency Use Authorization Only
Rx Only

REF 9003063

QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden

R2 MAT 1122908EN

Sample to Insight

QIAGEN

Contents

1 Introduction 5

1.1 About this user manual 5

1.2 General Information 6

1.3 Intended use of the QIAreach eHub 7

1.4 Symbols on the QIAreach eHub 8

2 Safety Information 10

2.1 Proper use 11

2.2 Electrical safety 11

2.3 Chemical safety 11

2.4 Biological safety 11

2.5 Waste disposal 12

3 General Description 13

3.1 System description 13

3.2 QIAreach eHub description 13

4 Installation Procedures 15

4.1 Site requirements 15

4.2 QIAreach eHub delivery and components 16

4.3 Unpacking and installing the QIAreach eHub 18

5 Operating the QIAreach eHub 19

5.1 Setting up the QIAreach eHub for use 19

5.2 Running a test on the QIAreach eHub 21

5.3 Shutting down the QIAreach eHub 22

6 QIAreach eHub Functions 23

6.1 Display screen icons 23

6.2 Battery LED indicator 24

7 Maintenance 25

7.1 Cleaning the QIAreach eHub after use 25

8 Troubleshooting 26

8.1 General information 26

8.2 Contacting QIAGEN Technical Services 26
8.3 QIAreach eHub error codes 26
9 Technical Specifications 32
9.1 Electromagnetic compatibility (EMC) 33
9.2 Electrical Safety 33
9.3 Cybersecurity 33
9.4 Software Validation 33
10 Appendix A – Technical Data 34
10.1 FCC Compliance: Supplier's Declaration of Conformity 34
10.2 Waste Electrical and Electronic Equipment (WEEE) 36
10.3 Disclaimer of warranties 36
11 Ordering Information 37
12 Document Revision History 38

1 Introduction

This manual describes how to operate the QIAreach eHub (also referred to as eHub herein). Before using the QIAreach eHub, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

1.1 About this user manual

This user manual provides information about QIAreach eHub in the following sections:

- Introduction
- Safety Information
- General Description
- Installation Procedures
- Operation
- System Functions
- Maintenance
- Troubleshooting
- Technical Specifications

The Appendix section contains the following information:

- Declaration of Conformity
- Waste Electrical and Electronic Equipment (WEEE)
- Disclaimer of warranties

1.2 General Information

This product has not been FDA cleared or approved but has been authorized for emergency use for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform moderate or high complexity tests.

This product has been authorized only for use with EUA-authorized QIAreach tests, and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1)of the Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.

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 QIAreach eHub or QIAGEN products in general, do not hesitate to contact us.

For technical assistance and more information, please see our Technical Support Center at www.qiagen.com/support/technical-support or call one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit www.qiagen.com).

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

- QIAreach eHub serial number
- Test type and test kit lot number
- Error code (if applicable)
- Timestamp when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Photo of error, if possible

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.

In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

1.3 Intended use of the QIAreach eHub

The QIAreach eHub is intended for use in conjunction with QIAreach Tests. QIAreach technology on the digital detection eStick provides diagnostic results that are displayed to the user on the QIAreach eHub visual display.

The QIAreach eHub and QIAreach Tests are intended for professional use only and not intended for self-testing. The QIAreach Tests are for in vitro diagnostic use, for Emergency Use Authorization Only, and for prescription use only.

1.3.1 Limitations of use

- The QIAreach eHub can only be used with eSticks according to the instructions contained in this user manual and in the Instructions for Use for the QIAreach Tests.
- When powering the QIAreach eHub or connecting to a computer, use only the USB cable supplied with this product.
- When charging the QIAreach eHub, use only the USB charger and USB cable supplied with this product.
- The QIAreach eHub should only be operated on a flat, horizontal surface with no angles or tilts.
- Do not re-run an eStick if it has already been used successfully or if it has been associated with an error or an incomplete run.
- Ensure that the QIAreach eHub is positioned away from any air conditioning outlets, heaters, or sources of intense light.
- Do not move the QIAreach eHub while a test is running.
- Do not remove an eStick from the QIAreach eHub before the run has completed.

