February 2022

QIAreach® Anti-SARS-CoV-2 Total Test Instructions for Use (Handbook)

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

Version 1

IVD

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Sample to Insight

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Intended Use

The QIAreach® Anti-SARS-CoV-2 Total Test is a rapid, digital lateral flow serological test, using nanoparticle fluorescence, intended for qualitative detection of total antibodies to SARS-CoV-2 in human serum and plasma (sodium heparin, lithium heparin, dipotassium EDTA, and tripotassium EDTA). The QIAreach® Anti-SARS-CoV-2 Total Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The QIAreach® Anti-SARS-CoV-2 Total Test should not be used to diagnose or exclude acute SARS-CoV-2 infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Testing is limited to 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.

Results are for the detection of SARS CoV-2 antibodies. Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the QIAreach® Anti-SARS-CoV-2 Total Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False-positive results for the QIAreach® Anti-SARS-CoV-2 Total Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different SARS-CoV-2 antibody test.

The QIAreach® Anti-SARS-CoV-2 Total 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 readily transmitted from both symptomatic and presymptomatic[2-4] individuals via respiratory droplets, aerosols, and upper respiratory secretions.[5-6] The incubation period is estimated to be 4.6–5.8 days with a median of ~5 days.[7] The symptoms of COVID-19 are non-specific, ranging from asymptomatic to severe pneumonia and death.[8] 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.[8-10] Roughly 20% of those infected with SARS-CoV-2 will experience severe symptoms, including Acute Respiratory Distress Syndrome (ARDS) that often requires mechanical ventilation.[11]

The standard medical practice for definitive diagnosis of active SARS-CoV-2 infection relies on the molecular detection of viral RNA.[12-14] Typically, IgA and IgM production occur simultaneously and shortly after viral infection with IgM ebbing rapidly in convalescence.[15-16] IgG antibody responses occur after IgM and IgA seroconversion and are longer sustained.[17] The QIAreach® Anti-SARS-CoV-2 Total Test detects total antibodies to SARS-CoV-2 and is an indirect test for indicating recent or prior infection in populations of interest. The clinical and public health applications of serologic assays may include support to clinical assessment in persons suspected of having a post-infectious syndrome and understanding transmission dynamics in populations.[18]

Principles of the assay

The QIAreach® Anti-SARS-CoV-2 Total Test is a rapid, qualitative serological test that detects total antibody responses to expressed SARS-CoV-2 viral antigens, in serum or plasma (sodium heparin, lithium heparin, dipotassium EDTA and tripotassium EDTA).

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

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

To perform the test, QIAreach Diluent Buffer is first added to the QIAreach Processing Tube and reconstitutes a SARS-CoV-2 viral S1 protein-fluorescent nanoparticle conjugate that is spray dried on an immobilized accretion pad within the tube. Patient serum or plasma is then added to the Processing Tube and mixed with the resuspended conjugate using a pipette. If anti-SARS-CoV-2 antibodies are present in the sample, they will bind to the SARS-CoV-2 S1 antigen-nanoparticle 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. The migrating anti-SARS-CoV-2 antibodies will bind to immobilized SARS-CoV-2 viral S1 protein at the test line, where they will bridge the two SARS-CoV-2 S1 viral proteins on the test line and in the conjugate. A 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® Anti-SARS-CoV-2 Total test results are determined as Positive or Negative according to the assay result algorithm on the eStick firmware.

Software is available to backup test results, generate test reports, and support online data transfer.

Time required for performing the assay

The time required to perform the QIAreach Anti-SARS-CoV-2 Total Test is estimated below. The time of testing multiple samples when batched is also indicated.

Digital detection:	Approx. 10 minutes for one test (1 individual)

<20 minutes labor in total

Add up to 3 minutes for each extra eStick

Pipet use

This assay requires use of an adjustable volume pipet. Users should familiarize themselves with pipet use prior to performing the QIAreach® Anti-SARS-CoV-2 Total Test.

Kit Contents

QIAreach® Anti-SARS-CoV-2 Total Test		
Catalog number		**645033**
Number of tests/pack		**60**
QIAreach Anti-SARS-CoV-2 Total Test Detection System Components*		
QIAreach eStick	Packaged together with Processing Tube in foil wrapper Contains recombinant SARS-CoV-2 S1 protein and human serum albumin	
QIAreach Processing Tube	Packaged together with eStick in foil wrapper Contains an accretion pad that contains spray dried fluorescent nanoparticles conjugated to SARS-CoV-2 S1 viral protein and bovine serum albumin, along with maltose.	
QIAreach Diluent Buffer	Contains bovine serum albumin and ProClin® 300	3 x 10 ml

*See Warnings and Precautions for precautions and hazard statements.

