

May 2023

QIAreach[®] SARS-CoV-2 Antigen Test Instructions for Use (Handbook)

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

Version 1

IVD

REF



R5 **MAT**

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Intended Use

The QIArearch® SARS-CoV-2 Antigen Test is a rapid, digital lateral flow assay, using nanoparticle fluorescence, intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in nasopharyngeal (NP) and anterior nasal (AN) swab specimens collected in COPAN® Diagnostic Universal Transport Medium® (UTM-RT®) from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset when tested at least twice over three days, with at least 48 hours in between tests. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate and high complexity tests.

The QIArearch® SARS-CoV-2 Antigen Test does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses, and the agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results should be treated as presumptive, and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures, such as isolating from others and wearing masks. Negative results

should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The QIAreach SARS-CoV-2 Antigen Test is only to be used with the QIAreach eHub.

The QIAreach SARS-CoV-2 Antigen Test is intended for use by trained clinical laboratory personnel specifically instructed on *in vitro* diagnostic procedures. The QIAreach SARS-CoV-2 Antigen Test is for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Summary and Explanation of the Test

COVID-19 (coronavirus disease 2019) is the disease caused by SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) viral infection.¹ The virus is transmitted from asymptomatic, symptomatic, and presymptomatic²⁻⁵ individuals via respiratory droplets, aerosols, and upper respiratory (tract) secretions.⁶⁻⁷ The incubation period is estimated to be 4.6–5.8 days with a median of ~5 days.⁸ The symptoms of COVID-19 are non-specific, ranging from asymptomatic to severe pneumonia and death.⁹ Fever and cough are the most common clinical symptoms but also include shortness of breath, fatigue, muscle aches, headache, new loss of smell or taste, sore throat, congestion or runny nose, diarrhea, and vomiting, which typically appear between 2–14 days following exposure to the virus.⁹⁻¹¹ Roughly 20% of those infected with SARS-CoV-2 will experience severe symptoms, including Acute Respiratory Distress Syndrome (ARDS) that often requires mechanical ventilation.¹²

The standard medical practice for definitive diagnosis of active SARS-CoV-2 infection relies on the molecular detection of viral RNA using real-time reverse transcriptase-polymerase chain reaction (RT-PCR).¹³⁻¹⁶ The QIAreach SARS-CoV-2 Antigen Test detects nucleocapsid protein of SARS-CoV-2 and is a rapid *in vitro*

diagnostic test for acute infection in populations of interest. The clinical and public health applications of antigen detection assays may include support to the clinical assessment of persons presenting with symptoms, or asymptomatic persons at high-risk of infection and to guide contact tracing, treatment options, and isolation requirements of afflicted individuals that help to mitigate the spread of the virus in the community.¹⁷

Principles of the assay

The QIArearch SARS-CoV-2 Antigen Test is a rapid, digital lateral flow diagnostic assay that detects nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab (NPS) and anterior nasal swab (ANS) specimens in collected Copan Diagnostic Universal Transport Medium (UTM-RT), hereinafter referred to as transport medium (TM) samples, from individuals who are suspected of COVID-19 by healthcare professionals or who are at high risk of SARS-CoV-2 infection.

Viral antigen detection is measured on a single-use, lateral flow, digital detection cartridge (eStick) via nanoparticle fluorescence. The eStick contains optoelectronic technology and a microprocessor that converts a fluorescent signal into a qualitative readout for the presence of SARS-CoV-2 specific antigen in patient test samples.

The QIArearch SARS-CoV-2 Antigen Test is performed by inserting the QIArearch SARS-CoV-2 Antigen eStick into a QIArearch eHub (sold separately). The QIArearch eHub is a connection hub that provides power to perform multiple QIArearch SARS-CoV-2 Antigen Tests simultaneously. The eHub acts as a power source and features a rechargeable lithium battery to allow QIArearch SARS-CoV-2 Antigen Tests to be performed when a continuous power supply is not available.

To perform the test, QIArearch SARS-CoV-2 Antigen Diluent Buffer is first added to the QIArearch SARS-CoV-2 Antigen Processing Tube and resolubilizes fluorescent-

nanoparticle conjugated detection SARS-CoV-2 nucleocapsid antibody that is spray-dried on an immobilized accretion pad within the tube. Patient TM sample is then added to the Processing Tube and mixed with the resuspended conjugate. If SARS-CoV-2 nucleocapsid (N) antigens are present in the sample, they will bind to the conjugate. The sample is then transferred from the Processing Tube to the eStick sample port.

Once in the eStick, the test sample migrates on a nitrocellulose membrane and across the test line where the immobilized SARS-CoV-2 capture antibody resides. If SARS-CoV-2 antigen is present in the TM sample, the migrating SARS-CoV-2 antigen bound to the fluorescent nanoparticle conjugated detection SARS-CoV-2 nucleocapsid antibody will bind to the SARS-CoV-2 antibody immobilized at the test line and a fluorescent signal is measured on a photosensor in the eStick. The photosensor will detect light emitted from the fluorescent nanoparticles in the presence of excitation light filtered onto the test line. Signal is interpreted on the eStick firmware and transmitted to the eHub, which then communicates a positive or negative test result to the user by means of a visual display.

QIAreach SARS-CoV-2 Antigen Test results are determined as Positive or Negative according to the assay result algorithm on the eStick firmware.

Optional use of the software is available to backup test results, generate test reports, and support data transfer.

Time required for performing the assay

The time required to perform the QIAreach SARS-CoV-2 Antigen Test is estimated below.

- Digital detection: Approx. 2–15 minutes for one individual test (multiple tests can be run in parallel – up to 8 tests per eHub.)

Pipette use

This assay requires use of an adjustable volume pipette. Users must be proficient with pipette use prior to performing the QIArearch SARS-CoV-2 Antigen Test.

Kit Contents

QIAreacH SARS-CoV-2 Antigen Test		
Catalog number		646533
Number of tests/pack		60
QIAreacH SARS-CoV-2 Antigen Detection System Components*		
QIAreacH SARS-CoV-2 Antigen eStick	Packaged together with Processing Tube in foil wrapper Contains SARS-CoV-2 nucleocapsid antibody and bovine serum albumin	X 60
QIAreacH SARS-CoV-2 Antigen Processing Tube	Packaged together with eStick in foil wrapper Coated with SARS-CoV-2 nucleocapsid antibody, bovine serum albumin, and mouse serum	X 60
QIAreacH SARS-CoV-2 Antigen Diluent Buffer	Contains bovine serum albumin and ProClin® 300	2 x 10 ml

* See Warnings, Precautions, and Safety Information for precautions and hazard statements.

Materials Required but not Provided

- Nasal or nasopharyngeal specimen collection swabs*
- Specimen transport medium options
 - Copan Diagnostics Universal Transport Medium (UTM-RT)
- Pipette tips (Recommended 200 µl, 1000 µl tips)
- QIAreacH SARS-CoV-2 Antigen Controls (Cat. No. 646030) (as required to meet local and organizational compliance)

Equipment required but not provided

- QIAreacH eHub (Cat. No. 9003063)[†]
- Calibrated pipettes for delivery of 100 µl and 400 µl with disposable tips
- Optional: QIAreacH Software (cat. no. 1118894 and can be downloaded from www.qiagen.com)

* See **Limitations** for the list of incompatible collection swabs.

[†] See **warnings, Precautions, and Safety Information** for precautions and hazard statements.

Storage and Handling

Kit reagents

- Store kit reagents at 2–30°C.

