May 2022

# 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 646533

QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden

R4 MAT 1122911EN

Sample to Insight

QIAGEN

# Contents

# Intended Use

The QIAreach® SARS-CoV-2 Antigen Test is a rapid, digital lateral flow assay, using nanoparticle fluorescence, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and anterior nasal (AN) swab specimens collected in Copan® Diagnostic Universal Transport Media (UTM-RT™) from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. 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 QIAreach® 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. Antigen 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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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 decisions. 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 clinical laboratory personnel specifically instructed on *in vitro* diagnostic procedures. The QIAreach SARS-CoV-2 Antigen Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

# 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 presymptomatic[2-5] 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 QIAreach 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 Media (UTM-RT), hereinafter referred to as transport media (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 QIAreach SARS-CoV-2 Antigen Test is performed by inserting the QIAreach SARS-CoV-2 Antigen eStick into a QIAreach eHub (sold separately). The QIAreach eHub is a connection hub that provides power to perform multiple QIAreach SARS-CoV-2 Antigen Tests simultaneously. The eHub acts as a power source and features a rechargeable lithium battery to allow QIAreach SARS-CoV-2 Antigen Tests to be performed when a continuous power supply is not available.

To perform the test, QIAreach SARS-CoV-2 Antigen Diluent Buffer is first added to the QIAreach 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 QIAreach 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<br>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<br>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 and Precautions for precautions and hazard statements.

# Materials Required but not Provided

- Nasal or nasopharyngeal specimen collection swabs*
- Specimen transport medium options
    - Copan Diagnostics Universal Transport Media (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 under Warnings and Precautions for the list of incompatible collection swabs.
† See Warnings and Precautions 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 ≤ 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 and Precautions

- For *in vitro* diagnostic use only.
- For prescription use only.
- 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.
- 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 diagnostic tests 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.
- 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.
- Negative results should be treated as presumptive, and 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. 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, and confirmed with a molecular assay, if necessary for patient management.

- 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. The agent detected may not be the definite cause of disease.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- 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.
- Strict adherence to this product's test instructions is necessary to obtain accurate results.
- 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.

## 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). 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.

| | | |
|---|---|---|
| **CAUTION**  | Handle all specimens as potentially infectious. Observe 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. | (C1) |

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

| | | |
|---|---|---|
| **WARNING**  | QIAreach SARS-CoV-2 Antigen Diluent Buffer<br><br>Contains ProClin 300: 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. | (W1) |

| | | |
|---|---|---|
| **WARNING**  | QIAreach eHub<br><br>Do not open the eHub. No serviceable parts inside. Opening of the eHub device could lead to electric shock or damage of the device. | (W2) |

| | | |
|---|---|---|
| **CAUTION**  | QIAreach SARS-CoV-2 Antigen eStick<br><br>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. | (C2) |

## Further information

- Deviations from the QIAreach SARS-CoV-2 Antigen Test Instructions for Use may yield erroneous results. Please read the instructions carefully before use.
- 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 Media (UTM-RT). Do not use other VTMs as these have not been evaluated with this product.
- Specimens in transport media 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 media 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

- QIAreach SARS-CoV-2 Antigen Processing Tube (packaged together with eStick in foil wrapper)
- QIAreach SARS-CoV-2 Antigen eStick (packaged together with Processing Tube in foil wrapper)
- QIAreach SARS-CoV-2 Antigen Diluent Buffer
- QIAreach eHub (with associated power cable and adapter), sold separately
- QIAreach SARS-CoV-2 Antigen Controls or other suitable control material (as required to meet local and organizational compliance)
- Calibrated pipettes for delivery of 100 µl and 400 µl 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 QIAreach SARS-CoV-2 Antigen Test must be started within 60 minutes of removing the components from the packaging.

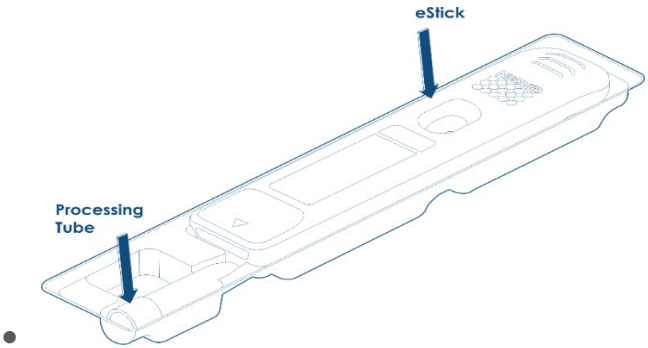



**Figure 1. Contents of foil wrapper packaging – Processing Tube and eStick.**

- 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.