Materials Required but not Provided

Collection tubes for patient serum and plasma (lithium heparin, sodium heparin, dipotassium EDTA, tripotassium EDTA)
QIAreach® eHub (including USB adapter and cable)*- Catalogue# 9003063
QIAreach® Anti-SARS-CoV-2 Controls (Catalogue # 647030)

Equipment required but not provided

Calibrated pipets* for delivery of 50 µl, 150 µl, and 300 µl with disposable tips
Optional: Centrifuge for isolating patient serum or plasma
Optional: QIAreach Software (Catalogue# 1118894)

Storage and Handling

Kit reagents

Store kit reagents at 2–30°C for up to 4 months.

Stability

The test must be initiated within 60 minutes of opening the foil-wrapped eStick and Processing Tube.
The QIAreach® Anti-SARS-CoV-2 Total 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.

* See Warnings and Precautions for precautions and hazard statements.

QIAreach Diluent Buffer should be used within 3 months after opening the bottle.

Warnings and Precautions

Warnings

For prescription use only. For in vitro diagnostic use only. For Emergency Use Authorization Only.

This 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 certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet the requirements to perform moderate or high complexity tests.

This test has been authorized only for detecting the presence of total antibodies to SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this test 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.

Do not use kits or reagents after the expiration dates shown on the labels.

Ensure test is run away from direct sunlight.

Do not use damaged test kit. Do not reuse the test kit.

Human serum and plasma samples should be considered as potentially infectious. Operators should wear protective clothing, masks, gloves and take other appropriate safety precautions to avoid or reduce the risk of infection.

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).

CAUTION 	Handle all human blood serum, and plasma as if potentially infectious. Observe relevant blood and blood product handling guidelines. Dispose of samples and materials in contact with blood or blood products in accordance with federal, state, and local regulations.	(C1)

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

Hazard statements

WARNING	**QIAreach Diluent Buffer** 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)

WARNING 	QIAreach® **eHub** 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 eStick** 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® *Anti-SARS-CoV-2 Total 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 broken eSticks.
Discard used or unused materials and biological samples in accordance with local and government regulations.
Do not use the QIAreach® Anti-SARS-CoV-2 Total Test kit after the expiration date.
Do not mix consumables and reagents from multiple lots.

Procedures

Preparing samples

Note: The QIAreach® Anti-SARS-CoV-2 Total Test requires 50 µl of serum or plasma for an individual test.

Follow all instructions provided by the manufacturer of the sample collection device when collecting test specimens. Collect all specimens using standard procedures. Refer to the following guidelines[19] for handling of samples prior to performing the QIAreach® Anti-SARS-CoV-2 Total Test.

Samples that require fractionation from red blood cells should be isolated by appropriate means (e.g. centrifugation using a gel separator) prior to analysis. Samples collected in serum tubes should be allowed to clot prior to serum separation.

Samples should optimally be tested as soon as possible following collection and may be held at room temperature (17–27°C) for up to 8 hours prior to testing.

Samples may be stored for up to 2 days at 2–8°C prior to testing.

Samples that require long term storage prior to testing may be stored at ≤ –20°C. Specimens may be frozen and thawed once.

Detection assay

Materials required

QIAreach Processing Tube (packaged together with eStick in foil wrapper)
QIAreach eStick (packaged together with Processing Tube in foil wrapper)
QIAreach Diluent Buffer
QIAreach® eHub (with associated power cable and adapter), sold separately

Important points before starting

All samples and reagents (if stored in the refrigerator), must be brought to room temperature (17–27°C) before use. Allow at least 60 minutes for sample equilibration to room temperature. Any clots visible in the samples may be removed by centrifugation.

The eStick and Processing Tube are packaged together in a foil wrapper. The packaging should only be opened before performing the assay.

Important: The QIAreach® Anti-SARS-CoV-2 Total Test must be started within 60 minutes of removing the components from the packaging.