Stability


- The test must be initiated within 60 minutes of opening the foil-wrapped eStick and Processing Tube.
- Following mixing of the patient specimen with Diluent Buffer in the Processing Tube, the sample should be added to the eStick within 15 minutes.
- The QIAreach SARS-CoV-2 Antigen Test should be performed in a test environment with $\leq 65\%$ relative humidity.
- Refer to the expiration date printed on the device labeling for component shelf life.
- QIAreach SARS-CoV-2 Antigen Diluent Buffer should be used within 3 months after opening the bottle.

Warnings, Precautions, and Safety Information


- For *in vitro* diagnostic use.
- For prescription use only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- The product has not been FDA cleared or approved; the test has been authorized under an Emergency Use Authorization (EUA) for use by authorized laboratories; laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that meet requirements to perform moderate to high complexity tests.
- In the U.S., 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 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Viscous samples that are difficult to pipette should not be used as these may affect test performance and result in an error code or erroneous result.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.


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- Use appropriate precautions in the collection, handling and storage of patient samples. Refer to CDC Interim Guidelines for Collection, Handling and Transportation of clinical specimens from persons with Coronavirus Disease 2019 (COVID-19) at <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>, and to WHO's Interim guidance for Laboratory testing for coronavirus disease (COVID -19) in suspected human cases at <http://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117>, as amended and supplemented. Refer to the WHO website for additional publications.
 - Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
 - This test is not for use in point-of-care or at-home testing settings.
 - Test Devices are single use only and should be discarded after use. Do not re-use the Test Device.
 - Do not use if any of the test kit contents or packaging is damaged.
 - Do not touch the swab tip.
 - Once opened, the test eStick should be used within 60 minutes.
 - Using the test after 60 minutes may lead to an invalid result.
 - For more information on EUAs please visit: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
 - For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19


- When working with chemicals, always wear a suitable lab coat, disposable gloves, and eye protection goggles. For more information, please consult the appropriate safety data sheets (SDSs). Avoid direct contact with potentially infectious substances by wearing appropriate personal protective equipment such as laboratory coats, goggles, and disposable gloves. Wash hands thoroughly after removal of gloves.
- Do not use the kit contents beyond the expiration date.
- Avoid contact with your [e.g., skin, eyes, nose, or mouth]. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your [e.g., skin, eyes, nose, or mouth], flush with large amounts of water. If irritation persists, seek medical advice: <https://www.poisonhelp.org> or 1-800-222-1222.

<p>CAUTION</p> 	<p>Handle all specimens as potentially infectious. Observe (C1) relevant specimen collecting and handling guidelines. Dispose of samples and materials in contact with specimen or specimen products in accordance with federal, state, and local regulations.</p>
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The following hazards and precautionary statements apply to components of the QIAreacH SARS-CoV-2 Antigen Test kit.

<p>Warning</p>  <p>H317 / H412</p> <p>/ P280 / P501</p>	<p>QIAreacH SARS-CoV-2 Antigen Diluent Buffer (W1)</p> <p>Contains ProClin 300 (0.045% v/v): castor oil, ethoxylated / Mixture of 2-methyl-1,2-thiazol-3(2H)-one and 5-chloro-2-methyl-1,2-thiazol-3(2H)-one. Warning! May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects. Wear protective gloves/ protective clothing/ eye protection/ face protection. Dispose of contents/ container to an approved waste disposal plant.</p>
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<p>WARNING</p> 	<p>QIAreacH eHub (W2)</p> <p>Do not open the eHub. No serviceable parts inside. Opening of the eHub device could lead to electric shock or damage of the device.</p>
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<p>CAUTION</p> 	<p>QIAreacH SARS-CoV-2 Antigen eStick (C2)</p> <p>Do not open the eStick. No serviceable parts inside. Opening of the eStick could lead to user exposure of infectious patient body fluids. Opening the eStick could also damage the eStick device.</p>
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- Important: Inspect materials prior to use. Do not use kit if the Diluent Buffer, Processing Tube, or eStick show signs of damage or leakage, or if the seals have been compromised prior to use.
 - Do not handle or use broken eSticks.
 - Discard used or unused materials and biological samples in accordance with local and government regulations. All samples, even after the pre-analytical inactivation procedure, and reagents containing biological materials used for this product must be considered as potentially able to transmit infectious agents and must be handled with utmost care and disposed of in compliance with the laboratory guidelines.
 - Do not use the QIAreacH SARS-CoV-2 Antigen Test kit after the expiration date.
 - Do not mix consumables and reagents from multiple lots.
 - Avoid splashing or aerosolization of samples or reagents as droplets are a means of transmission of SARS-CoV-2 virus. All drops and spills must be wiped up with an appropriate disinfectant such as a sodium hypochlorite solution with 0.5% active chlorine, and all soiled materials must be disposed of as infectious waste.
 - Do not eat, drink, smoke or apply cosmetics during the assay.

Procedures

Sample collection

For anterior nasal and NP specimen collection, follow all guidelines and instructions provided by the Centers for Disease Control and Prevention (CDC) at <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html> and swab manufacturer when collecting test specimens.

Note: The QIAreacH SARS-CoV-2 Antigen Test requires 400 µl of TM sample for an individual test.

Refer to the following guidelines for handling of samples prior to performing the QIAreacH SARS-CoV-2 Antigen Test:

- Following collection, the swab should be placed immediately into Copan Diagnostics Universal Transport Medium (UTM-RT). Do not use other VTMs as these have not been evaluated with this product.
- Specimens in transport medium may be held at room temperature (15–30°C) for up to 8 hours prior to testing.
- Specimens may be stored for up to 72 hours at 2–8°C prior to testing.
- Specimens in transport medium that require long term storage prior to testing may be stored at ≤ –20°C. The specimen should undergo no more than 3 freeze/thaw cycles prior to testing.

Detection assay

Materials required

- QIArearch SARS-CoV-2 Antigen Processing Tube (packaged together with eStick in foil wrapper)
- QIArearch SARS-CoV-2 Antigen eStick (packaged together with Processing Tube in foil wrapper)
- QIArearch SARS-CoV-2 Antigen Diluent Buffer
- QIArearch eHub (with associated power cable and adapter), sold separately
- QIArearch SARS-CoV-2 Antigen Controls or other suitable control material (as required to meet local and organizational compliance)
- Calibrated pipettes for delivery of 100 μ l and 400 μ l with disposable tips

Important points before starting

- All samples and reagents must be brought to room temperature (15–30°C) before use (e.g., if stored in the refrigerator). Allow at least 60 minutes for sample equilibration to room temperature.
- The eStick and Processing Tube should remain packaged in the foil wrapper and only opened just prior to performing the assay.
- Important: The QIArearch SARS-CoV-2 Antigen Test must be started within 60 minutes of removing the components from the packaging.

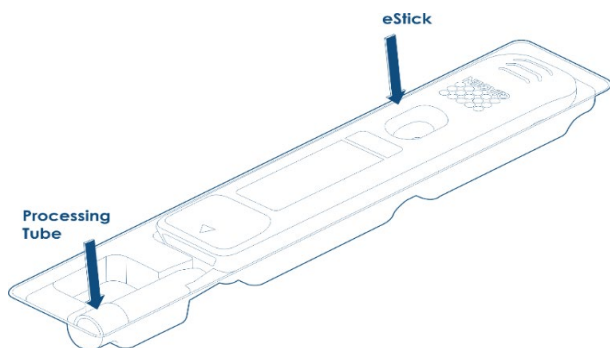


Figure 1. Contents of foil wrapper packaging – Processing Tube and eStick.