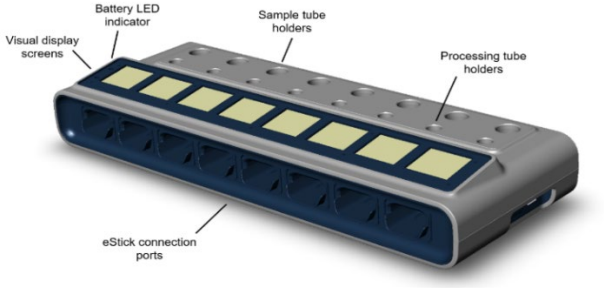



**Figure 2. QIAreach eHub layout.** Note: The dust cover should be in place when the eHub is not in use.

- 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.

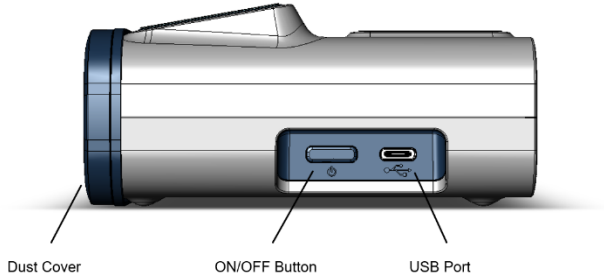
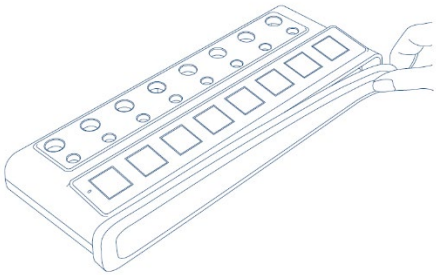


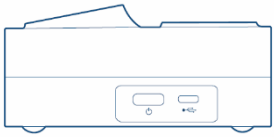

**Figure 3. Side panel view of eHub with dust cover, ON/OFF switch, and USB connection port.**

## Procedure

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

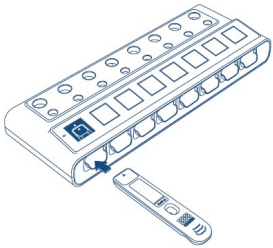


2. Press the ON/OFF switch on the right side of the eHub to turn it on.

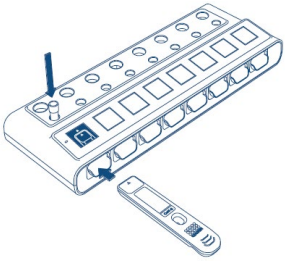


3. Remove the eStick from the packaging, label with patient identifier, and insert into the eHub.

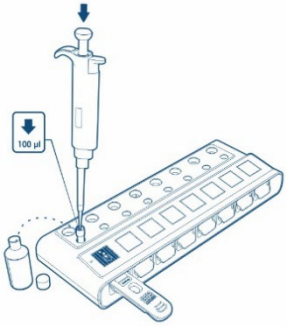
   Note: The test sample must be added to the eStick sample port within 60 minutes of eStick removal from the foil packaging.



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

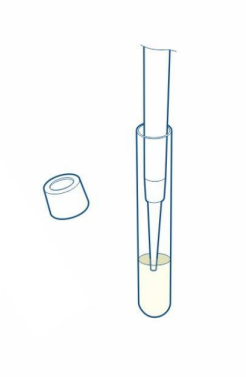


5. Add 100 µl of QIAreach SARS-CoV-2 Antigen Diluent Buffer to the Processing Tube using a pipette.

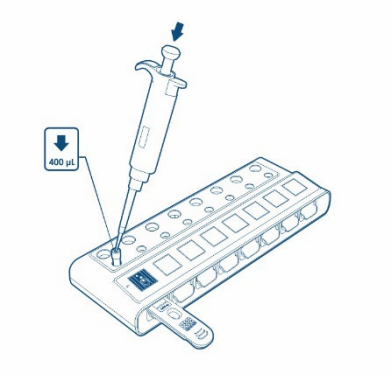



6. Remove 400 µl of the patient specimen in transport media using a pipette.

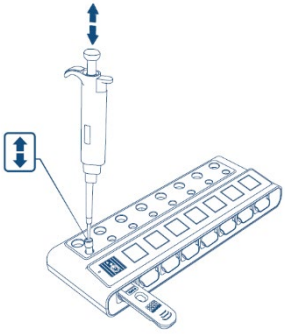
   Note: Viscous samples that are difficult to pipette should not be used as these may affect test performance and result in an error code or erroneous result.