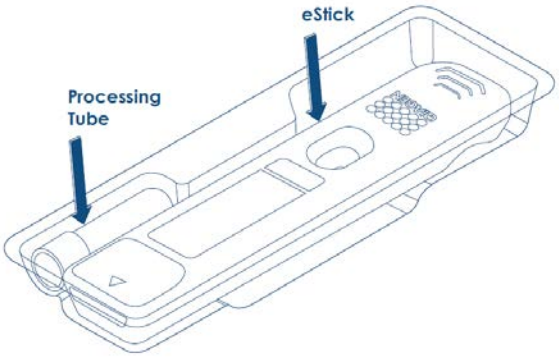


Figure 1. Contents of foil wrapper packaging – QIAreach Processing Tube and eStick.

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 critical component of the QIAreach® Anti-SARS-CoV-2 Total Test. DO NOT remove the pad from the Processing Tube. This pad will not be dislodged or come loose 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 QIAreach® Anti-SARS-CoV-2 Total Test should not be performed if the eHub battery power is less than 10% and is not connected to a power source. The battery LED indicator will display the battery status. The battery level can also be checked by connecting the eHub to a laptop via 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 (provided with the optional QIAreach software) 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.

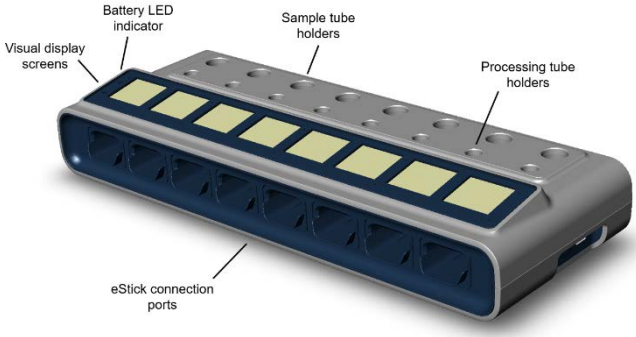


Figure 2. eHub layout. Note: The cover should be in place when the eHub is not in use.

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. We also recommend that the eHub is connected to a USB power source (either a USB adapter or PC) during operation.

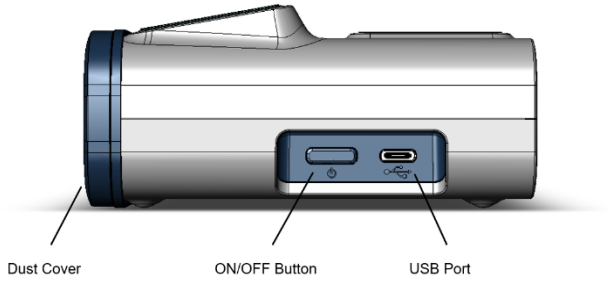
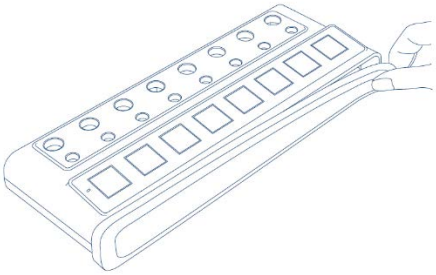


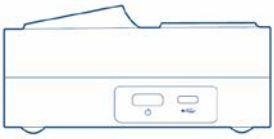
Figure 3. Side panel view of eHub with dust cover, ON/OFF switch and USB connection port.

Procedure

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

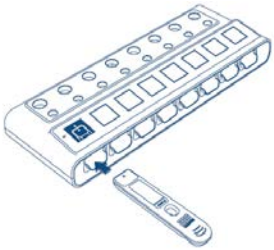


2. Press the **ON/OFF** switch on the right side of the eHub to turn it on.

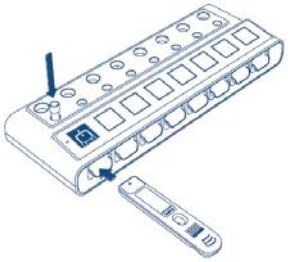


3. Remove the eStick from the packaging, label with patient identifier, and insert into the eHub.

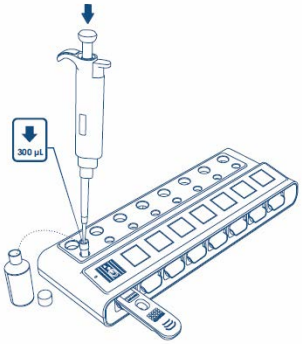
   Note: The test sample must be added to the eStick sample port within 60 minutes of removal from the foil packaging.