- The eStick is a single use device. It is recommended to label the eStick with test information using a permanent marker or by applying a label directly on the eStick. If a label is applied to the eStick, ensure that the label is not placed over the sample port or the sloped front end (with arrow) of the eStick as this could affect the connection between the eStick and eHub.
- There is a small white pad contained within the Processing Tube that is a critical component of the QIAreach SARS-CoV-2 Antigen Test. DO NOT remove the pad from the Processing Tube. This pad will not be dislodged during pipetting.
- If not connected to a power source, the eHub should have sufficient battery power to complete the test. A fully charged eHub should maintain internal battery power for 8 hours. The battery LED indicator displays the battery status. The QIAreach SARS-CoV-2 Antigen Test should not be performed if the eHub is not connected to a power source and the battery power is less than 10%, as denoted by a red battery LED indicator. The battery level can also be checked by connecting the eHub to a laptop 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. Refer to the *QIAreach eHub User Manual* and software guide for details.

- The eHub comes with a cover to protect the internal ports from dust buildup and contamination. The cover should be placed over the front panel of the eHub when the eHub is not in use.

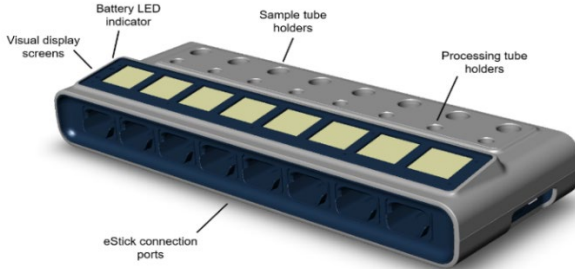


Figure 2. QIArearch eHub layout. Note: The dust cover should be in place when the eHub is not in use.

- Note: It is recommended to fully charge the eHub in a switched off state overnight (when not in use) or to charge for 4 hours before use. To charge the unit, connect the eHub to a power outlet using the provided USB power adapter and USB cable. It is also recommended that the eHub is connected to a USB power source (either a USB adapter or PC) during operation.

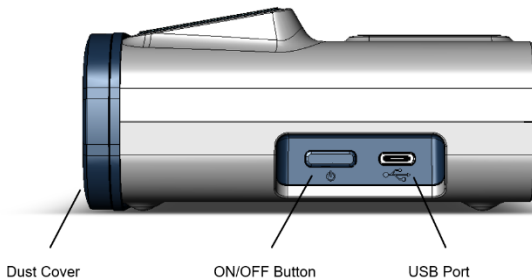
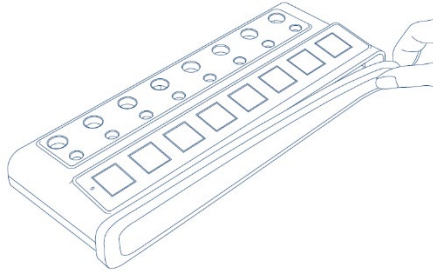


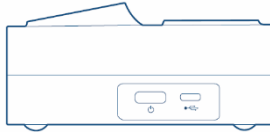
Figure 3. Side panel view of eHub with dust cover, ON/OFF switch, and USB connection port.

Procedure

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

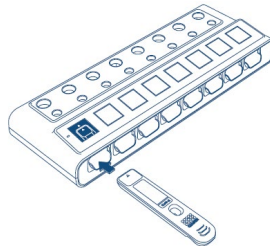


2. Press the ON/OFF switch on the right side of the eHub to turn it on.

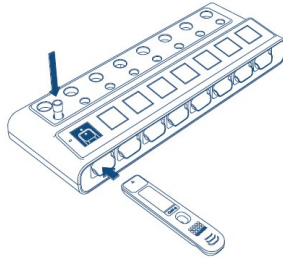


3. Remove the eStick from the packaging, label with patient identifier, and insert into the eHub.

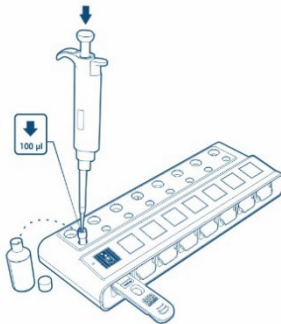
Note: The test sample must be added to the eStick sample port within 60 minutes of eStick removal from the foil packaging.



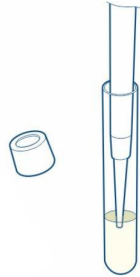
4. Remove the Processing Tube from the packaging and insert into the empty tube slot directly in line with the eStick.



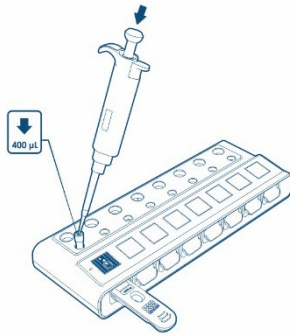
5. Add 100 μ l of QIArearch SARS-CoV-2 Antigen Diluent Buffer to the Processing Tube using a pipette.



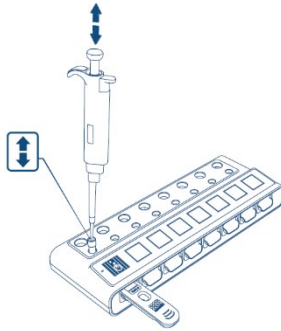
6. Remove 400 μ l of the patient specimen in transport medium using a pipette.
Note: Viscous samples that are difficult to pipette should not be used as these may affect test performance and result in an error code or erroneous result.



7. Add 400 μ l of patient specimen in transport medium to the Processing Tube containing the QIArearch SARS-CoV-2 Antigen Diluent Buffer.

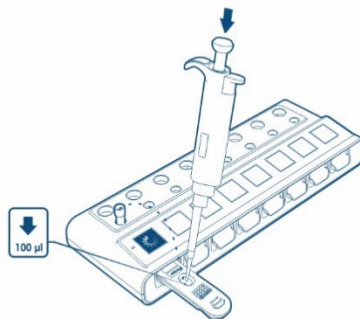


8. Mix the contents of the Processing Tube by pipetting up and down at least 4 times. Take care to not introduce foam while pipetting.



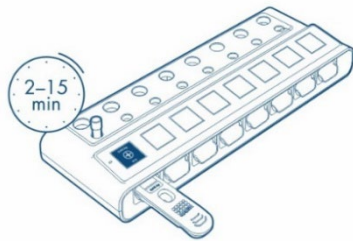
9. Remove 100 μ l of the mixed sample from the Processing Tube and dispense into the sample port of the inserted eStick.

Note: The mixed sample must be loaded onto the eStick within 15 minutes of sample mixing in the Processing Tube.



10. Following sample addition, the loading icon may appear on the eHub display for an additional 30–60 seconds before the sample is detected by the eStick. Once sample is detected, the test will start automatically, which is signaled by a countdown timer on the eHub display. Do not remove the inserted eStick until

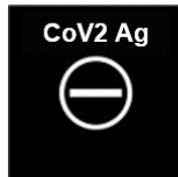
the test is complete and a result is displayed. If the loading icon on the eHub display remains 5 minutes after sampling addition, then the eStick likely cannot detect the presence of sample due to high viscosity. A new patient sample should be obtained if possible.