1.4 Symbols on the QIAreach eHub

The following symbols may appear on the packaging or labelling.

Symbol	Location	Description
	Type plate and outer box label of the QIAreach eHub	CE mark
	Type plate on the bottom of the QIAreach eHub	FCC Mark
	Type plate and outer box label of the QIAreach eHub	WEEE Mark for Europe
	Type plate and outer box label of the QIAreach eHub	Legal Manufacturer
	Type plate and outer box label of the QIAreach eHub	Catalog Number
	Type plate and outer box label of the QIAreach eHub	Serial Number
	Type plate and outer box label of the QIAreach eHub	Global Trade Item Number
	Outer box label of the QIAreach eHub	Fragile
	Type plate and outer box label of the QIAreach eHub	Electrical Safety Regulatory Compliance Mark (Australia and New Zealand)
	Type plate and outer box label of the QIAreach eHub	Consult Instructions for Use

	Type plate and outer box label of the QIAreach eHub	Attention

2 Safety Information

Before using the QIAreach eHub, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the QIAreach eHub and to maintain a safe working condition.

Possible hazards that could harm the user or result in damage to the instrument are clearly stated at the appropriate places throughout this user manual.

If the QIAreach eHub is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

The following types of safety information appear throughout the *QIAreach eHub User Manual*.

WARNING 	The term WARNING is used to inform you about situations that could result in personal injury to you or others. Details about these circumstances are given in a box like this one.

CAUTION 	The term CAUTION is used to inform you about situations that could result in damage to the QIAreach eHub or to other equipment. Details about these circumstances are given in a box like this one.

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 normal safety requirements prevailing in the user's country.

2.1 Proper use

- Use the QIAreach eHub according to this user manual. We recommend you carefully read and become acquainted with the Instructions for Use before running a QIAreach Test.
- Improper use of the QIAreach eHub may cause personal injuries or damage to the QIAreach eHub.
- The QIAreach eHub must only be operated by qualified and appropriately trained QIAGEN personnel.

2.2 Electrical safety

Observe all general safety precautions that apply to electrical instruments. This device has been tested for compliance with electrical safety requirements as per IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.

WARNING/ CAUTION 	Do not open the QIAreach eHub. No user-serviceable parts inside. (W1) Opening of the QIAreach eHub device could lead to user injury or damage of the device.

2.3 Chemical safety

Safety Data Sheets (SDSs) for QIAreach Tests kit materials are available and can be requested from QIAGEN. Used eSticks should be disposed of in accordance with all national, state, and local health and safety regulations and laws.

2.4 Biological safety

Samples tested on the QIAreach eHub may contain infectious agents. Users should be aware of the health hazard presented by such agents and should use, store and dispose of such samples according to the required safety regulations. Wear personal protective equipment when handling reagents or samples, and wash hands thoroughly thereafter.

Always observe safety precautions as outlined in relevant guidelines. Avoid contamination of the QIAreach eHub and workspace by handling samples and eSticks with care. In the event of contamination, clean and decontaminate the affected area of the QIAreach eHub.

For instructions on cleaning and decontaminating the QIAreach eHub, see Maintenance.

2.5 Waste disposal

For disposal of waste electrical and electronic equipment (WEEE), see Waste Electrical and Electronic Equipment (WEEE).

3 General Description

3.1 System description

The QIAreach eHub, in combination with eSticks, provides a simplified workflow for multiple in vitro diagnostic tests, using state-of-the-art nanoparticle fluorescence detection technology. The eSticks are single-use tests that include a lateral flow strip and optoelectronics that perform test measurements and interpret results. The QIAreach eHub provides power to the eStick to run the test when the eStick is connected to any one of the eHub-eStick ports. The QIAreach eHub visually communicates test progress and results to the user via a display screen specific to each QIAreach eHub port.

Optional QIAreach software is not provided with the QIAreach eHub and can be purchased separately from Qiagen (Catalog # 1118894). The QIAreach eHub will transmit test information and results when connected to a computer running QIAreach software.