7. Add 400 µl of patient specimen in transport media to the Processing Tube containing the QIAreach SARS-CoV-2 Antigen Diluent Buffer.

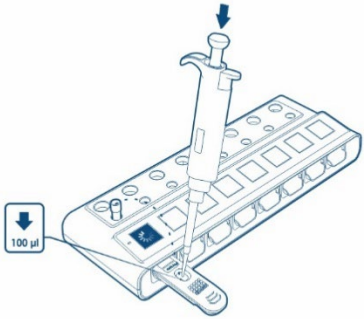



8. Mix the contents of the Processing Tube by pipetting up and down at least 4 times. Take care to not introduce foam while pipetting.



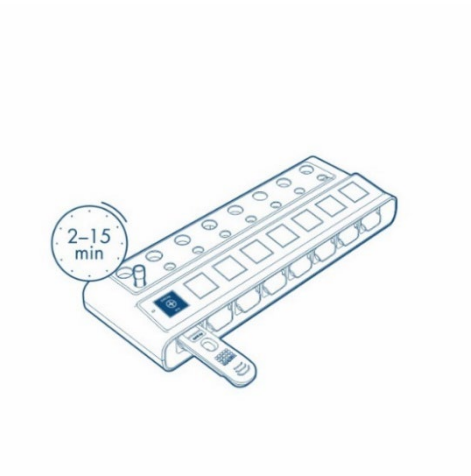
9. Remove 100 µl of the mixed sample from the Processing Tube and dispense into the sample port of the inserted eStick.

   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 (QIAreach 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)

| 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 |

## 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.

2. Controls are to be substituted with the patient sample (swab and transport media) 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

QIAreach SARS-CoV-2 Antigen Test results are interpreted using the following criteria:

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

| QIAreach SARS-CoV-2 Antigen Test result | Report/interpretation |
|---|---|
| Positive | SARS-CoV-2 infection likely |
| Negative | SARS-CoV-2 infection NOT likely |

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. QIAreach SARS-CoV-2 Antigen Test results should not be used to diagnose or exclude acute infection. Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.

If acute infection is suspected, confirmatory testing for SARS-CoV-2 with a molecular assay is necessary, if recommended by healthcare professionals.

## 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

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. This is especially important if the patient has had recent exposure to COVID -19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. In this case, direct testing for the SARS-CoV-2 virus (e.g. PCR testing) should be considered. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.

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.

Positive test results are not intended to rule out other non-SARS-CoV-2 viral or bacterial infections, or co-infections with other viruses or pathogens. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.

Clinical performance was established on frozen specimens collected in Copan Universal Transport Media (UTM-RT) media.

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

It is unknown if any of the individuals who were included in the clinical study had prior vaccination for SARS-COV-2. SARS-CoV-2 vaccination status was neither recorded nor considered during subject screening and enrollment. Performance has not been established for use with specimens other than direct nasal swabs or NP swabs stored in COPAN UTM. Other specimen types have not been evaluated and should not be used with this assay. Performance in fresh specimens has not been established and may differ. Important: Swabs with calcium alginate tips, swabs with preservatives, and swabs with wooden shafts must not be used in patient sample collection.

*The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2020 to February 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 SARSCoV-2 and their prevalence, which change over time.*

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.

Note: Unreliable results may occur due to deviations from the procedure described in this handbook.

## 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 QIAreach 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 QIAreach 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 QIAreach 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 QIAreach 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)**

| | Number of Positive Results | | | |
|---|---|---|---|---|
| **Days Since Symptoms Onset** | **Reference Method** | **CoV-2 Ag** | **Positive Percent Agreement (%)** | **Cumulative Positive Percent Agreement (%)** |
| 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 QIAreach SARS-CoV-2 Antigen Test when compared with an FDA EUA high sensitivity SARS-CoV-2 RT-PCR assay.

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

| QIAreach 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 QIAreach 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 QIAreach 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 QIAreach 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 QIAreach 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: Reference Method | Number of Positive Results: CoV-2 Ag | Positive Percent Agreement (%) | Cumulative Positive Percent Agreement (%) |
|---|---|---|---|---|
| 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 QIAreach SARS-CoV-2 Antigen Test when compared with an FDA EUA high sensitivity SARS-CoV-2 RT-PCR assay.

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

| QIAreach 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%) | | |

# 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 x $10^6$ $TCID_{50}$/mL. 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 QIAreach 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 QIAreach 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 8).