11. After completion of the test, the result will be displayed on the eHub.



Positive



Negative

Results Analysis and Test Interpretation

The standard time from eStick sample detection to test result is 2–15 minutes. The time to result will be less than 15 minutes for positive samples containing high concentrations of SARS-CoV-2 antigen. The time to result will be displayed on the QIAreach eHub alongside the sample result.

QIAreach SARS-CoV-2 Antigen Test raw data is analyzed on the eStick firmware, which determines a positive or negative QIAreach SARS-CoV-2 Antigen Test result based on an internal algorithm. The result is transmitted to the QIAreach eHub, which displays the result. Once the result is displayed, the result is retained on the eStick, and it can be removed from the QIAreach eHub. The retained result can be retrieved from the eStick by re-inserting into the QIAreach eHub. If the optional QIAreach Software is used, the QIAreach eHub can be used to transfer the test result to a computer for data transfer, backup, and report printing.

Quality control of test

All QIAreach SARS-CoV-2 Antigen eSticks have built-in controls to ensure reliable performance of the eStick optoelectronics and lateral flow strip and also monitor procedural steps after sample addition to confirm suitability. A failure alert will be communicated to the user in the form of a test error if any fault conditions are detected on the eStick firmware.

Mechanical performance controls are in place to confirm that the eStick components are functioning correctly and are not compromised due to improper handling or transport. Once the sample is added to the eStick, the eStick will continually monitor progress, including the proper flow rate of sample across the strip as well as the correct range of detector particles in the sample. The eStick has extensive controls built into the firmware to alert the user if the test has not been

successfully completed or if the test strip has been compromised, providing an additional level of control over standard lateral flow tests that rely on a single control line.

External positive and negative controls (QIArearch SARS-CoV-2 Antigen Controls, cat. no. 646030) are not supplied with this kit and are available from QIAGEN separately. QIAGEN recommends that both the Positive and Negative Controls be run:

- Once for each new operator
- Once for each new lot or each new shipment of kits

As required by organizational quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.

External Control kit contents (sold separately)

QIArearch SARS-CoV-2
Antigen Controls

Catalog number

646030

**Number of Controls
per pack**

4 Positive
Controls and 4
Negative
Controls

QIArearch SARS-CoV-2 Antigen Controls Components

QIArearch SARS-CoV-2 Ag Positive Control	Contains SARS-CoV-2 nucleocapsid protein, bovine serum albumin, ProClin 300, and buffer	4 x 0.5 ml
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QIArearch SARS-CoV-2 Negative Control	Contains bovine serum albumin, ProClin 300, and buffer	4 x 0.5 ml
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External Control Procedure

1. Equilibrate all controls to room temperature (15–30°C) prior to use. Controls should be used within 4 hours of thawing. Do not refreeze vials after thawing.

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2. Controls are to be substituted with the patient sample (swab and transport medium) in Steps 6 and 7 of the Procedures/Detection assay section above ; 400 µl of control sample should be added directly from the control vial into the Processing Tube containing 100 µl Diluent Buffer.
 3. All control vials are single use only. Discard opened vials after use in accordance with the local and government regulations.

Note: See Technical Information for the list of error codes and the associated recommended actions.

Interpretation of Results

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting QIArearch SARS-CoV-2 Antigen Test results:

Table 1. Interpretation of QIArearch SARS-CoV-2 Antigen Test results

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the QIArearch SARS-CoV-2 Antigen Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid

If the test is invalid, re-test with a new swab and new test device.

Limitations

This test is only to be used in CLIA certified laboratories that meet requirements to perform moderate or high complexity testing and not in point-of-care or at-home testing settings.

Swabs with the following properties should not be used:

- Calcium alginate tips
- Preservatives
- Wooden shafts

The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after six days are more likely to be negative compared to RT-PCR.

Individuals using fluticasone propionate may cause false positive results.

A negative test result does not rule out SARS-CoV-2 infection. It may occur due to the level of antigen in a sample being below the detection limit of the assay. Clinical performance was established on frozen specimens collected in Copan Universal Transport Medium (UTM-RT).

This device is only used for testing human nasopharyngeal and anterior nasal swab specimens in viral transport medium (VTM). Do not use direct swab specimens.

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 11/02/2020 and 04/07/2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary

depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

There is a higher chance of false-negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.

If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.

If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.

Incorrect test results may occur if a specimen is incorrectly collected or handled.

This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

CONDITIONS OF AUTHORIZATION FOR LABORATORY

The QIAreacH SARS-CoV-2 Antigen Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for patients, and authorized labeling are available on the FDA website: (<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2>)

However, to assist clinical laboratories using the QIAreacH SARS-CoV-2 Antigen test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories* using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories using your product must use your product as outlined in the "authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating tests.

D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Qiagen GmbH (via email: techservice-na@qiagen.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit and use your product in accordance with the labeling.

G. Qiagen GmbH and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity and high complexity tests.

Performance Characteristics

Clinical performance of nasal (anterior nares) swab samples

The clinical performance of the QIArearch SARS-CoV-2 Antigen Test was estimated by evaluating healthcare professional-collected nasal swab samples in Copan Universal Transport Medium (UTM) (Copan cat. no. 330C and Copan cat. no. 3C047N) from subjects suspected of COVID-19 by their healthcare provider within the first 6 days of symptom onset. A total of 61 frozen reference method positive samples meeting eligibility criteria were tested using the QIArearch SARS-CoV-2 Antigen Test system and were compared to an EUA high-sensitivity RT-PCR assay. A total of 210 frozen reference method negative samples meeting eligibility criteria were tested using the QIArearch SARS-CoV-2 Antigen Test system and were compared to an EUA high-sensitivity RT-PCR assay.

Age and gender distribution along with the positivity rate are presented in Table 2. The overall positive rate for ANS samples was 13.4%. The ages of the subjects ranged from 19 to 82 years old. Note that patient age was not available for all ANS samples.

Table 2. Age Group and Gender Distribution and Positivity Rates by QIArearch SARS-CoV-2 Antigen Test for Symptomatic Subjects (ANS samples)

Age group (years)	Total number	Number of Females	Number of Males	Number of Positives	Positivity rate
0-21	7	2	5	1	14.3%
22-59	162	97	65	23	14.2%
60+	40	28	12	4	10.0%
Total	209	127	82	28	13.4%

Positive Percent Agreement (PPA) stratified by days since symptom onset is presented in Table 3.

Table 3. Positive Percent Agreement Since Days of Symptom Onset (ANS Samples)

Days Since Symptoms Onset	Number of Positive Results		Positive Percent Agreement (%)	Cumulative Positive Percent Agreement (%)
	Reference Method	CoV-2 Ag		
0	5	5	100.00% (95% CI: 47.82–100.00%)	100.00% (5/5, 95% CI: 47.82–100.00%)
1	11	11	100.00% (95% CI: 71.51–100.00%)	100.00% (16/16, 95% CI: 79.41–100.00%)
2	18	17	94.44% (95% CI: 72.71–99.86%)	97.06% (33/34, 95% CI: 84.67–99.93%)
3	12	8	66.67% (95% CI: 34.89–90.08%)	89.13% (41/46, 95% CI: 76.43–96.38%)
4	8	6	75.00% (95% CI: 34.91–96.81%)	90.38% (47/52, 95% CI: 78.97–96.80%)
5	2	1	50.00% (95% CI: 1.26–98.74%)	88.89% (48/54, 95% CI: 77.37–95.81%)
6	4	3	75.00% (95% CI: 19.41–99.37%)	85.00% (51/60, 95% CI: 73.43–92.90%)
7	0	0	N/A	N/A

Table 4 summarizes the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the QIArearch SARS-CoV-2 Antigen Test when compared with an FDA EUA high sensitivity SARS-CoV-2 RT-PCR assay.

