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QIArearch® 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



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Intended Use

The QIArearch® SARS-CoV-2 Antigen Test is a rapid, digital lateral flow assay, using nanoparticle fluorescence, intended for the qualitative detection of the 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 QIArearch® SARS-CoV-2 Antigen Test does not differentiate between SARS-CoV or SARS-CoV-2 viruses.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. 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 QIArearch SARS-CoV-2 Antigen Test is only to be used with the QIArearch eHub.

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

The standard medical practice for definitive diagnosis of active SARS-CoV-2 infection relies on the molecular detection of viral RNA using real-time reverse transcriptase-polymerase chain reaction (RT-PCR).¹³⁻¹⁶ The QIArearch SARS-CoV-2 Antigen Test detects nucleocapsid protein of SARS-CoV-2 and is a rapid *in vitro* diagnostic test for acute infection in populations of interest. The clinical and public health applications of antigen detection assays may include support to the clinical assessment of persons presenting with symptoms, or asymptomatic persons at high-risk of infection and to guide contact tracing, treatment options, and isolation requirements of afflicted individuals that help to mitigate the spread of the virus in the community.¹⁷

Principles of the assay

The QIArearch SARS-CoV-2 Antigen Test is a rapid, digital lateral flow diagnostic assay that detects nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab (NPS) and anterior nasal swab (ANS) specimens in collected Copan Diagnostic Universal Transport 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 QIArearch SARS-CoV-2 Antigen Test is performed by inserting the QIArearch SARS-CoV-2 Antigen eStick into a QIArearch eHub (sold separately). The QIArearch eHub is a connection hub that provides power to perform multiple QIArearch SARS-CoV-2 Antigen Tests simultaneously. The eHub acts as a power source and features a rechargeable lithium battery to allow QIArearch SARS-CoV-2 Antigen Tests to be performed when a continuous power supply is not available.

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

Once in the eStick, the test sample migrates on a nitrocellulose membrane and across the test line where the immobilized SARS-CoV-2 capture antibody resides. If SARS-CoV-2 antigen is

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

QIArearch 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 QIArearch SARS-CoV-2 Antigen Test is estimated below.

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

Pipette use

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

Kit Contents

QIArearch SARS-CoV-2 Antigen Test		
Catalog number		646533
Number of tests/pack		60
QIArearch SARS-CoV-2 Antigen Detection System Components*		
QIArearch SARS-CoV-2 Antigen eStick	Packaged together with Processing Tube in foil wrapper Contains SARS-CoV-2 nucleocapsid antibody and bovine serum albumin	X 60
QIArearch SARS-CoV-2 Antigen Processing Tube	Packaged together with eStick in foil wrapper Coated with SARS-CoV-2 nucleocapsid antibody, bovine serum albumin, and mouse serum	X 60
QIArearch 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)
- QIArearch SARS-CoV-2 Antigen Controls (Cat. No. 646030) (as required to meet local and organizational compliance)

Equipment required but not provided

- QIArearch eHub (Cat. No. 9003063)[†]
- Calibrated pipettes for delivery of 100 µl and 400 µl with disposable tips
- Optional: QIArearch 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 QIArearch SARS-CoV-2 Antigen Test should be performed in a test environment with $\leq 65\%$ relative humidity.
- Refer to the expiration date printed on the device labeling for component shelf life.
- QIArearch 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.

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- Use appropriate precautions in the collection, handling and storage of patient samples. Refer to CDC Interim Guidelines for Collection, Handling and Transportation of clinical specimens from persons with Coronavirus Disease 2019 (COVID-19) at <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>, and to WHO's Interim guidance for Laboratory testing for coronavirus disease (COVID - 19) in suspected human cases at <http://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117>, as amended and supplemented. Refer to the WHO website for additional publications.
 - 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 (C1) 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.
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The following hazards and precautionary statements apply to components of the QIArearch SARS-CoV-2 Antigen Test kit.

WARNING 	QIArearch SARS-CoV-2 Antigen Diluent Buffer (W1) 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.
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WARNING 	QIArearch eHub (W2) Do not open the eHub. No serviceable parts inside. Opening of the eHub device could lead to electric shock or damage of the device.
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CAUTION 	QIArearch SARS-CoV-2 Antigen eStick (C2) 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.
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Further information

- Deviations from the QIArearch 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 QIArearch SARS-CoV-2 Antigen Test kit after the expiration date.

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- 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 QIArearch 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 QIArearch 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.

