November 2020

QIAreach™ SARS-CoV-2 Antigen Test Instructions for Use (Handbook)

For *in vitro* diagnostic use
The QIAreach SARS-CoV2 Antigen Test has been validated but FDA's independent review of this validation is pending.
Rx only

Version 1

IVD

REF 646533

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R2 MAT L1122673EN

Sample to Insight

QIAGEN

Contents

Intended Use

The QIAreach™ SARS-CoV-2 Antigen Test is a rapid, digital lateral flow diagnostic assay, using nanoparticle fluorescence, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens collected in BD™ Universal Viral Transport Media, Remel™ M4RT® Transport Media, Copan® Diagnostic Universal Transport Media (UTM-RT), Thermo Fisher Scientific®/Life Technologies Viral Transport Media (VTM), Hardy® Diagnostics VTM, Teknova™ VTM (CDC formulation), Bartels® FlexTrans™ Transport Media, CDC's formulation of VTM, or Gibco™ Phosphate Buffered Saline (PBS) from individuals who are suspected of COVID-19 by their healthcare provider. 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 high complexity tests.

Results are for the identification of SARS-CoV-2 nucleocapsid 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 positive results to the appropriate public health authorities.

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.

The QIAreach SARS-CoV-2 Antigen Test is intended for use by clinical laboratory personnel specifically instructed on *in vitro* diagnostic procedures.

The QIAreach SARS-CoV-2 Antigen Test has been validated but FDA's independent review of this validation is pending.

Summary and Explanation of the Test

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

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

Principles of the assay

The QIAreach SARS-CoV-2 Antigen Test is a rapid, digital lateral flow diagnostic assay that detects nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab (NPS) specimens in collected BD Universal Viral Transport Media, Remel M4RT Transport Media, Copan Diagnostic Universal Transport Media (UTM-RT™), Thermo Fisher/Life Technologies Viral Transport Media (VTM), Hardy Diagnostics VTM, Teknova VTM (CDC formulation),

Bartels FlexTrans Transport Media, CDC's formulation of VTM, or Gibco Phosphate Buffered Saline (PBS) transport media, hereinafter referred to as transport media (TM) samples, from individuals who are suspected of COVID-19 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 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 antigen in patient test samples.

The CoV2 Ag test is performed by inserting the CoV2 Ag eStick into a QIAreach eHub (sold separately). The QIAreach eHub is a connection hub that provides power to perform multiple CoV2 Ag tests simultaneously. The eHub acts as a power source and features a rechargeable lithium battery to allow CoV2 Ag tests to be performed when a continuous power supply is not available.

To perform the test, CoV2 Ag Diluent Buffer is first added to the CoV2 Ag 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.

CoV2 Ag 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 CoV2 Ag is estimated below. The time of testing multiple samples when batched is also indicated.

- Digital detection: Approx. 2–15 minutes for one test (1 individual)

Pipette use

This assay requires use of an adjustable volume pipette. Users should familiarize themselves with pipette use prior to performing the CoV2 Ag test.

Materials required

Kit contents

QIAreach SARS-CoV-2 Antigen Test		
Catalog number		**646533**
Number of tests/pack		**60**
CoV2 Ag Detection System Components*		
CoV2 Ag Stick	Packaged together with Processing Tube in foil wrapper Contains SARS-CoV-2 nucleocapsid antibody and bovine serum albumin	
CoV2 Ag Processing Tube	Packaged together with eStick in foil wrapper Coated with SARS-CoV-2 nucleocapsid antibody, bovine serum albumin, and mouse serum	
CoV2 Ag Diluent Buffer	Contains bovine serum albumin and ProClin® 300	2 x 10 ml
QIAreach SARS-CoV2 Antigen Test Instructions for Use (Handbook)		1

* See Warnings and Precautions for precautions and hazard statements.

Materials Required but not Provided

- Specimen collection swabs*
- Specimen transport medium options†
  - BD Universal Viral Transport Media
  - Remel M4RT Transport Media
  - Copan Diagnostic Universal Transport Media (UTM-RT)
  - Thermo Fisher/ Life Technologies Viral Transport Media (VTM)
  - Hardy Diagnostics VTM
  - Teknova VTM (CDC formulation)
  - Bartels FlexTrans Transport Media
  - CDC's formulation of VTM
  - Gibco Phosphate Buffered Saline (PBS)
- Pipette tips
- QIAreach eHub‡

* See Limitations under Warnings and Precautions for the list of incompatible collection swabs.
† See Limitations under Warnings and Precautions for the list of incompatible transport mediums.
‡ See Warnings and Precautions for precautions and hazard statements.

Storage and Handling

Equipment required but not provided

- Calibrated pipettes* for delivery of 100 µl and 400 µl with disposable tips
- Optional: QIAreach Software (cat. no. 1118894)

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.
- The CoV2 Ag 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.
- CoV2 Ag Diluent Buffer should be used within 3 months after opening the bottle.