Table 4. Clinical Performance of QIArearch SARS-CoV-2 Antigen Test vs FDA EUA High Sensitivity SARS-CoV-2 RT-PCR Assay (ANS Samples)

QIArearch SARS-CoV-2 Antigen Test	EUA high-sensitivity SARS-CoV-2 RT-PCR assay.		
	Positive	Negative	Total
Positive	51	2	53
Negative	9	208	217
Total	60	210	270
Prevalence	22.2% (60/270)		
PPA (95% CI)	85.00% (73.43–92.90%)		
NPA (95% CI)	99.05% (96.60–99.88%)		

Clinical performance of nasopharyngeal swab (NPS) samples

The clinical performance of the QIArearch SARS-CoV-2 Antigen Test was estimated by evaluating healthcare professional-collected nasopharyngeal swab samples in Copan UTM (Copan cat. no. 330C and Copan cat. no. 3C047N) from subjects suspected of COVID-19 by their healthcare provider within the first 6 days of symptom onset. A total of 62 frozen reference method positive samples meeting eligibility criteria were tested using the QIArearch SARS-CoV-2 Antigen Test system and were compared to an EUA high-sensitivity RT-PCR assay. A total of 178 reference method negative samples meeting eligibility criteria were tested using the QIArearch SARS-CoV-2 Antigen Test system and were compared to an EUA high-sensitivity RT-PCR assay.

Age and gender distribution along with the positivity rate are presented in Table 5. The overall positive rate for NPS samples was 22.1%. The ages of the subjects ranged from 14 to 89 years old.

Table 5. Age Group and Gender Distribution and Positivity Rates by QIArearch SARS-CoV-2 Antigen Test for Symptomatic subjects (NPS samples)

Age group (years)	Total number	Number of Females	Number of Males	Number of Positives	Positivity rate
0-21	13	8	5	4	30.8%
22-59	183	108	75	43	23.5%
60+	44	32	12	6	13.6%
Total	240	148	92	53	22.1%

Positive Percent Agreement (PPA) stratified by days since symptom onset is presented in Table 6.

Table 6. Positive Percent Agreement Since Days of Symptom Onset (NPS Samples)

Days Since Symptoms Onset	Number of Positive Results		Positive Percent Agreement (%)	Cumulative Positive Percent Agreement (%)
	Reference Method	CoV-2 Ag		
0	9	7	77.78% (95% CI: 39.99–97.19%)	77.78% (7/9, 95% CI: 39.99–97.19%)
1	12	11	91.67% (95% CI: 61.52–99.79%)	85.71% (18/21, 95% CI: 63.66–96.95%)
2	16	14	87.50% (95% CI: 61.65–98.45%)	86.49% (32/37, 95% CI: 71.23–95.46%)
3	10	8	80.00% (95% CI: 44.39–97.48%)	85.11% (40/47, 95% CI: 71.69–93.80%)
4	10	7	70.00% (95% CI: 34.75–93.33%)	82.46% (47/57, 95% CI: 70.09–91.25%)
5	4	3	75.00% (95% CI: 19.41–99.37%)	81.97% (50/61, 95% CI: 70.02–90.64%)
6	1	0	0.00% (95% CI: 0.00–97.50%)	80.65% (50/62, 95% CI: 68.63–89.58%)
7	0	0	N/A	N/A

Table 7 summarizes the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) for the QIArearch SARS-CoV-2 Antigen Test when compared with an FDA EUA high sensitivity SARS-CoV-2 RT-PCR assay.

Table 7. Clinical Performance of QIArearch SARS-CoV-2 Antigen Test vs FDA EUA High Sensitivity SARS-CoV-2 RT-PCR Assay (NPS Samples)

QIArearch SARS-CoV-2 Antigen Test	EUA high-sensitivity SARS-CoV-2 RT-PCR assay.		
	Positive	Negative	Total
Positive	50	3	53
Negative	12	175	187
Total	62	178	240
Prevalence	25.8% (62/240)		
PPA (95% CI)	80.65%% (68.63–89.58%)		
NPA (95% CI)	98.31% (95.13–99.65%)		

Performance of SARS-CoV-2 Antigen Test with Serial Testing

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection.

Performance of the antigen test with serial testing in individuals is described in Table 8.

Table 8: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULTS	SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)		
	1 Test	2 Tests	3 Tests
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	

1. Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2. Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3. Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

Analytical performance

Limit of Detection (Analytical sensitivity)

The limit of detection (LoD) for the QIAreacH SARS-CoV-2 Antigen Test system was determined by limiting dilution studies using heat-inactivated SARS-CoV-2, isolate USA-WA1/2020 (ZeptoMetrix™, 0810587CFHI), which was supplied frozen at a concentration of 3.80×10^6 TCID₅₀/mL. Fifty (50) µl of heat inactivated virus in clinical matrix was spiked onto nasopharyngeal swabs for determination of the LoD.

LoD screening

An initial LoD screening study was performed with the QIArearch SARS-CoV-2 Antigen Test using a four-point dilution series of the heat-inactivated virus made in a pooled negative clinical matrix composed of RT-PCR confirmed SARS-CoV-2 negative clinical human nasopharyngeal swab (NPS) specimens in Copan UTM-RT. Dilutions were tested in triplicate. The lowest concentration at which all (3/3) replicates were positive was chosen for further evaluation and refined using an additional dilution series (5 dilutions in total) of the heat-inactivated SARS-CoV-2 virus made in negative clinical matrix, with five (5) replicates tested at each dilution. The lowest detectable concentration demonstrating 100% positive results was set as the tentative LoD for confirmation.

LoD confirmation

The LoD of the QIArearch SARS-CoV-2 Antigen Test system was confirmed by testing twenty (20) replicates at the tentative LoD. The final confirmed LoD, as measured on the collected patient swab demonstrated 95% (19/20) positive results (Table 9).

Table 9. LoD confirmation (*Based upon the testing procedure for this study, the LoD of 5.0×10^4 TCID₅₀/mL equates to 2.5×10^3 TCID₅₀ per swab)

LoD Measurement	SARS-CoV-2 concentration	QIArearch SARS-CoV-2 Antigen Test result	% Positive
Patient swab*	5.0×10^4 TCID ₅₀ /mL	19/20 Positive	95%

Cross-reactivity (analytical specificity) and microbial interference

The QIArearch SARS-CoV-2 Antigen Test was evaluated for potential cross-reactivity and microbial interference with a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens (Table 8). A total of 27 pathogenic microorganisms (15 viruses, 11 bacteria, 1 yeast/fungi) and 1 pooled human nasal wash, representative of normal respiratory (tract) microbial flora that may be present in the nasal cavity, were tested in triplicate in SARS-CoV-2 RT-PCR-confirmed negative clinical matrix (swab diluted in transport medium) either in the absence of inactivated SARS-CoV-2 to assess the likelihood of a false-positive result or presence of the virus at 3x the final test sample LoD (1200 TCID₅₀/mL) to assess the likelihood of a false negative result. Bacterial and viral pathogens were prepared to a target test concentration of 1×10^6 CFU/mL or IFU/mL, 1×10^5 TCID₅₀/mL or 1×10^5 EID₅₀/mL in negative clinical matrix, respectively. Pooled human nasal wash was tested at a concentration of 10% (v/v) in negative clinical matrix. These concentrations represent the concentrations of bacterial and viral pathogens, or pooled human nasal wash in the collected transport medium before mixing with the Diluent Buffer. No cross-reactivity or interference was observed with the following microorganisms and pooled human nasal wash when tested at the listed concentrations presented (Table 10).