**Table 8. LoD confirmation**

| LoD Measurement | SARS-CoV-2 concentration | QIAreach SARS-CoV-2 Antigen Test result | % Positive |
|---|---|---|---|
| Patient swab | $5.0 \times 10^4$ $TCID_{50}$/mL | 19/20 Positive | 95% |

## Cross-reactivity (analytical specificity) and microbial interference

The QIAreach 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 media) 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 $TCID_{50}$/mL) to assess the likelihood of a false negative result. Bacterial and viral pathogens were prepared to a target test concentration of 1 x $10^6$ CFU/mL or IFU/mL, 1 x $10^5$ $TCID_{50}$/mL or 1 x $10^5$ $EID_{50}$/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 Media 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 9).

**Table 9. Cross-reactivity and microbial interference summary for the QIAreach 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† | *in silico* | 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 |
| *Haemophilus influenzae* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Streptococcus pneumoniae* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |

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**Table 9. Cross-reactivity and microbial interference summary for the QIAreach SARS-CoV-2 Antigen Test (cont'd)**

| Pathogen | Concentration tested | Cross-reactivity (Negative result/total tested) | Interference (SARS-CoV-2 positive result/total tested) |
|---|---|---|---|
| *Streptococcus pyogenes* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Candida albicans* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Bordetella pertussis* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Mycoplasma pneumoniae* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Chlamydia pneumonaie* | 1 x $10^6$ IFU/mL | 3/3 | 3/3 |
| *Legionella pneumophila* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Staphylococcus aureus* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Staphylococcus epidermidis* | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Mycobacterium tuberculosis*† | 1 x $10^6$ CFU/mL | 3/3 | 3/3 |
| *Pneumocystis jirovecii* (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 QIAreach SARS-CoV-2 Antigen Test was not performed. However, the antibodies used in the QIAreach SARS-CoV-2 Antigen Test have been shown to exhibit cross-reactivity with SARS-CoV nucleocapsid. Thus, the QIAreach 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 $TCID_{50}$/mL) to

assess the likelihood of a false negative result. The concentrations of endogenous interference substances represent the concentrations in the collected Transport Media 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 media) and negative clinical matrix spiked with heat inactivated SARS-CoV-2 virus. Results from endogenous interference test are displayed in Table 10.

**Table 10. Summary of endogenous interfering substance testing**

| Interference substances | Concentration tested | Negative Matrix (QIAreach SARS-CoV-2 Antigen Test negative result/total tested) | Positive Matrix (QIAreach 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 QIAreach SARS-CoV-2 Antigen Test up to a concentration of 1.15 x $10^6$ $TCID_{50}$/mL using heat inactivated SARS-CoV-2 (ZeptoMetrix™, 0810587CFHI).

# Technical Information

## eHub display icons

**Table 11. 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.<br>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 13. “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 14. "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. |

Table continued on next page

Table continued from previous page

**Table 15. "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).

# References


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# Symbols

The following symbols may appear on the packaging and labelling:

| Symbol | Symbol definition |
|---|---|
|  | *In vitro* 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. |
|---|---|---|
| QIAreach SARS-CoV-2 Antigen Test Kit | 60 QIAreach SARS-CoV-2 Antigen eSticks / Processing Tubes<br>2 x 10 ml QIAreach SARS-CoV-2 Antigen Diluent Buffer | 646533 |
| **Relative Products** | | |
| QIAreach SARS-CoV-2 Antigen Controls | 4 QIAreach SARS-CoV-2 Antigen Positive Controls and 4 QIAreach SARS-CoV-2 Antigen Negative Controls | 646030 |
| QIAreach eHub | QIAreach eHub, power adapter, and USB connector cable | 9003063 |
| QIAreach 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 |

**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:

1. The product may be used solely in accordance with the protocols provided with the product and this handbook and for use with components contained in the kit only. QIAGEN grants no license under any of its intellectual property to use or incorporate the enclosed components of this kit with any components not included within this kit except as described in the protocols provided with the product, this handbook, and additional protocols available at www.qiagen.com. Some of these additional protocols have been provided by QIAGEN users for QIAGEN users. These protocols have not been thoroughly tested or optimized by QIAGEN. QIAGEN neither guarantees them nor warrants that they do not infringe the rights of third-parties.
2. Other than expressly stated licenses, QIAGEN makes no warranty that this kit and/or its use(s) do not infringe the rights of third-parties.
3. This kit and its components are licensed for one-time use and may not be reused, refurbished, or resold.
4. QIAGEN specifically disclaims any other licenses, expressed or implied other than those expressly stated.
5. The purchaser and user of the kit agree not to take or permit anyone else to take any steps that could lead to or facilitate any acts prohibited above. QIAGEN may enforce the prohibitions of this Limited License Agreement in any Court, and shall recover all its investigative and Court costs, including attorney fees, in any action to enforce this Limited License Agreement or any of its intellectual property rights relating to the kit and/or its components.