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

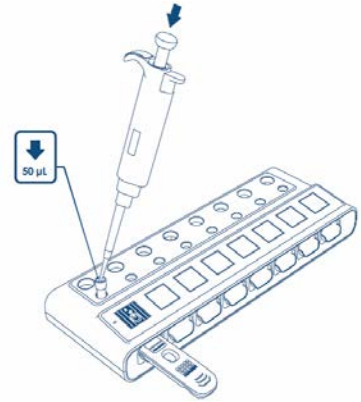


5. Add 300 µl of QIAreach Diluent Buffer to the Processing Tube using a pipet.

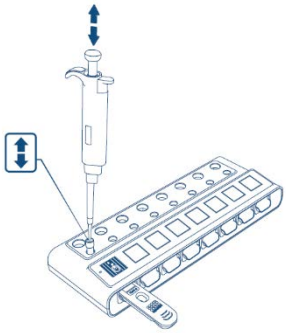


6. Carefully remove 50 µl of the patient sample (serum or plasma) from the sample tube using a pipet.

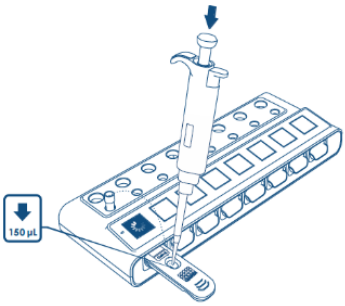
7. Add the patient sample to the Processing Tube containing the QIAreach Diluent Buffer.



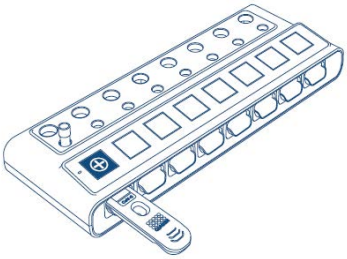
8. With the pipette set to 150 µl, mix the contents of the Processing Tube by pipetting up and down at least 4 times. Take care to not introduce foam while pipetting.



9. Remove 150 µl of the mixed sample from the Processing Tube and dispense into the sample port of the inserted eStick.



10. The test will start automatically within approximately 30 seconds following sample addition, signaled by a countdown timer on the display. Do not remove the inserted eStick until the test is complete and a result is displayed.



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 sample addition to the eStick to the test result is 10 minutes. The time to result will be less than 10 minutes for positive samples containing elevated anti-SARS-CoV-2 antibody levels. The time to test result will be displayed on the eHub following a positive result.

QIAreach Anti-SARS-CoV-2 Total Test raw data is analyzed on the eStick firmware, which then interprets a positive or negative QIAreach® Anti-SARS-CoV-2 Total Test result based on an internal algorithm. The result is transmitted to the eHub, which displays the result. If the optional QIAreach software (Catalogue# 1118894) is used, the eHub will transfer the test result to a computer for data backup and report printing. Please refer to the QIAreach software user manual for detailed instructions about how to use the QIAreach software with the QIAreach Anti-SARS-CoV-2 Total Test.

Quality control of test

All 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 at least 48 unique 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 are required but not supplied with this kit; and are available for purchase separately from QIAGEN (QIAreach® Anti-SARS-CoV-2 Controls, Catalog # 647030). 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 when 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.

If the test is invalid, an error code will be displayed on the eHub. The test should be repeated if there is ≥ 50 µl of patient sample remaining. See Table 7 in the Technical Information section for the list of QIAreach Anti-SARS-CoV-2 Total test error codes.

Interpretation of results

Assessment of QIAreach Anti-SARS-CoV-2 Total Test results is to be performed after the positive and negative controls have been examined, as recommended in Quality Control section above, and determined to be valid and acceptable. If the controls are not valid, the results cannot be interpreted.

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

Table 1. Interpretation of QIAreach® Anti-SARS-CoV-2 Total Test results

QIAreach Anti-SARS-CoV-2 Total Test result	Report/Interpretation
Positive (+)	Positive for antibodies for SARS-CoV-2
Negative (-)	Negative for antibodies for SARS-CoV-2

QIAreach Anti-SARS-CoV-2 Total 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. **Important**: Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

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.
- This test can only be used for the analysis of serum and plasma (sodium heparin, lithium heparin, dipotassium EDTA and tripotassium EDTA) samples. Do not use with venous or fingerstick (capillary) whole blood samples.