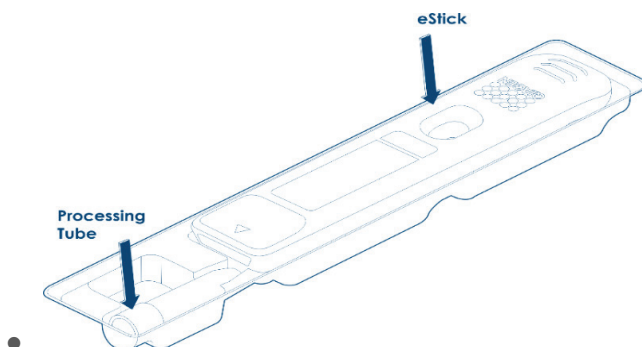


Figure 1. Contents of foil wrapper packaging – Processing Tube and eStick.

- 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 QIArearch 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 QIArearch 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 *QIArearch eHub User Manual* and software guide for details.

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

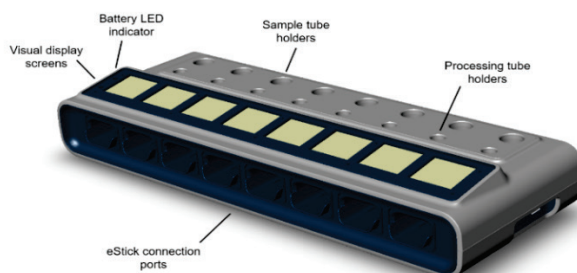


Figure 2. QIArearch eHub layout. Note: The dust cover should be in place when the eHub is not in use.

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

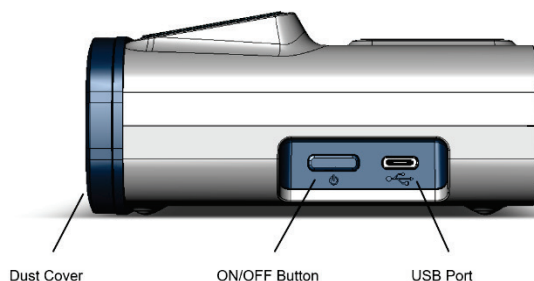
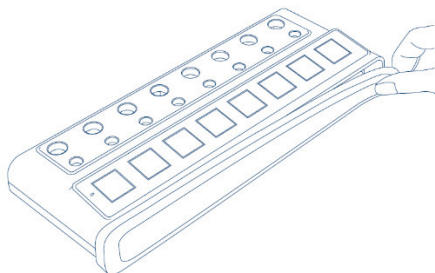


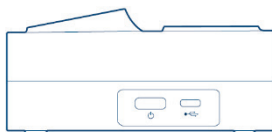
Figure 3. Side panel view of eHub with dust cover, ON/OFF switch, and USB connection port.

Procedure

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

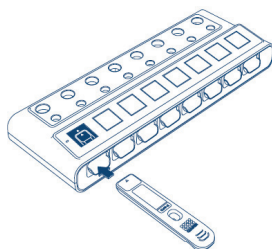


2. Press the ON/OFF switch on the right side of the eHub to turn it on.

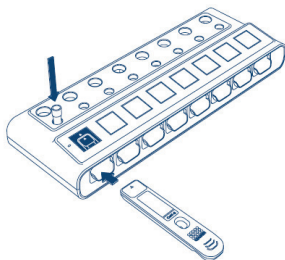


3. Remove the eStick from the packaging, label with patient identifier, and insert into the eHub.

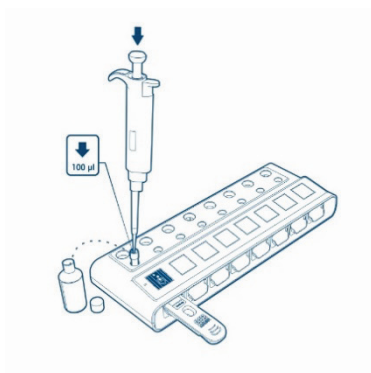
Note: The test sample must be added to the eStick sample port within 60 minutes of eStick removal from the foil packaging.