3.2 QIAreach eHub description

The QIAreach eHub is a connection hub that provides power to perform multiple QIAreach Tests simultaneously. The QIAreach eHub is connected to a power source using the provided connection cable and features a rechargeable lithium battery to allow QIAreach Tests to be performed when a continuous power supply is not available. QIAreach Test results are interpreted on the eStick firmware, and results are transmitted to the QIAreach eHub which then communicates to the user by means of a visual display.

The QIAreach eHub USB charger and USB cable allow the QIAreach eHub to be powered from either an electrical outlet or from a computer equipped with USB ports. Use of the optional QIAreach software (Catalogue# 1118894) requires the QIAreach eHub to be connected to a computer. For instructions on how to use the software, refer to the QIAreach software user guide (available separately),

The QIAreach eHub includes the following elements:

- eStick connection ports for up to eight (8) separate tests
- Visual display screen centered above each individual eStick connection port
- QIAreach processing tube holder slot positioned directly behind each visual display screen
- Sample tube holder slot positioned directly behind each processing tube holder slot, to be used for applicable tubes sizes for specific test type.

- USB-C port for connection to a USB charger (supplied) or computer
- Battery LED indicator

Figures 1 and 2 show the location of various QIAreach eHub features.

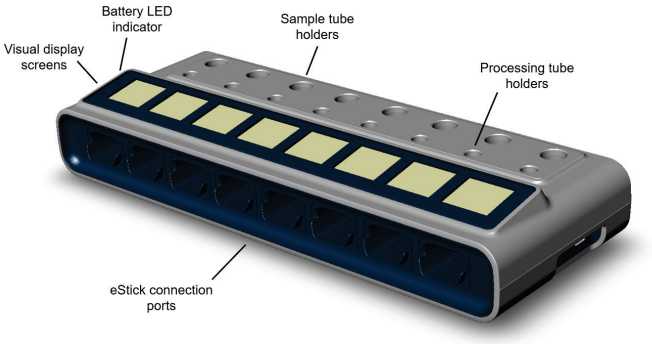


Figure 1. Front view of QIAreach eHub.

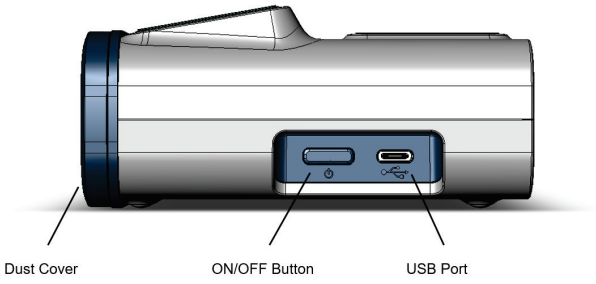


Figure 2. Side view of QIAreach eHub.

4 Installation Procedures

4.1 Site requirements

Select a flat, dry, and clean workbench space for the QIAreach eHub. Make sure that the space is free of excessive moisture and dust, protected from direct sunlight, large temperature fluctuations, heat sources, vibration and electrical interference. Refer to Section 9 for the weight and dimensions of the QIAreach eHub and the correct operating conditions (temperature and humidity). There should be sufficient clearance on the workbench to allow unimpeded access to the eStick connection ports, USB port, and ON/OFF button.

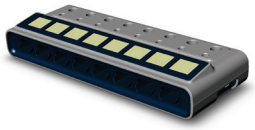
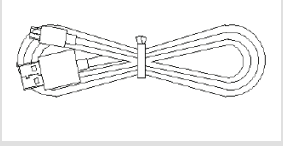
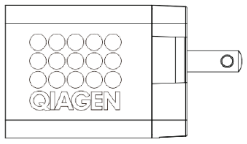
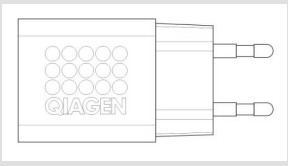
Note: Before installing and using the QIAreach eHub, see Operating the to become familiar with the QIAreach eHub operating conditions.