Table 10. Cross-reactivity and microbial interference summary for the QIArearch SARS-CoV-2 Antigen Test

Pathogen	Concentration tested	Cross-reactivity (Negative result/total tested)	Interference (SARS-CoV-2 positive result/total tested)
Human coronavirus 229E	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Human coronavirus OC43	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Human coronavirus NL63	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
MERS-coronavirus	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Human coronavirus HKU1 [†]	<i>in silico</i>	n/a	n/a
Adenovirus C1 Ad. 71	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Human Metapneumovirus (hMPV)	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Parainfluenza virus 1	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Parainfluenza virus 2	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Parainfluenza virus 3	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Parainfluenza virus 4	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Influenza A	1 x 10 ⁵ EID ₅₀ /mL	3/3	3/3
Influenza B	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Enterovirus	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Respiratory Syncytial Virus (RSV)	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
Rhinovirus	1 x 10 ⁵ TCID ₅₀ /mL	3/3	3/3
<i>Haemophilus influenzae</i>	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Streptococcus pneumoniae</i>	1 x 10 ⁶ CFU/mL	3/3	3/3

Table continued on next page

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Table 10. Cross-reactivity and microbial interference summary for the QIArearch SARS-CoV-2 Antigen Test (cont'd)

Pathogen	Concentration tested	Cross-reactivity (Negative result/total tested)	Interference (SARS-CoV-2 positive result/total tested)
<i>Streptococcus pyogenes</i>	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Candida albicans</i>	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Bordetella pertussis</i>	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Mycoplasma pneumoniae</i>	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Chlamydia pneumoniae</i>	1 x 10 ⁶ IFU/mL	3/3	3/3
<i>Legionella pneumophila</i>	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Staphylococcus aureus</i>	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Staphylococcus epidermidis</i>	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Mycobacterium tuberculosis</i> [†]	1 x 10 ⁶ CFU/mL	3/3	3/3
<i>Pneumocystis jirovecii</i> (PJP) [†]	1 x 10 ⁶ CFU/mL	3/3	3/3
Pooled Human Nasal Wash	10% v/v	3/3	3/3

[†] *in silico* analysis was performed.

Wet testing of SARS-Coronavirus (SARS-CoV) on the QIArearch SARS-CoV-2 Antigen Test was not performed. However, the antibodies used in the QIArearch SARS-CoV-2 Antigen Test have been shown to exhibit cross-reactivity with SARS-CoV nucleocapsid. Thus, the QIArearch SARS-CoV-2 Antigen Test result cannot differentiate between SARS-CoV and SARS-CoV-2 infection.

In silico cross reactivity was analyzed using BLAST performed on the QIAGEN CLC Genomics Workbench 20.0.4 against the NCBI non-redundant database limited by each of the organisms below, using the [ORGN] limiter to reduce the search space, to determine the likelihood of cross- reactivity.

- *Pneumocystis jirovecii*
- 32% identity and 45% positivity (similarity) was found in one particular segment of a sequence with 10% overlap. Thus, a very low likelihood of cross-reactivity exists between SARS-CoV-2 and *P. jirovecii*. Wet testing showed no cross-reactivity (Table 8), however cross-reactivity cannot be ruled out.
- *Mycobacterium tuberculosis*
- No sequence homology was found between SARS-CoV-2 and *M. tuberculosis*. Thus, no cross-reactivity likely exists between SARS-CoV-2 and *M. tuberculosis*. Wet testing showed no cross-reactivity (Table 8).
- For Human Coronavirus HKU1, homology exists between the SARS-CoV-2 nucleocapsid protein and Human Coronavirus HKU1. BLAST results resulted in 65 nucleocapsid protein sequence IDs with homology. Sequence ID AJQ24069.1 had the highest alignment score and 46% identity and 60% positivity (similarity) was found across 32% of the overlap sequences. The homology is relatively low, but cross-reactivity cannot be ruled out.

Endogenous interference

A total of 14 potentially interfering substances that may be found in the upper respiratory tract, including blood and a selection of the active ingredients of commonly used cold and flu medications, were evaluated to demonstrate they do not cross-react or interfere with the QIAreacH SARS-CoV-2 Antigen Test. The QIAreacH SARS-CoV-2 Antigen Test was evaluated by spiking interfering substances and testing at concentrations as listed in Table 9, either in the absence of inactivated SARS-CoV-2 virus to assess the likelihood of a false-positive result or in the presence of heat inactivated SARS-CoV-2 at 3x the final test sample LoD (1200 TCID₅₀/mL) to

assess the likelihood of a false negative result. The concentrations of endogenous interference substances represent the concentrations in the collected transport medium before mixing with the Diluent Buffer. Testing was performed on five (5) replicates per substance in both SARS-CoV-2 RT-PCR-confirmed negative clinical matrix (patient swab diluted in transport medium) and negative clinical matrix spiked with heat inactivated SARS-CoV-2 virus. Results from endogenous interference test are displayed in Table 11.

Table 11. Summary of endogenous interfering substance testing

Interference substances	Concentration tested	Negative Matrix (QIArearch SARS-CoV-2 Antigen Test negative result/total tested)	Positive Matrix (QIArearch SARS-CoV-2 Antigen Test positive result/total tested)
Whole blood	4% v/v	5/5	5/5
Mucin	0.5%	5/5	5/5
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	5/5	5/5
Naso GEL (NeilMed)	5% v/v	5/5	5/5
CVS Nasal Drops (Phenylephrine)	15% v/v	5/5	5/5
Afrin (Oxymetazoline)	15% v/v	5/5	5/5
NasalCrom (Cromolyn)	15% v/v	5/5	5/5
Zicam	5% v/v	5/5	5/5
Homeopathic (Alkalol)	1:10 dilution	5/5	5/5
Sore Throat Phenol Spray	15% v/v	5/5	5/5
Tobramycin	4 µg/mL	5/5	5/5
Mupirocin	10 mg/mL	5/5	5/5
Fluticasone Propionate	5% v/v	2/5	5/5
Fluticasone Propionate*	3.5% v/v	2/5	n/a
Fluticasone Propionate*	2.5% v/v	5/5	n/a
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	5/5	5/5

*- Testing repeated due to observed interference at a higher test concentration.

No interference was observed for all substances, except for fluticasone propionate. False positive results were observed for 2/5 of the fluticasone propionate replicates at 5% v/v and 3.5% v/v, with no false positives observed at or below 2.5% v/v.








High dose hook effect

No clinically relevant high dose hook effect was observed with the QIArearch SARS-CoV-2 Antigen Test up to a concentration of 1.15×10^6 TCID₅₀/mL using heat inactivated SARS-CoV-2 (ZeptoMetrix™, 0810587CFHI).

Technical Information

eHub display icons

Table 12. eHub display icons

Icon	ID	Description
	Please Insert	The 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. The test will take up to 15 minutes.
	Positive	QIAreach SARS-CoV-2 Antigen Test Positive: SARS-CoV-2 infection likely. The time shown is the time required for the positive result to be calculated.
	Negative	QIAreach SARS-CoV-2 Antigen Test Negative: SARS-CoV-2 infection NOT likely.
	Error	The eStick has encountered an error. The letter denotes the type and the numbers are code for the error. Refer to the eHub error code section for more information.