- The test is limited to the qualitative detection of total antibodies specific for the SARS-CoV-2 virus.

- Results from antibody testing should not be used to diagnose acute SARS-CoV-2 infection or to inform infection status. An assay that directly detects the virus should be used to evaluate symptomatic patients for acute COVID-19.

- It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to infection.

- False negative results may occur for immune-compromised individuals or individuals who receive immunosuppressive therapy.

- Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Antibodies may not be detected in the first few days of infection; The sensitivity of QIAreach® Anti-SARS-CoV-2 Total Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

- False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible cause. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

- A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second, different serology test to confirm an adaptive immune response.

- Significantly hemolyzed (reddish brown) samples can potentially interfere with the QIAreach® Anti-SARS-CoV-2 Total Test optical measurement system. The eStick firmware features built-in controls to determine unacceptably high levels of hemolysate (> 5mg/ml) and will return an invalid result in the form of an error code if interference is present. Refer to the troubleshooting section if observing elevated hemolysate in samples.

- Not to be used for the screening of donated blood.

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

- The performance of this test has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.

- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The specimens for the negative agreement studies were collected in Pennsylvania, USA between July 2019 and September 2019 and in Florida, USA between August 2018 and October 2019. The specimens for the positive agreement studies were collected in Florida, Louisiana, Texas, and the state of Washington, USA between April 2020 and June 2020 and in Lima, Peru in May 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Conditions of Authorization for the Laboratory

The QIAreach® Anti-SARS-CoV-2 Total Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, 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.

Authorized laboratories using the QIAreach® Anti-SARS-CoV-2 Total Test (referred to as “your product” in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

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

- Authorized laboratories 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.

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

- 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.

- 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 to you (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.

- All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

- Authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Performance Characteristics

Clinical performance

Positive Percent Agreement (PPA)/Sensitivity

PPA/Sensitivity was estimated by evaluating serum and plasma samples from study subjects with PCR-confirmed symptomatic SARS-CoV-2 infection. A total of 65 previously collected samples from 65 subjects, collected from April 2020 to July 2020 in the United States (43 samples) and Peru (22 samples), were tested using the QIAreach Anti-SARS-CoV-2 Total Test.

The following table describes the positive percent agreement by time of sampling after onset of symptoms.

Table 2. Clinical sensitivity by days post-symptom onset

Number of days after symptom onset	Number of samples tested	Number of QIAreach® Anti-SARS-CoV-2 Total Test positive results	Positive percent agreement	95% confidence interval
0 – 7 days	3	2	66.67 %	9.43 – 99.16 %
8 – 14 days	13	12	92.31 %	63.97 – 99.81 %
≥ 15 days	49	47	95.92 %	86.02 – 99.50 %
All	65	61	93.85 %	84.99 – 98.30 %

Negative Percent Agreement/Specificity

NPA/Specificity was estimated by evaluating samples collected before the start of the SARS-CoV-2 pandemic (before December 2019). A total of 230 previously collected serum and plasma samples from 230 subjects in the United States were tested using the QIAreach Anti-SARS-CoV-2 Total Test. The following table shows the negative percent agreement.

Table 3. Negative Percent Agreement

Number of samples tested	Number of QIAreach® Anti-SARS-CoV-2 Total Test negative results	Negative percent agreement	95% confidence interval
230	225	97.83 %	95.00 – 99.29 %

Independent evaluation of clinical performance

The QIAreach Anti-SARS-CoV-2 Total Test was tested on December 10, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). Tests were from lot number 86652. The test was evaluated against "Panel 3" which is a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both SARS-CoV-2 IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the QIAreach Anti-SARS-CoV-2 Total Test. The presence of SARS-CoV-2 antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include i) seventy (70) samples selected without regard to clinical status, "Negatives" and ii) Ten (10) samples selected from banked serum from HIV+ patients, "HIV+". Testing was performed by one operator using 1 lot of QIAreach Anti-SARS-CoV-2 Total Test.

Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).