CAUTION 	Do not place the QIAreach eHub in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation. For more information, see FCC Compliance: Supplier's Declaration of Conformity. (C2)

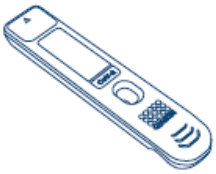
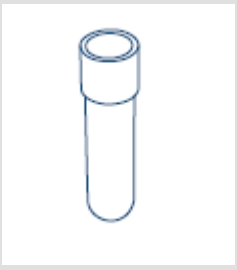
4.2 QIAreach eHub delivery and components

The QIAreach eHub is delivered in a single box and includes all the necessary components for setting up and connecting the QIAreach eHub. The contents of the box are described below:

Note: QIAreach Tests kits (sold separately) are required to perform testing on QIAreach eHub devices.

Components	Description
	1x QIAreach eHub
	1x Dust cover
	1x USB-C – USB-A Cable, 1.5m length
	1x USB Charger Power adapter with region specific plugs
	1x USB Charger Power adapter with fixed EU plug

The following components are required for testing but are provided separately in the QIAreach Anti-SARS-CoV-2 Total Test kit (Cat# 645033) and for the QIAreach SARS-CoV-2 Antigen Test (Cat # 646533).

Components	Description
	QIAreach eStick
	QIAreach Processing Tube
	QIAreach Diluent Buffer

4.3 Unpacking and installing the QIAreach eHub

The QIAreach eHub is delivered ready for use and does not require any hands-on assembly procedures.

Remove the QIAreach eHub from its delivery box and place on a flat, level surface.

The QIAreach eHub should be charged prior to use. To charge the QIAreach eHub, connect the USB cable from the QIAreach eHub USB port to either the supplied power adapter or to a computer.

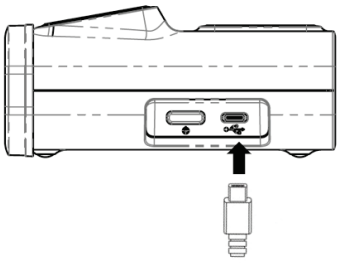


Figure 3. Connecting the USB cable to the QIAreach eHub USB port.

Note: The QIAreach eHub will charge more quickly when charged through the supplied USB charging adapter, compared to when it is charged through a computer USB port.

The QIAreach eHub comes with a dust cover to protect the internal ports from dust buildup and contamination. The cover should always be placed over the front panel of the QIAreach eHub when not in use. When ready to operate the QIAreach eHub, the dust cover can be removed from the front panel and set aside.

5 Operating the QIAreach eHub

5.1 Setting up the QIAreach eHub for use

1. Remove the dust cover from the front panel of the QIAreach eHub and set aside.

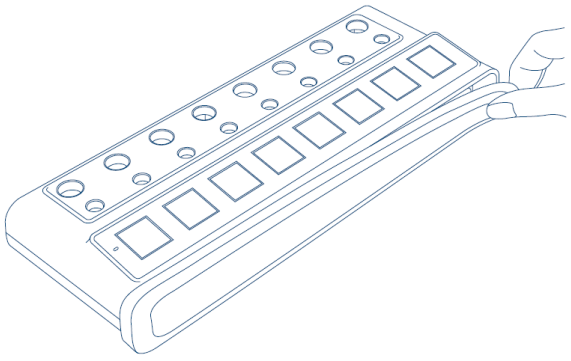


Figure 4. Removing the dust cover from the front of QIAreach eHub prior to use.

2. Ensure that the provided USB cable is connected to the QIAreach eHub and an adequate power source (power outlet or computer).

   Note: We recommend to fully charge the QIAreach eHub in a switched off state overnight (when not in use). We also recommend that you connect the QIAreach eHub to a USB power source (either a USB adapter or computer) during operation. If testing is performed without the use of associated QIAreach software, then we recommend connecting the QIAreach eHub to a power outlet (if available) through the provided USB power adapter and USB cable.