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

# QIAreach® SARS-CoV-2 Antigen Test Quick Reference Guide

The QIAreach® SARS-CoV-2 Antigen Test is a rapid, digital lateral flow diagnostic assay, using nanoparticle fluorescence, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and anterior nasal (AN) swab specimens collected in Copan® Diagnostic Universal Transport Media (UTM-RT™)from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. 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 QIAreach® 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. Antigen 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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

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 decisions. 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 clinical laboratory personnel specifically instructed on in vitro diagnostic procedures.

The QIAreach SARS-CoV-2 Antigen Test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This QIAreach SARS-CoV-2 Antigen Test 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.

Due to the risk of false-positive results, confirmation of positive results should be considered using a different molecular assay. Please study the QIAreach SARS-CoV-2 Antigen Test Instructions for Use (Handbook) thoroughly before referring to this Quick Reference Guide. This Quick Reference Guide is not intended as an exhaustive instructional document.

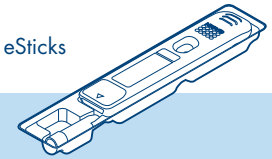
**IVD** **RX ONLY**

For use under Emergency Use Authorization (EUA) only

**REF** 646533

## Test Kit Contents (REF 646533)

60 x QIAreach SARS-CoV-2 Antigen eSticks

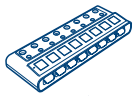


60 x QIAreach SARS-CoV-2 Antigen Processing Tubes

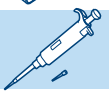
2 x 10ml QIAreach SARS-CoV-2 Antigen Diluent Buffer

## Additional Components Required

QIAreach eHub

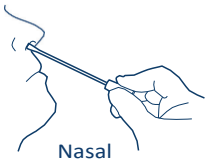


Adjustable Volume Pipettes + tips
Volume/s required: 100µl, 400µl

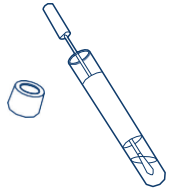


Swab and transport media (Copan UTM®)
Minimum collection volume 1ml

## Pre-analytical Steps



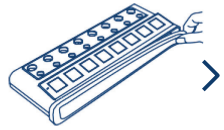

Patient sample collected through Nasal or Nasopharyngeal swab. For Nasal and Nasopharyngeal swab collection, follow swab manufacturer instructions and CDC guidelines.

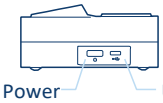
Patent sample stored in viral transport media (Copan UTM) to Manufacturer's instructions. Please refer to IFU for further details.

## QIAreach eHub Setup

Remove QIAreach eHub from its packaging.



Remove the dust cover from the front of the QIAreach eHub.




Connect the eHub to power via USB (wall plug or PC). Press the power button to turn on the QIAreach eHub.

**NB:** Refer to QIAreach eHub User Manual for a complete guide to device operation and troubleshooting.

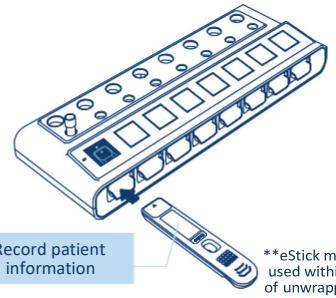
www.qiagen.com
800-344-3631
Technical support: techservice-na@qiagen.com

Digital Detection Technology designed by and licensed from ellume
ellumehealth.com

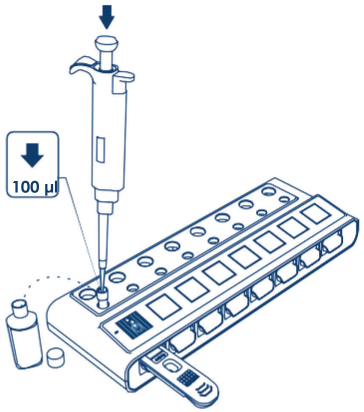
# Test Procedure

**Note:** Refer to the *QIAreach SARS-CoV-2 Antigen Test Instructions for Use* for Warnings and Precautions, Directions for Use, Results, Analysis and Test Interpretation, Technical Information, and Troubleshooting. For required positive and negative control testing associated with the QIAreach SARS-CoV-2 Antigen Test, use the QIAreach SARS-CoV-2 Antigen Controls product; this product is sold separately and is available from QIAGEN (Catalog Number 646030). External controls should be run as outlined in the procedure for testing the samples. Positive and negative controls are required to be tested each time a new lot is used, when a new operator performs the test, or when the test is run in a new room/laboratory, etc., as a good laboratory practice to confirm the test procedure and to verify proper test performance.