For more information, refer to *QIAreach eHub User Manual*.

Error codes

The following tables list the QIAreach SARS-COV-2 Antigen Test error codes and the associated recommended actions:

Table 12. QIAreach SARS-CoV-2 Antigen Test 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 13. “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.

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Table 14. “A” error codes (cont’d)

Error code	Description	Recommended action
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.
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 14. “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 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 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	Flow rate error†	Check sample viscosity*. Discard and use new eStick.

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Table 15. "B" error codes (cont'd)

Error code	Description	Recommended action
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.

* Viscous samples that are difficult to pipette should not be used as these may affect test performance and result in an error code or erroneous result.

† If the test does not start within 5 minutes of adding the sample, then the eStick likely cannot detect the presence of sample due to high viscosity. Obtain a new patient sample if possible.

Table 15. "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-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.

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Table 16. “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.

Troubleshooting Guide

This troubleshooting guide may be helpful in solving any problems that may arise. For more information, see also the Frequently Asked Questions page at our Technical Support Center: www.qiagen.com/FAQ/FAQList.aspx. The scientists in QIAGEN Technical Services are always happy to answer any questions you may have about either the information or protocols in this handbook (for contact information, see back cover or visit www.qiagen.com).

QIAreach SARS-CoV-2 Antigen Test troubleshooting

See Technical Information for the list of error codes and associated recommended actions.

Additional user warnings

- When cleaning, avoid any deliberate water ingress deep into the test ports. The eHub can be cleaned using mild detergent, 10% bleach, or 70% EtOH.
- Only use the eHub with the USB cable and USB adapter supplied with the device.

Contact Information

For technical assistance and more information, please see our Technical Support Center at www.qiagen.com/support, call 800-344-3631, email techservice-na@qiagen.com, or contact one of the QIAGEN Technical Service Departments or local distributors (see back cover or visit www.qiagen.com).

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Symbols

The following symbols may appear on the packaging and labelling:

Symbol	Symbol definition
	<i>In vitro</i> diagnostic
	Use by date
	Temperature limitation
	Catalog number
	Material number
	Manufacturer
	Protect from light
	Consult instructions for use
	Caution
	Do not open electrical unit
	Do not reuse

Ordering Information

Product	Contents	Cat. no.
QIArearch SARS-CoV-2 Antigen Test Kit	60 QIArearch SARS-CoV-2 Antigen eSticks / Processing Tubes 2 x 10 ml QIArearch SARS-CoV-2 Antigen Diluent Buffer	646533
Relative Products		
QIArearch SARS-CoV-2 Antigen Controls	4 QIArearch SARS-CoV-2 Antigen Positive Controls and 4 QIArearch SARS-CoV-2 Antigen Negative Controls	646030
QIArearch eHub	QIArearch eHub, power adapter, and USB connector cable	9003063
QIArearch Software	N/A	Download from www.qiagen.com

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.

Document Revision History

Revision	Description
R1, March 2021	Initial release
R2, April 2021	Removal of BD Universal Viral Transport media, remove additional media limitations and update clinical section
R3, August 2021	Updates in Limit of Detection (Analytical sensitivity), Cross-reactivity (analytical specificity) and microbial interference, and Endogenous interference
R4, December 2021	Addition to Limitation section as additional condition of authorization. Language around clinical performance not established with all circulating variants
R5, May 2023	Addition of language related to serial testing per FDA conditions of authorizations

Limited License Agreement for QIAreach® SARS-CoV-2 Antigen Test

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

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QIAreach® SARS-CoV-2 Antigen Controls Instructions for Use (Handbook)

Intended use

For use with the QIAreach® SARS-CoV-2 Antigen Test

IVD

REF

646030

The QIAreach SARS-CoV-2 Antigen Controls are intended for use as positive and negative external quality controls to assess the performance of the QIAreach SARS-CoV-2 Antigen Test. The QIAreach SARS-CoV-2 Antigen Controls are provided to assist laboratories with training new operators and qualifying individual lots of the QIAreach SARS-CoV-2 Antigen Test.



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Phone: +1-800-426-8157

R1 MAT

1124093

The QIAreach SARS-CoV-2 Antigen Controls are designed for quality assurance purposes, and should be used when:

- Training new operators
- Qualifying new lots or shipments of the QIAreach SARS-CoV-2 Antigen Test.
- Identifying systematic issues at a particular lab or testing site.
- External controls are deemed necessary by organizational quality control procedures, and/or in accordance with Local, State and Federal regulations or accreditation requirements.

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- For Emergency Use Authorization Only.

Summary and explanation

The QIAreach SARS-CoV-2 Antigen Controls test consists of the QIAreach SARS-CoV-2 Ag Positive Control and the QIAreach SARS-CoV-2 Negative Control. The Negative Control contains bovine serum albumin, ProClin® 300, and buffer. The Positive Control contains SARS-CoV-2 nucleocapsid protein, bovine serum albumin, ProClin 300, and buffer.

Principles of the procedure

The QIAreach SARS-CoV-2 Antigen Controls are provided frozen in single-use vials and are substituted with the patient sample in the QIAreach SARS-CoV-2 Antigen Test workflow. For instructions on how to perform the test, refer to the *QIAreach SARS-CoV-2 Antigen Test Instructions For Use (Handbook)*.

Kit contents


QIAreach SARS-CoV-2 Antigen Controls		
Catalog number		646030
Number of Controls per pack		4 Positive Controls and 4 Negative Controls
QIAreach SARS-CoV-2 Antigen Controls Components		
QIAreach SARS-CoV-2 Ag Positive Control	Contains SARS-CoV-2 nucleocapsid protein, bovine serum albumin, ProClin 300, and buffer	4 x 0.5 ml
QIAreach SARS-CoV-2 Negative Control	Contains bovine serum albumin, ProClin 300, and buffer	4 x 0.5 ml

Store the QIAreach SARS-CoV-2 Antigen Controls at -30 to -15°C . Do not use after the expiration date printed on the labeling. Each control vial is single-use only and should be used within 4 hours of thawing to room temperature.

Warnings and Precautions

When working with chemicals, always wear a suitable lab coat, disposable gloves, and eye protection goggles. For more information, please consult the appropriate safety data sheets (SDSs). Refer to the *QIAreach SARS-CoV-2 Antigen Test Instructions For Use (Handbook)* for further safety information.

The following hazards and precautionary statements apply to components of the QIAreach SARS-CoV-2 Antigen Controls.

WARNING 	QIAreach SARS-CoV2 Antigen Controls (W1) Contains: Mixture of 2-methyl-1,2-thiazol-3(2H)-one, and 5-chloro-2-methyl-1,2-thiazol-3(2H)-one. Warning! May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects. Wear protective gloves/protective clothing/eye protection/face protection.
---	---

Important: Inspect vials prior to use. Do not use control vials that show signs of damage or if the vial cap has been compromised. Do not handle broken vials. Take appropriate safety precautions to dispose of vials safely.

Procedure

1. Equilibrate all controls to room temperature (15–30°C) prior to use. Controls should be used within 4 hours of thawing. Do not refreeze vials after thawing.
2. The QIAreach SARS-CoV-2 Antigen Test assay workflow remains the same as instructed in the *QIAreach SARS-CoV-2 Antigen Test Instructions For Use (Handbook)*. Controls are substituted with the patient sample (swab and transport media) in Steps 6 and 7 of the Procedures/Detection assay section ; 400 µl of control sample should be added directly from the control vial into the Processing Tube containing 100 µl Diluent Buffer.
3. Discard opened vials after use in accordance with the local and government regulations.