3. To turn on the QIAreach eHub, press ON/OFF on the side of the unit until the visual display screen lights up.

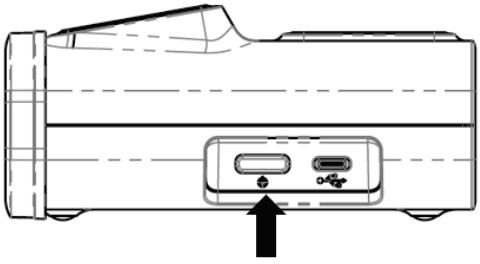


Figure 5. Press the ON/OFF switch to turn on the QIAreach eHub.

4. Check battery LED indicator to ensure that the QIAreach eHub has sufficient charge for the test operation. For different battery LED indicator states, see Battery LED indicator.

5. Once the QIAreach eHub is ready for use, the visual display screen above each available eStick connection port will display the “Insert eStick” icon shown below.

Figure 6. Insert eStick icon. This signifies that an QIAreach eHub port is available for use.

5.2 Running a test on the QIAreach eHub

Important: The steps described in this section are general test workflow cues provided on the QIAreach eHub visual display screen. Refer to the QIAreach Tests Instructions for Use for instructions on performing a test with the QIAreach eHub.

Note: Each of the connection ports on the QIAreach eHub operates separately. Up to eight (8) QIAreach Anti-SARS-CoV-2 Total tests can be run simultaneously.

1. When an eStick has been inserted in an eHub-eStick connection port, the self-test icon will be displayed while the eStick performs a self-test.

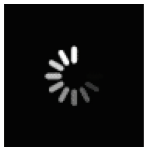


Figure 7. Self-test screen display.

2. Once the eStick self-test has successfully completed, the "Add sample" icon will be displayed, signifying the eStick is ready for sample addition.

Figure 8. Add sample screen display.

3. After the test sample has been added to the eStick, the "Processing" icon will be displayed along with a test countdown timer.

   Important: The eStick must not be removed from the QIAreach eHub until the test has been completed.

Figure 9. Processing screen display and countdown timer.

4. Once the QIAreach Test has completed, the test result will be displayed on the screen and the eStick can be safely removed.

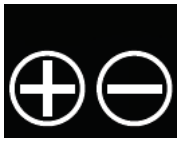


Figure 10. Test result screen.

5. If an error occurs during the test, the error icon will appear along with a specific error code. Refer to the Troubleshooting section of this manual for more information.

Figure 11. Error icon and associated error code.

5.3 Shutting down the QIAreach eHub

After use, the QIAreach eHub should be turned off by pressing the ON/OFF button. The QIAreach eHub battery will continue to charge when turned off if connected to a power source.

After each use, clean the QIAreach eHub according to the instructions in Cleaning the QIAreach eHub after use.

Replace the dust cover on the front panel of the QIAreach eHub to protect the eStick connection ports from moisture and dust.

6 QIAreach eHub Functions

6.1 Display screen icons

Table 1. Display screen icons

Icon	ID	Description
	Please Insert	The QIAreach eHub port is available for eStick use.
	Self-test	The eStick has been inserted and a self-test is being performed.
	Add sample	The eStick is ready for sample addition to the detection port. The sample must be added within 60 minutes of removing the eStick from the foil packaging.
	Processing	The eStick has detected sample and is processing the test. A test countdown timer is displayed. Do not remove the eStick until a result is displayed. Test times may vary across Access products.
	Positive (varies with test)	The test has returned a positive result.
	Negative (varies with test)	The test has returned a negative result.
	Error	The test has encountered an error. The letter denotes the type and the numbers are code for the error. Refer to the Troubleshooting section for more information.

6.2 Battery LED indicator

If not connected to a power source, the QIAreach eHub should have sufficient battery power to complete all in-progress QIAreach Tests. A fully charged QIAreach eHub should maintain internal battery power for at least 8 hours. QIAreach tests should not be performed if the battery power is less than 10% and is not connected to a power source. The battery level can be checked by connecting the QIAreach eHub to a computer through the provided USB cable and launching the software. The software displays the level of battery charge in the bottom right hand corner of the screen. The battery level is also indicated by the various battery LED states listed below.