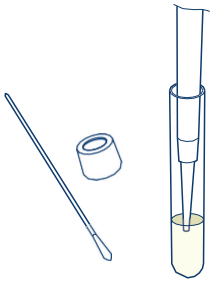
1 Ensure that the QIAreach eHub is turned on, then insert the QIAreach Processing Tube and eStick.



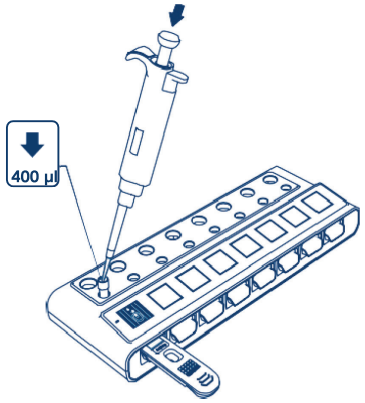

2 Transfer 100 µl of QIAreach Diluent Buffer solution into the QIAreach Processing Tube.



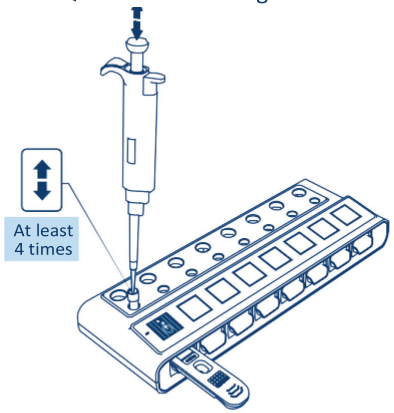

3 Draw 400 µl of patient sample from transport media (Copan UTM).
Refer to IFU for further detail.



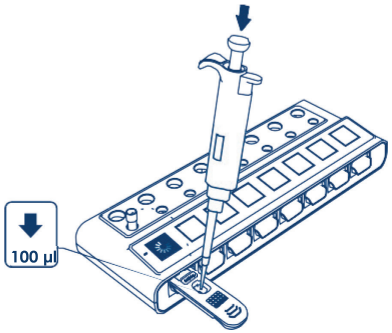
4 Transfer the sample to the QIAreach Processing Tube.



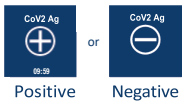

5 Mix the contents at least 4 times to mix the sample in the QIAreach Processing Tube.



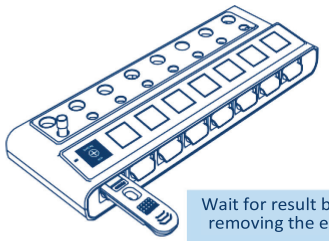

6 Transfer 100 µl from the QIAreach Processing Tube to the eStick.




7 The test will run automatically and display a result within 2–15 minutes.




Positive Negative




**Disclaimer:**
- QIAreach SARS-CoV-2 Antigen results should not be used to diagnose or exclude acute infection. Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.

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

## Intended use

IVD

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

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.

QIAGEN, 19300,
Germantown Road,
Germantown, MD
20874, USA
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<br>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. | (W1) |

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.

August 2021

# QIAreach® eHub User Manual

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

REF 9003063

QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden

R2 MAT 1122908EN

Sample to Insight

QIAGEN

# Contents

# 1 Introduction

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

## 1.1 About this user manual

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

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

The Appendix section contains the following information:

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

## 1.2 General Information

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

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

### 1.2.1 Technical assistance

At QIAGEN®, we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the QIAreach eHub or QIAGEN products in general, do not hesitate to contact us.

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

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

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

### 1.2.2 Policy statement

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

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

## 1.3 Intended use of the QIAreach eHub

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

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

### 1.3.1 Limitations of use

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

## 1.4 Symbols on the QIAreach eHub

The following symbols may appear on the packaging or labelling.

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

| | | |
|---|---|---|
|  | Type plate and outer box label of the QIAreach eHub | Attention |

# 2 Safety Information

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

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

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

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

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

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

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

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

The guidance provided in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

## 2.1 Proper use

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

## 2.2 Electrical safety

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

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

## 2.3 Chemical safety

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

## 2.4 Biological safety

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

Always observe safety precautions as outlined in relevant guidelines. Avoid contamination of the QIAreach eHub and workspace by handling samples and eSticks

with care. In the event of contamination, clean and decontaminate the affected area of the QIAreach eHub.