For the evaluation of cross-reactivity with HIV+, it was determined whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the following tables:

Table 4. Summary Results

	Comparator Method			Collected pre-2020		Total
	Antibody Positive			Antibody Negative		
QIAreach Anti- SARS-CoV-2 Total Test	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	Total
Pan Ig+	30			2		32
Pan Ig-				68	10	78
Total	30			70	10	110

Table 5. Summary Statistics

Measure	Estimate	Confidence Interval
Pan Ig Sensitivity	100% (30/30)	(88.7%; 100%)
Pan Ig Specificity	97.5% (78/80)	(91.3%; 99.3%)
Combined Sensitivity	100% (30/30)	(88.7%; 100%)
Combined Specificity	97.5% (78/80)	(91.3%; 99.3%)
Combined PPV for prevalence = 5.0%	67.8%	(35.0%; 88.4%)
Combined NPV for prevalence = 5.0%	100%	(99.4%; 100%)
Combined NPV for prevalence = 5.0%	100%	(99.4%, 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

Important limitations:

1. Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device
2. These results are based on serum and ACD plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.
3. The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

Cross-reactivity

QIAreach® Anti-SARS-CoV-2 Total Test was evaluated for potential cross-reactivity with antibodies to the pathogens listed below. All samples were collected from

SARS-CoV-2 negative individuals prior to November 2019 (pre-pandemic). A total of 167 individual specimens were tested. No cross-reactivity was observed.

Table 6. Cross-reactivity summary for QIAreach® Anti-SARS-CoV-2 Total test*

Pathogen	Sample type	N	Number of cross-reactive	Number of non-reactive
Adenovirus	Plasma	28	0	28
Anti-nuclear Antibody (ANA)	Serum	5	0	5
Bordetella pertussis	Plasma	31	0	31
Chlamydia pneumoniae	Plasma	42	0	42
CoV 229E	Serum	17	0	17
CoV HKU1	Serum	5	0	5
CoV NL63	Serum	5	0	5
CoV OC43	Serum	14	0	14
Dengue	Serum	10	0	10
Enterovirus	Plasma	20	0	20
Haemophilus influenzae	Plasma	5	0	5
Hepatitis B- HBc	Serum	5	0	5
Hepatitis B- HBs	Serum	5	0	5
Hepatitis C	Serum	5	0	5
Influenza A	Plasma	63	0	63
Influenza A	Serum	5	0	5
Influenza B	Plasma	72	0	72
Legionella pneumophila	Plasma	12	0	12
Mycoplasma pneumoniae	Plasma	81	0	81
Parainfluenza	Plasma	103	0	103
Respiratory Syncytial Virus (RSV)	Plasma	76	0	76
Respiratory Syncytial Virus (RSV)	Serum	5	0	5

* This table evaluates cross-reactivity separately for each pathogen category. With several specimens, containing antibodies to multiple pathogens, some specimens are listed more than once, but in separate pathogen categories.

Interference

The effect of potentially interfering substances on QIAreach® Anti-SARS-CoV-2 Total Test was evaluated by spiking endogenous and exogenous interferents at CLSI recommended high level concentrations into SARS-CoV-2 negative plasma and negative plasma spiked with low titer SARS-CoV-2 antibody. No significant interference was observed at the following concentrations:

Bilirubin, conjugated	0.4 mg/ml
Bilirubin, unconjugated	0.4 mg/ml
Hemoglobin*	5 mg/ml
Prednisolone	0.12 mg/ml
Triglycerides	15 mg/ml

* Hemoglobin levels above 5 mg/ml (reddish brown colored samples) can potentially interfere with the QIAreach® Anti-SARS-CoV-2 Total Test optical measurement system. The eStick firmware features built-in controls to determine unacceptably high levels of hemolysate and will return an invalid result in the form of an error code if interference is present. See Troubleshooting Guide for more information.

Matrix equivalency

QIAreach Anti-SARS-CoV-2 Total Test performance was evaluated in serum, lithium heparin plasma, sodium heparin plasma, dipotassium EDTA plasma, and tripotassium EDTA plasma by obtaining each sample matrix in a single blood collection from each of five negative donors and one positive donor. Low and Medium level positive samples were contrived by diluting the positive subject sample into each of the

negative subject samples, with each sample matrix diluted into the same matrix that was being assessed in order to maintain matrix integrity. The contrived Low and Medium positive samples were tested in parallel with uncontrived negative samples, with 2 replicates tested at each concentration level. QIAreach Anti-SARS-CoV-2 Total Test results were evaluated against the expected Negative result for uncontrived samples and the expected Positive result for Low and Medium level contrived positive samples. Result agreement is shown in Table 7.