Table 2. Battery levels

Display	LED state	Meaning
None	off	The QIAreach eHub is off
	Flashing green	Battery charging in progress
	Solid green	The QIAreach eHub is turned on, battery charge > 50%
	Solid amber	The QIAreach eHub is turned on, battery charge 10 – 50%
	Solid red	The QIAreach eHub is turned on, battery charge < 10%
	Flashing red	The QIAreach eHub is turned on, battery fault

7 Maintenance

The QIAreach eHub does not require any service maintenance or calibration.

7.1 Cleaning the QIAreach eHub after use

WARNING/ CAUTION 	Risk of personal injury and material damage Disconnect the QIAreach eHub from all power sources before cleaning. Ensure the QIAreach eHub is turned off before cleaning.	(W2) (C3)

CAUTION 	Risk of damage to the QIAreach eHub When cleaning, avoid any deliberate water ingress into the eStick connection ports.	(C4)

CAUTION 	Risk of damage to the QIAreach eHub Avoid the use of excessive volumes of liquid that could enter the interior of the unit when cleaning the QIAreach eHub.	(C5)

Only use the following materials to clean the QIAreach eHub exterior surfaces:

- Mild detergent
- Water

When cleaning the QIAreach eHub surface:

- Wear laboratory gloves, coat, and protective glasses.
- Wet a paper towel in mild detergent and wipe down the QIAreach eHub surface and the surrounding workbench area. Take care not to intentionally wet the eStick connection ports or ON/OFF button and USB port.
- Dry the QIAreach eHub surface with a fresh paper towel.

8 Troubleshooting

8.1 General information

This section provides information on some issues that may occur with the QIAreach eHub along with possible causes and solutions. Specific information may vary with QIAreach Tests. For troubleshooting relevant to specific QIAreach Tests, see the kit instructions for use.

8.2 Contacting QIAGEN Technical Services

When contacting QIAGEN Technical Services about an error with the QIAreach eHub, note the steps leading up to the error. This information will help QIAGEN Technical Services solve the problem.

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

- QIAreach eHub serial number
- Test type and test kit lot number
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Photo of error, if possible

8.3 QIAreach eHub error codes

If the QIAreach eHub displays an error code, refer to the table below specific error descriptions and solutions.

Table 3. QIAreach eHub error codes categories – general description

Error type	Error code format	**Description**
Self-Test	A-[Error code]	eStick electronic failure
Algorithm	B-[Error code]	Run error or user workflow error
Communication/ Other	C-[Error code]	Invalid data or missed communication between eStick and eHub

Table 4. "A" error codes

Error code	Description	**Recommended action**
A-1	Used eStick	Discard and use new eStick.
A-2	Metadata error	Discard and use new eStick.
A-4	Metadata error	Discard and use new eStick.
A-8	Voltage Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-16	Voltage Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-32	Voltage Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-64	Voltage Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-128	Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-256	Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-512	Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-1024	Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-2048	LED Current Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.

Table continued on next page

Table continued from previous page

Table 4. "A" error codes (cont'd)

Error code	Description	**Recommended action**
A-4096	LED Current Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-8192	LED Current Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-16384	LED Current Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-32768	Dark Frequency Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick.
A-65535	Unknown value	Remove and re-insert the eStick. If error persists, discard and use new eStick.