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

## 2.5 Waste disposal

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

# 3 General Description

## 3.1 System description

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

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

## 3.2 QIAreach eHub description

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

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

The QIAreach eHub includes the following elements:

- eStick connection ports for up to eight (8) separate tests
- Visual display screen centered above each individual eStick connection port
- QIAreach processing tube holder slot positioned directly behind each visual display screen

- Sample tube holder slot positioned directly behind each processing tube holder slot, to be used for applicable tubes sizes for specific test type.
- USB-C port for connection to a USB charger (supplied) or computer
- Battery LED indicator

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

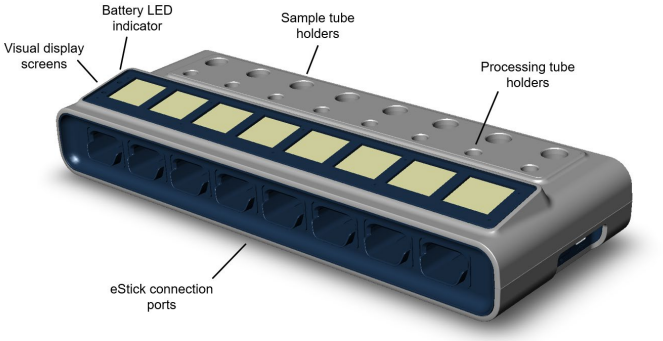



**Figure 1. Front view of QIAreach eHub.**

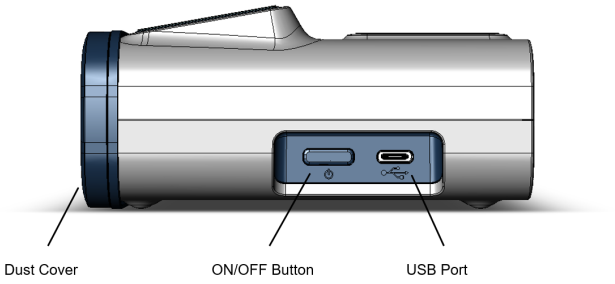



**Figure 2. Side view of QIAreach eHub.**

# 4 Installation Procedures

## 4.1 Site requirements

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

Note: Before installing and using the QIAreach eHub, see

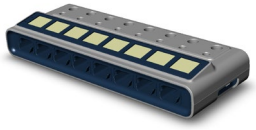
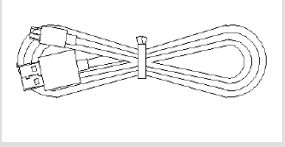
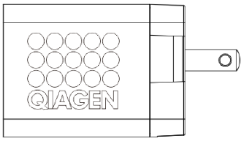
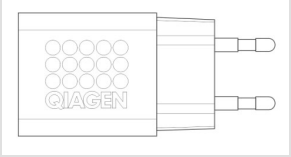
Operating the to become familiar with the QIAreach eHub operating conditions.

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

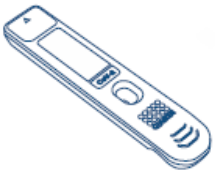
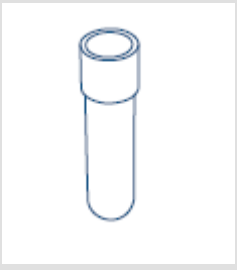
## 4.2 QIAreach eHub delivery and components

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

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

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

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

| Components | Description |
|---|---|
|  | QIAreach eStick |
|  | QIAreach Processing Tube |
|  | QIAreach Diluent Buffer |

## 4.3 Unpacking and installing the QIAreach eHub

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

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

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

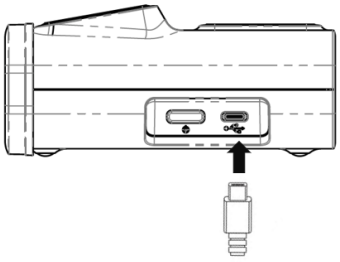


**Figure 3. Connecting the USB cable to the QIAreach eHub USB port.**

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

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

# 5 Operating the QIAreach eHub

## 5.1 Setting up the QIAreach eHub for use

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

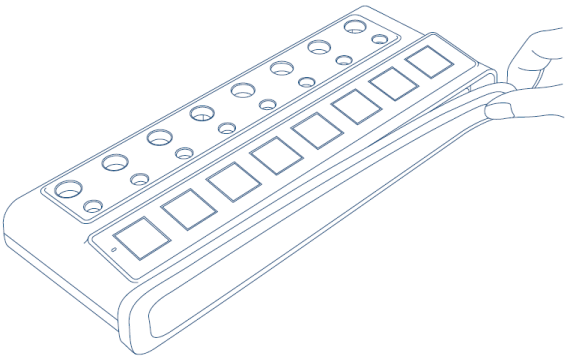


**Figure 4. Removing the dust cover from the front of QIAreach eHub prior to use.**

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

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

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

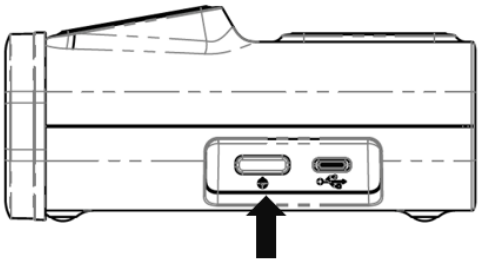


**Figure 5. Press the ON/OFF switch to turn on the QIAreach eHub.**

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.