* See Warnings and Precautions for precautions and hazard statements.

Warnings and Precautions

Limitations

- For *in vitro* diagnostic use only.
- For prescription use only.
- The QIAreach SARS-CoV-2 Antigen Test has been validated but FDA's independent review of this validation is pending.
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Sample collected from the following transport medias should **not** be used:
  - PrimeStore® MTM (molecular transport media)
  - Ruhof inactivate product code 354CVTK
  - Transport media containing Guanidine thiocyanate compounds
  - Molecular medium marketed to inactivated virus and preserve RNA/DNA
  - Liquid Amies transport medium
  - BD Eswabs
  - APTIMA® Swab Transport Medium (STM)
  - Lee BioSolutions Saline
- Swabs with the following properties should **not** be used:
  - Calcium alginate tips
  - Preservatives
  - Wooden shafts
- 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 true risk of infection, clinical correlation with patient history, and other diagnostic information are necessary to determine infection status or determine the need for validation testing with RT-PCR.
- 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 positive results to the appropriate public health authorities.

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 specimens as potentially infectious. Observe relevant specimen collecting and handling guidelines. Dispose of samples and materials in contact with specimen or specimen products in accordance with federal, state, and local regulations.	(C1)

The following hazards and precautionary statements apply to components of the CoV2 Ag kit.

WARNING 	**QIAreach SARS-CoV2 CoV2 Ag 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 SARS-CoV-2 Ag 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.

Further information

- Deviations from the QIAreach SARS-CoV-2 Antigen Test Instructions for Use may yield erroneous results. Please read the instructions carefully before use.
- **Important**: Inspect materials prior to use. Do not use kit if the Diluent Buffer, Processing Tube, or eStick show signs of damage or leakage, or if the seals have been compromised prior to use. Do not handle broken eSticks.
- Discard used or unused materials and biological samples in accordance with local and government regulations.
- Do not use the CoV2 Ag kit after the expiration date.
- Do not mix consumables and reagents from multiple lots.

Procedures

Sample collection

Note: The CoV2 Ag test requires 400 µl of TM sample for an individual test.

Follow all guidelines and instructions provided by the Centers for Disease Control and Prevention (CDC) at **www.cdc.gov** and swab manufacturer when collecting test specimens.

Refer to the following guidelines for handling of samples prior to performing the CoV2 Ag test:

- Specimens should be collected as soon as possible once a decision has been made to pursue testing, regardless of the time of symptom onset.
- Swab should be placed immediately into a sterile transport tube containing transport media.
- Samples should optimally be tested as soon as possible following collection and may be held at room temperature (15–30°C) for up to 8 hours prior to testing.
- Samples may be stored for up to 72 hours at 2–8°C prior to testing.
- Samples that require long term storage prior to testing may be stored at ≤ –20°C.

Detection assay

Materials required

- CoV2 Ag Processing Tube (packaged together with eStick in foil wrapper)
- CoV2 Ag eStick (packaged together with Processing Tube in foil wrapper)
- CoV2 Ag 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 (15–30°C) before use. Allow at least 60 minutes for sample equilibration to room temperature.
- The eStick and Processing Tube are packaged together in a foil wrapper. The packaging must only be opened before performing the assay.
  Important: The CoV2 Ag assay must be started within 60 minutes of removing the components from the packaging.

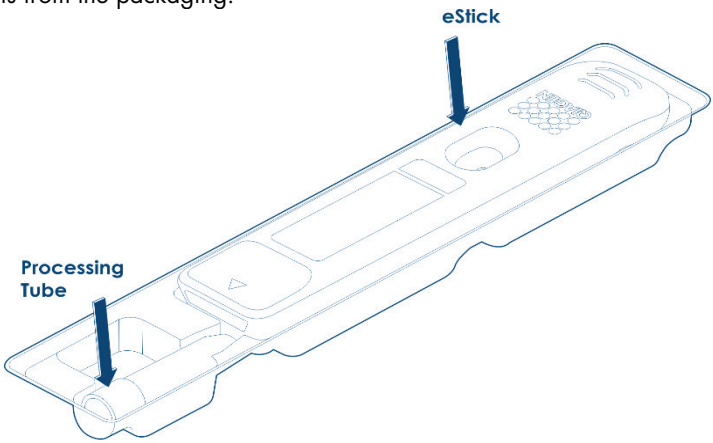


Figure 1. Contents of foil wrapper packaging – Processing Tube and eStick.

- 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 CoV2 Ag assay. 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 CoV2 Ag 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 through the provided USB cable and launching the software. The software displays the level of battery charge in the bottom right hand corner of the screen. Refer to the QIAreach eHub User Manual and software guide for details.
- The eHub comes with a cover to protect the internal ports from dust buildup and contamination. The cover should be placed over the front panel of the eHub when the eHub is not in use.