Table 5. "B" error codes

Error code	Description	**Recommended action**
B-0	No result	Discard and use new eStick.
B-8	Conjugate Wave Too Early	Ensure eStick is inserted prior to adding sample. Discard and use new eStick.
B-9	Conjugate Wave Too Early	Check sample color and/or viscosity*. Discard and use new eStick.
B-10	High Dark Frequency	Ensure test is run out of sunlight. Discard and use new eStick.
B-12	No Frequency	Discard and use new eStick.
B-13	No Frequency	Discard and use new eStick.
B-14	Sample not detected	Check sample color and/or viscosity*. Run test within 60 minutes of removing eStick from foil. Discard and use new eStick.
B-15	Frequency Out of Range	Discard and use new eStick.
B-16	Low Frequency	Ensure sample is mixed in processing tube prior to adding test sample. Discard and use new eStick.
B-17	High Frequency	Discard and use new eStick.
B-18	Frequency Out of Range	Discard and use new eStick.
B-19	Low Frequency	Ensure sample is mixed in processing tube prior to adding test sample. Discard and use new eStick.
B-21	Peak Data Failure	Check sample color and/or viscosity*. Discard and use new eStick.
B-22	Result Timeout	Discard and use new eStick.
B-23	Baseline Issue	Discard and use new eStick.
B-24	Baseline Issue	Discard and use new eStick.
B-25	Signal Noise	Discard and use new eStick.
B-255	Test Removed Early	Wait for test completion before removing eStick. Discard and use new eStick.

* See Troubleshooting Guide section of applicable kit Instructions for Use for further instructions.

Table 6. "C" error codes

Error code	Description	**Recommended action**
C-0	Connection Error	Remove and re-insert the eStick. If error persists, discard and use new eStick.
C-1	Expired eStick	Test is past expiry date. Use an eStick within expiration.
C-2	Sample Not Detected	Run test within 60 minutes of removing eStick from foil. Discard and use new eStick.
C-3	Start Not Acknowledged	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-4	Self Test Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-5	Metadata Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-6	Measurement Data Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-7	Measurement Data Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-8	Command Initialization Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-9	Algorithm Failure	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.

Table continued on next page

Table continued from previous page

Table 6. "C" error codes (cont'd)

Error code	Description	**Recommended action**
C-10	Unexpected Result Time	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-11	eStick Timeout	Run test within 60 minutes of removing eStick from foil. Discard and use new eStick.
C-12	Test Removed Too Early	Wait for test completion before removing eStick. Discard and use new eStick.
C-13	Connection Error	Remove and re-insert the eStick. If error persists, discard and use new eStick. If error persists with new eStick, discontinue use of eHub port.
C-14	eHub Low Battery	Charge eHub or connect to main power prior to repeating test. Remove and re-insert the eStick. If error persists, discard and use new eStick.
C-15	eHub Internal Error	The eHub can no longer be used. Contact QIAGEN Customer Support.
C-16	eHub RTC Failure	The eHub can no longer be used. Contact QIAGEN Customer Support.

9 Technical Specifications

Dimensions and weight

Dimensions	Width: 304 x 112 x 51 mm (12 x 4.4 x 2 in)
Weight	1000 g (2.2 lb)

Power requirements

EU and Interchangeable AC input plug USB Charger Power Adapter (supplied)

Voltage	90–264 VAC
Power	0.4A max
Frequency	50–60 Hz
Line regulation	± 1%
Load regulation	± 5%
Line Frequency Variation	± 3 Hz

QIAreach eHub device:

Voltage	5V DC
Power	1.0A

Internal Li-Ion battery (non user-seviceable):

- Voltage: 3.7V nominal
- Capacity: 3350 mAh nominal

Operating conditions

Air Temperature	15–30°C (59–86°F)
Relative Humidity	30–65% (non-condensing)
Place of Operation	For Indoor use only

Transport conditions

Air Temperature	-20–60°C (-4–140°F)
Relative Humidity	Maximum 70% relative humidity, non-condensing

Storage conditions

Air Temperature	15–30°C (59–86°F)
Relative Humidity	30–65% (non-condensing)

RoHS (Responsibility of Health and Safety) Compliance:

- Compliant with RoHS 3 EU Directive 2015/863: Restriction of the Use of certain Hazardous Substances in electrical and electronic equipment

9.1 Electromagnetic compatibility (EMC)

- Compliant with IEC 61326-1: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
- Meets the requirements of CISPR 11:2015: ISM Equipment Radiated RF Emissions as a Group 1, Class A device
- Meets the requirements of FCC Title 47 CFR Part 15 Subpart B– unintentional radiators as a Class A device

9.2 Electrical Safety

- Compliant with IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

9.3 Cybersecurity

- Negligible or acceptable failure modes or hazards identified after a failure mode and effects analysis (FMEA) of the cybersecurity risks to the test system, including the optional QIAreach software.
- Standard Windows Filesharing provides authenticated and encrypted communication.