Table 7. Sample matrix equivalency test agreement to expected result

Sample matrix	Negative agreement (n=10)	Low positive agreement (n=10)	Med positive agreement (n=10)	Overall agreement (n=40)
Serum	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
Lithium Heparin	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
Sodium Heparin	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
Dipotassium EDTA	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)
Tripotassium EDTA	10/10 (100%)	10/10 (100%)	10/10 (100%)	30/30 (100%)

Technical Information

Clotted plasma samples

Should fibrin clots occur with long-term storage of plasma samples at or below –20°C, the samples may be centrifuged to sediment clotted material and to facilitate pipetting of plasma.

eHub display icons

Table 8. 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 10 minutes.
	Positive	Anti-SARS-CoV-2 antibody present
	Negative	Anti-SARS-CoV-2 antibody NOT present
	Error	The eStick has encountered an error. The letter below the symbol denotes the type and the numbers are code for the error. Refer to the error code section for more information.

Error codes

The following table lists the error codes in the QIAreach Anti-SARS-CoV-2 test:

Table 9. QIAreach® Anti-SARS-CoV-2 Total 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 10. "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.

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Table 10. "A" error codes (cont'd)

Error code	Description	Recommended action
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 11. "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 color of sample*. Discard and use new eStick.
B-10	High Dark Frequency	Ensure test is run away from direct 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	No Conjugate Wave (Timeout)	Run test within 60 minutes of removing eStick from foil. Check color of sample. Discard and use new eStick.
B-15	Frequency Out of Range	Discard and use new eStick.
B-16	Low Frequency	Ensure sample is mixed well in processing tube prior to adding test sample to eStick. 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 well in processing tube prior to adding test sample to eStick. Discard and use new eStick.
B-21	Peak Data Failure	Check color of sample*. Discard and use new eStick.

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Table 11. "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.

* See Troubleshooting Guide section of applicable kit Instructions for Use regarding optical interference.

Table 12. "C" error codes

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

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Table 12. "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.

* The eHub does not have to be fully charged before running a test, but we recommend keeping the eHub plugged in to a power source and charging at all times, if possible.

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 Anti-SARS-CoV-2 Total Test troubleshooting

See Table 9-12 in Technical Information section for the list of QIAreach Anti-SARS-CoV-2 Total Test error codes.

Significantly hemolyzed (reddish brown) samples can potentially interfere with the QIAreach® Anti-SARS-CoV-2 Total Test optical measurement system. The eStick firmware features built-in controls to determine unacceptably high levels of hemolysate and will return an invalid result in the form of an error code if interference is present. If a reddish-brown test sample results in a “B” error code or if the sample is added to the eStick and the test will not start within 1 minute, then the sample may contain elevated levels of hemoglobin that interfere with the test. Causes of in vitro hemolysis may include improper sample collection from the patient and improper storage / handling of the sample prior to analysis. See Preparing samples for guidelines and for pre-analytical specimen stability and follow the sample collection device manufacturer’s recommendations for sample collection and centrifugation.

Additional user warnings

When cleaning, avoid any deliberate water ingress deep into the test ports. The eHub can be cleaned using mild detergent, 10% bleach or 70% EtOH.

Only use the eHub with the USB cable and USB adapter supplied with the device.

Contact Information

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

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Symbols

The following symbols may appear on the packaging and labelling:

Symbol	Symbol definition
	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® Anti-SARS-CoV-2 Total Test Kit	60 QIAreach eSticks / Processing Tubes 3 x 10 ml QIAreach Diluent Buffer	645033
Related Products		
QIAreach® eHub	QIAreach® eHub, power adapter and USB connector cable	9003063
QIAreach® Software	n/a	1118894
QIAreach® Anti-SARS-CoV-2 Controls	QIAreach Anti-SARS-CoV-2 Positive Control and the QIAreach Anti-SARS-CoV-2 Negative Control	647030

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

Date	Changes
R1, August 2020	Initial release
R2, December 2020	Rebranding from Access to QIAreach® Updated clinical agreement section for sensitivity, specificity and predictive value Updated available sample matrices study Updated Error Codes Table
R3, May 2021	Updated to include QIAreach® Anti-SARS-CoV-2 Controls. Corrected eHub catalog number
R4, February 2022	Updated link to access authorized labeling available on FDA website.

Limited License Agreement for QIAreach® Anti-SARS-CoV-2 Total Test

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

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