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

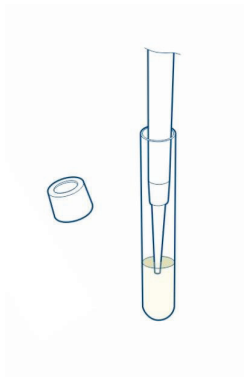


5. Add 100 μ l of QIArearch SARS-CoV-2 Antigen Diluent Buffer to the Processing Tube using a pipette.

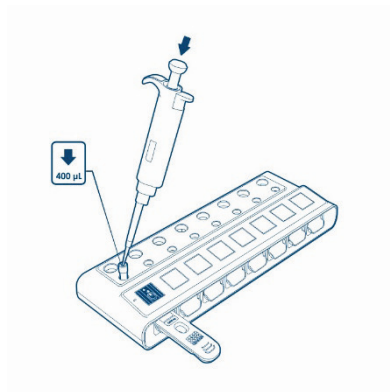


6. Remove 400 μ l of the patient specimen in transport media using a pipette.

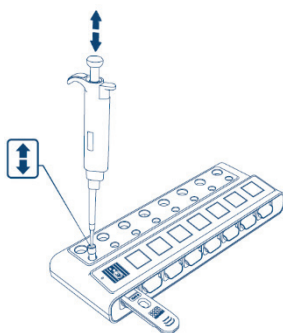
Note: Viscous samples that are difficult to pipette should not be used as these may affect test performance and result in an error code or erroneous result.



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

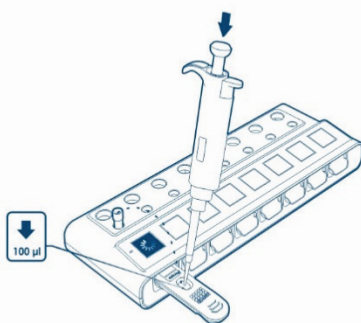


8. Mix the contents of the Processing Tube by pipetting up and down at least 4 times. Take care to not introduce foam while pipetting.



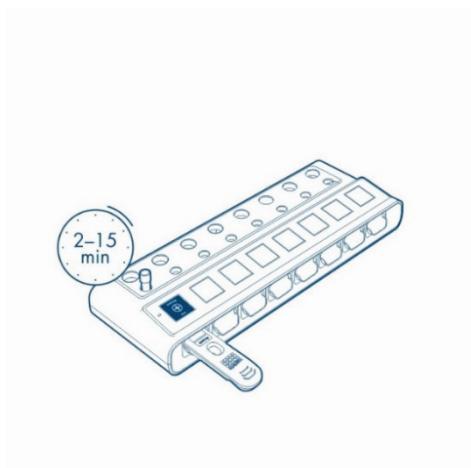
9. Remove 100 μ l of the mixed sample from the Processing Tube and dispense into the sample port of the inserted eStick.

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

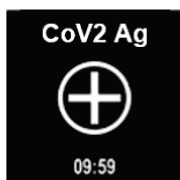


10. Following sample addition, the loading icon may appear on the eHub display for an additional 30–60 seconds before the sample is detected by the eStick. Once sample is detected, the test will start automatically, which is signaled by a countdown timer on the eHub display. Do not remove the inserted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

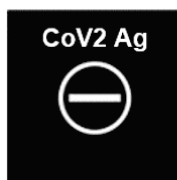
displayed. If the loading icon on the eHub display remains 5 minutes after sampling addition, then the eStick likely cannot detect the presence of sample due to high viscosity. A new patient sample should be obtained if possible.



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



Positive



Negative

Results Analysis and Test Interpretation

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

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

Quality control of test

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

Mechanical performance controls are in place to confirm that the eStick components are functioning correctly and are not compromised due to improper handling or transport. Once the sample is added to the eStick, the eStick will continually monitor progress, including the proper flow rate of sample across the strip as well as the correct range of detector particles in the sample. The eStick has extensive controls built into the firmware to alert the user if the test has not been successfully completed or if the test strip has been compromised, providing an additional level of control over standard lateral flow tests that rely on a single control line.

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

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

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

External Control kit contents (sold separately)

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

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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

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

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

QIArearch 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. QIArearch 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.

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 11/02/2020 and 04/07/2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

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.

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 QIArearch 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 QIArearch SARS-CoV-2 Antigen test ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

- A. Authorized laboratories* using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using your product must use your product as outlined in the "authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating tests.
- D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Qiagen GmbH (via email: techservice-na@qiagen.com) any suspected occurrence of false

positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

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

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

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

Performance Characteristics

Clinical performance of nasal (anterior nares) swab samples

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

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

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

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

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

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

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

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

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

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

Clinical performance of nasopharyngeal swab (NPS) samples

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

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

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

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

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

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

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

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

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

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

Analytical performance

Limit of Detection (Analytical sensitivity)

The limit of detection (LoD) for the QIArearch SARS-CoV-2 Antigen Test system was determined by limiting dilution studies using heat-inactivated SARS-CoV-2, isolate USA-WA1/2020 (ZeptoMetrix™, 0810587CFH1), which was supplied frozen at a concentration of 3.80×10^6 TCID₅₀/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 QIArearch SARS-CoV-2 Antigen Test using a four-point dilution series of the heat-inactivated virus made in a pooled negative clinical

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

LoD confirmation

The LoD of the QIArearch SARS-CoV-2 Antigen Test system was confirmed by testing twenty (20) replicates at the tentative LoD. The final confirmed LoD, as measured on the collected patient swab demonstrated 95% (19/20) positive results (Table 8).