9.4 Software Validation

- Compliant with ISO 62304: Software verification of the QIAreach software has been done in accordance with the Ellume Quality System Design Control Procedures and ISO 62304 on both the 32-bit and 64-bit version.

10 Appendix A – Technical Data

10.1 FCC Compliance: Supplier's Declaration of Conformity

47 CFR § 2.1077 Compliance Information

Unique Identifier: 9003063 – QIAGEN QIAreach eHub

Responsible Party – U.S. Contact Information

QIAGEN Inc. - USA

19300 Germantown Road

Germantown, MD 20874

Telephone: (800-362-7737)

Email: customercare-us@qiagen.com

FCC Compliance Statement

This product has been tested and found to comply with the limits for a Class A digital device pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the manufacturer's instruction manual, may cause harmful interference with radio communications. Operation of this product in a residential area is likely to cause harmful interference, in which case you will be required to correct the interference at your own expense.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause harmful interference.

2) This device must accept any interference received, including interference that may cause undesired operation.

Notice: The FCC regulations provide that changes or modifications not expressly approved by QIAGEN, Inc. could void your authority to operate this equipment.

These limits are designed to provide reasonable protection against harmful interference in a non-residential installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with radio or television reception, which can be determined by turning the equipment off and on, you are encouraged to try to correct the interference by one or more of the following measures:

• Reorient or relocate the antenna of the radio/television receiver.

• Increase the separation between this equipment and the radio/television receiver.

• Plug the equipment into a different outlet so that the equipment and the radio/television receiver are on different power mains branch circuits.

• Consult a representative of QIAGEN or an experienced radio/television technician for additional suggestions.

In order to maintain compliance with FCC regulations, this equipment must be used with the supplied USB cable and USB Charger. Operation with non-approved equipment or alternate cables may result in interference to radio and TV reception.

10.2 Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.

Recycling can be provided by QIAGEN upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements and where a replacement product is being supplied by QIAGEN, free recycling of its WEEE-marked electronic equipment is provided.

To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

10.3 Disclaimer of warranties

EXCEPT AS PROVIDED IN QIAGEN TERMS AND CONDITIONS OF SALE FOR THE QIAREACH EHUB, QIAGEN ASSUMES NO LIABILITY WHATSOEVER AND DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY RELATING TO THE USE OF THE QIAREACH EHUB INCLUDING LIABILITY OR WARRANTIES RELATING TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF ANY PATENT, COPYRIGHT, OR OTHER INTELLECTUAL PROPERTY RIGHT ANYWHERE IN THE WORLD.

11 Ordering Information

Product	Contents	Cat. no.
QIAreach eHub	Includes 1 QIAreach eHub; 1 USB charging cable; 2 power adapters; 1 QIAreach eHub dust cover	9003063
Optional QIAreach Software	N/A	1118894

For up-to-date licensing information 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.

12 Document Revision History

Date	Changes
R1, May 2021	Initial release
R2, August 2021	Addition of QIAreach SARS-CoV-2 Antigen Test

Limited License Agreement for QIAreach eHub

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.
2. Other than expressly stated licenses, QIAGEN makes no warranty that this kit and/or its use(s) do not infringe the rights of third-parties.
3. This kit and its components are licensed for one-time use and may not be reused, refurbished, or resold.
4. QIAGEN specifically disclaims any other licenses, expressed or implied other than those expressly stated.
5. The purchaser and user of the kit agree not to take or permit anyone else to take any steps that could lead to or facilitate any acts prohibited above. QIAGEN may enforce the prohibitions of this Limited License Agreement in any Court, and shall recover all its investigative and Court costs, including attorney fees, in any action to enforce this Limited License Agreement or any of its intellectual property rights relating to the kit and/or its components.

For updated license terms, see www.qiagen.com.