Expected results

The QIAreach SARS-CoV-2 Ag Positive Control should return a Positive result and the QIAreach SARS-CoV-2 Negative Control should return a Negative result in the QIAreach SARS-CoV-2 Antigen Test. Control test results that do not match with the expected results may identify a potential issue with operator training, laboratory handling procedures or with a specific QIAreach SARS-CoV-2 Antigen Test lot or shipment.

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.

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August 2021

QIAreacH® eHub User Manual

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



CE

REF

9003063



QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden

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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 QIArearch 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 QIArearch 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:

- QIArearch 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
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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*.

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

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

<p>Important</p>	<p>The term Important is used to highlight information that is critical for the completion of a task or optimal performance of the system.</p>
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<p>Note</p>	<p>The term Note is used for information that explains or clarifies a specific case or task.</p>
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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.

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

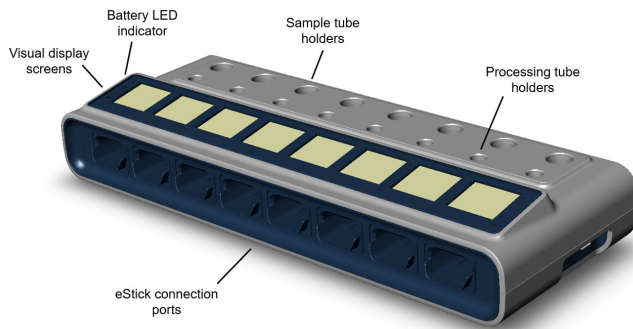


Figure 1. Front view of QIAreach eHub.

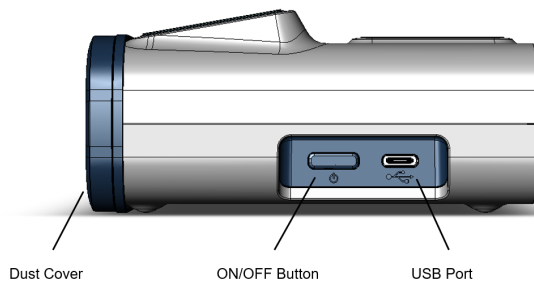


Figure 2. Side view of QIAreach eHub.

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

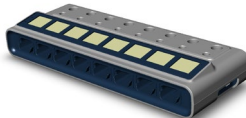

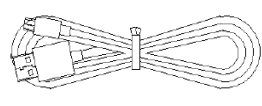
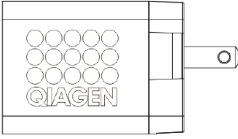
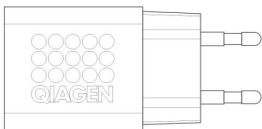
Operating the to become familiar with the QIAreach eHub operating conditions.

CAUTION	Do not place the QIAreach eHub in close proximity to sources (C2) 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.
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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 QIArearch Anti-SARS-CoV-2 Total Test kit (Cat# 645033) and for the QIArearch SARS-CoV-2 Antigen Test (Cat # 646533).

Components	Description
	QIArearch eStick
	QIArearch Processing Tube
	QIArearch 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.

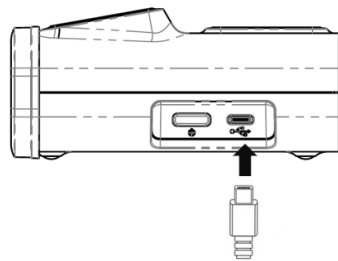


Figure 3. Connecting the USB cable to the QIAreach eHub USB port.

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.

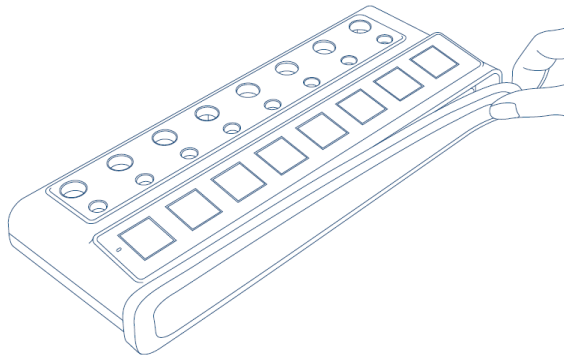


Figure 4. Removing the dust cover from the front of QIAreach eHub prior to use.

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.

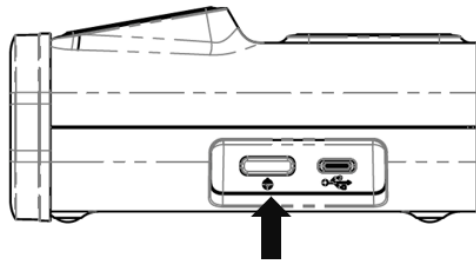


Figure 5. Press the ON/OFF switch to turn on the QIAreach eHub.

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

4. Battery LED indicator.

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.

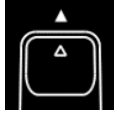


Figure 6. Insert eStick icon. This signifies that an QIAreach eHub port is available for use.

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.

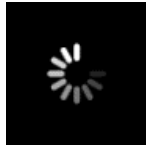


Figure 7. Self-test screen display.

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

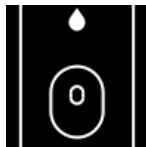


Figure 8. Add sample screen display.

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 (W2)
	Disconnect the QIAreach eHub from all power sources before cleaning. (C3) Ensure the QIAreach eHub is turned off before cleaning.

CAUTION 	Risk of damage to the QIAreach eHub (C4) When cleaning, avoid any deliberate water ingress into the eStick connection ports.
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CAUTION 	Risk of damage to the QIAreach eHub (C5) Avoid the use of excessive volumes of liquid that could enter the interior of the unit when cleaning the QIAreach eHub.
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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 2. 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 3. "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.

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Table 3. "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 4. "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 5. "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.

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Table 5. "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-serviceable):	
● 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.
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QIAreach® eHub



Emergency Use Authorization (EUA) only

Please be advised:

- o This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- o 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.

Please find the full instructions for use at the following web address:
<https://www.qiagen.com/us/products/diagnostics-and-clinical-research/infectious-disease/qiareach-solutions/qiareach-anti-sars-cov-2-total-us/?clear=true#orderinginformation>.

Please contact QIAGEN Technical Services (1-800-426-8157) if you require a printed copy free of charge.

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QIAreacH[®] SARS-CoV-2 Antigen Test



Emergency Use Authorization (EUA) only

Please be advised:

- o This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- o This product has been authorized only for the detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal and nasal swab specimens, not for any other viruses or pathogens, 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.

Please find the full instructions for use and the Quick Reference Guide instructions at the following web address:
<https://www.qiagen.com/products/diagnostics-and-clinical-research/infectious-disease/qiareach-solutions/qiareach-sars-cov-2-antigen-test-us>

Please contact QIAGEN Technical Services (1-800-426-8157) if you require a printed copy free of charge.

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QIArearch® SARS-CoV-2 Ag Controls



Emergency Use Authorization (EUA) only

Please be advised:

- o This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- o This product has been authorized only for use as a positive and negative external quality control product to assess the performance of the QIArearch SARS-CoV-2 Antigen Test, 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.

Please find the full instructions for use at the following web address:
<https://www.qiagen.com/products/diagnostics-and-clinical-research/infectious-disease/qiareach-solutions/qiareach-sars-cov-2-antigen-test-us/>

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