Table 8. LoD confirmation

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

Cross-reactivity (analytical specificity) and microbial interference

The QIArearch SARS-CoV-2 Antigen Test was evaluated for potential cross-reactivity and microbial interference with a panel of related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in clinical specimens (Table 8). A total of 27 pathogenic microorganisms (15 viruses, 11 bacteria, 1 yeast/fungi) and 1 pooled human nasal wash, representative of normal respiratory (tract) microbial flora that may be present in the nasal cavity, were tested in triplicate in SARS-CoV-2 RT-PCR-confirmed negative clinical matrix (swab diluted in transport 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 TCID₅₀/mL) to assess the likelihood of a false

negative result. Bacterial and viral pathogens were prepared to a target test concentration of 1×10^6 CFU/mL or IFU/mL, 1×10^5 TCID₅₀/mL or 1×10^5 EID₅₀/mL in negative clinical matrix, respectively. Pooled human nasal wash was tested at a concentration of 10% (v/v) in negative clinical matrix. These concentrations represent the concentrations of bacterial and viral pathogens, or pooled human nasal wash in the collected Transport 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 QIArearch SARS-CoV-2 Antigen Test

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

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

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

† *in silico* analysis was performed.

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

In silico cross reactivity was analyzed using BLAST performed on the QIAGEN CLC Genomics Workbench 20.0.4 against the NCBI non-redundant database limited by each of the

organisms below, using the [ORGN] limiter to reduce the search space, to determine the likelihood of cross-reactivity.

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

Endogenous interference

A total of 14 potentially interfering substances that may be found in the upper respiratory tract, including blood and a selection of the active ingredients of commonly used cold and flu medications, were evaluated to demonstrate they do not cross-react or interfere with the QIArearch SARS-CoV-2 Antigen Test. The QIArearch SARS-CoV-2 Antigen Test was evaluated by spiking interfering substances and testing at concentrations as listed in Table 9, either in the absence of inactivated SARS-CoV-2 virus to assess the likelihood of a false positive result or in the presence of heat inactivated SARS-CoV-2 at 3x the final test sample LoD (1200 TCID₅₀/mL) to assess the likelihood of a false negative result. The concentrations of endogenous interference substances represent the concentrations in the collected Transport 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 (QIArearch SARS-CoV-2 Antigen Test negative result/total tested)	Positive Matrix (QIArearch SARS-CoV-2 Antigen Test positive result/total tested)
Whole blood	4% v/v	5/5	5/5
Mucin	0.5%	5/5	5/5
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	5/5	5/5
Naso GEL (NeilMed)	5% v/v	5/5	5/5
CVS Nasal Drops (Phenylephrine)	15% v/v	5/5	5/5
Afrin (Oxymetazoline)	15% v/v	5/5	5/5
NasalCrom (Cromolyn)	15% v/v	5/5	5/5
Zicam	5% v/v	5/5	5/5
Homeopathic (Alkalol)	1:10 dilution	5/5	5/5
Sore Throat Phenol Spray	15% v/v	5/5	5/5
Tobramycin	4 µg/mL	5/5	5/5
Mupirocin	10 mg/mL	5/5	5/5
Fluticasone Propionate	5% v/v	2/5	5/5
Fluticasone Propionate*	3.5% v/v	2/5	n/a
Fluticasone Propionate*	2.5% v/v	5/5	n/a
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	5/5	5/5

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

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

High dose hook effect

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

Technical Information

eHub display icons

Table 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	QIArearch SARS-CoV-2 Antigen Test Positive: SARS-CoV-2 infection likely. The time shown is the time required for the positive result to be calculated.
	Negative	QIArearch 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 *QIArearch eHub User Manual*.

Error codes

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

Table 12. QIArearch 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.

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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).

QIArearch SARS-CoV-2 Antigen Test troubleshooting

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

Additional user warnings

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

Contact Information

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

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Symbols

The following symbols may appear on the packaging and labelling:

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

Ordering Information

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

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

Document Revision History

Revision	Description
R1, March 2021	Initial release
R2, April 2021	Removal of BD Universal Viral Transport media, remove additional media limitations and update clinical section
R3, August 2021	Updates in Limit of Detection (Analytical sensitivity), Cross-reactivity (analytical specificity) and microbial interference, and Endogenous interference

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