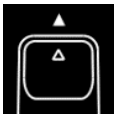


**Figure 6. Insert eStick icon.** This signifies that an QIAreach eHub port is available for use.

## 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.

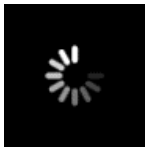


**Figure 7. Self-test screen display.**

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

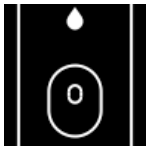


**Figure 8. Add sample screen display.**

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. Battey 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<br><br>Disconnect the QIAreach eHub from all power sources before cleaning.<br>Ensure the QIAreach eHub is turned off before cleaning. | (W2)<br><br>(C3) |

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

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

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

- Mild detergent
- Water

When cleaning the QIAreach eHub surface:

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

# 8 Troubleshooting

## 8.1 General information

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

## 8.2 Contacting QIAGEN Technical Services

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

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

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

## 8.3 QIAreach eHub error codes

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

**Table 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-seviceable):

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

Operating conditions

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

Transport conditions

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

Storage conditions

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

**RoHS (Responsibility of Health and Safety) Compliance:**

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

## 9.1 Electromagnetic compatibility (EMC)

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

## 9.2 Electrical Safety

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

## 9.3 Cybersecurity

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

## 9.4 Software Validation

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

# 10 Appendix A – Technical Data

## 10.1 FCC Compliance: Supplier's Declaration of Conformity

**47 CFR § 2.1077 Compliance Information**

Unique Identifier: 9003063 – QIAGEN QIAreach eHub

**Responsible Party – U.S. Contact Information**

QIAGEN Inc. - USA

19300 Germantown Road

Germantown, MD 20874

Telephone: (800-362-7737)

Email: customercare-us@qiagen.com

**FCC Compliance Statement**

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

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

1) This device may not cause harmful interference.

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

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

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

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

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

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

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

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

## 10.2 Waste Electrical and Electronic Equipment (WEEE)

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

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

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

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

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

## 10.3 Disclaimer of warranties

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

# 11 Ordering Information

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

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

# 12 Document Revision History

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

**Limited License Agreement for QIAreach eHub**

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

1. The product may be used solely in accordance with the protocols provided with the product and this handbook and for use with components contained in the kit only. QIAGEN grants no license under any of its intellectual property to use or incorporate the enclosed components of this kit with any components not included within this kit except as described in the protocols provided with the product, this handbook, and additional protocols available at www.qiagen.com. Some of these additional protocols have been provided by QIAGEN users for QIAGEN users. These protocols have not been thoroughly tested or optimized by QIAGEN. QIAGEN neither guarantees them nor warrants that they do not infringe the rights of third-parties.
2. Other than expressly stated licenses, QIAGEN makes no warranty that this kit and/or its use(s) do not infringe the rights of third-parties.
3. This kit and its components are licensed for one-time use and may not be reused, refurbished, or resold.
4. QIAGEN specifically disclaims any other licenses, expressed or implied other than those expressly stated.
5. The purchaser and user of the kit agree not to take or permit anyone else to take any steps that could lead to or facilitate any acts prohibited above. QIAGEN may enforce the prohibitions of this Limited License Agreement in any Court, and shall recover all its investigative and Court costs, including attorney fees, in any action to enforce this Limited License Agreement or any of its intellectual property rights relating to the kit and/or its components.

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

# QIAreach® eHub


Emergency Use Authorization (EUA) only

Please be advised:

- 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.

- 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.



1122905 Rev. 02

# QIAreach® SARS-CoV-2 Antigen Test


Emergency Use Authorization (EUA) only

Please be advised:

- 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.

- 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.



1122907 Rev. 02

# QIAreach® SARS-CoV-2 Ag Controls


Emergency Use Authorization (EUA) only

Please be advised:

- 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.

- This product has been authorized only for use as a positive and negative external quality control product to assess the performance of the QIAreach 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/

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



1124093 Rev. 02