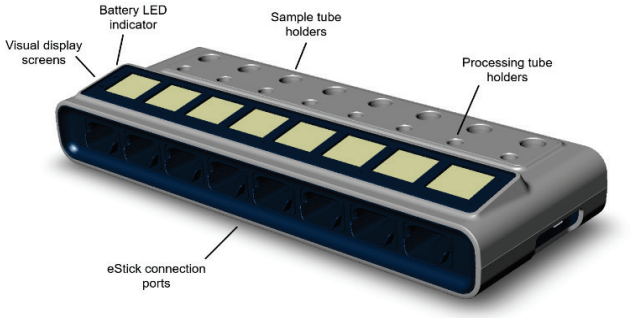


Figure 2. QIAreach eHub layout. Note: The dust cover should be in place when the eHub is not in use.

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

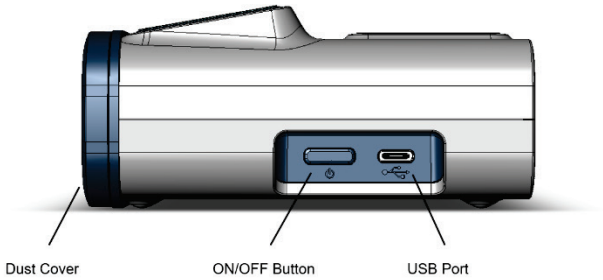
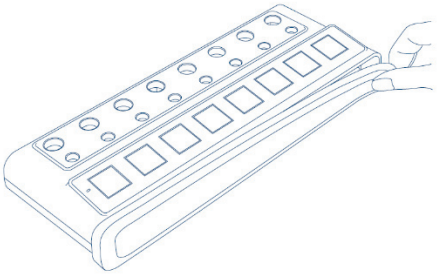


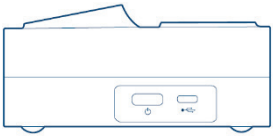
Figure 3. Side panel view of eHub with dust cover, ON/OFF switch, and USB connection port.

Procedure

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

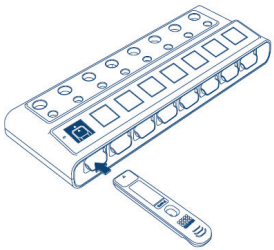


2. Press the **ON/OFF** switch on the right side of the eHub to turn it on.

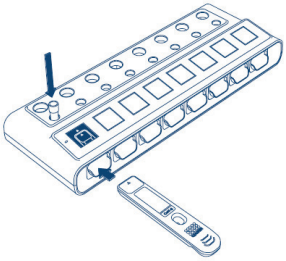


3. Remove the eStick from the packaging, label with patient identifier, and insert into the eHub.

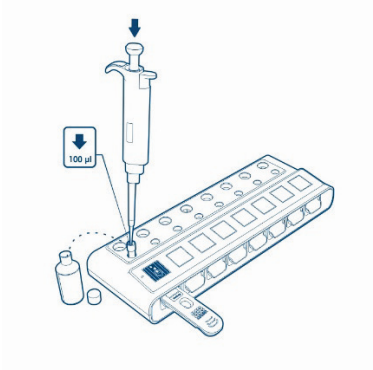
   Note: The test sample must be added to the eStick sample port within 60 minutes of eStick removal from the foil packaging.



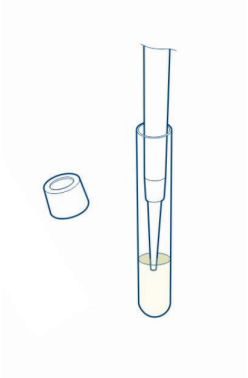
4. Remove the Processing Tube from the packaging and insert into the empty tube slot directly in line with the eStick.



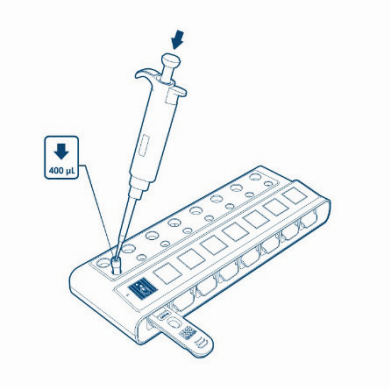
5. Add 100 µl of CoV2 Ag Diluent Buffer to the Processing Tube using a pipette.



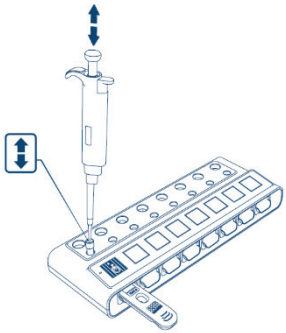
6. Carefully remove 400 µl of the patient TM sample from the sample tube using a pipette.



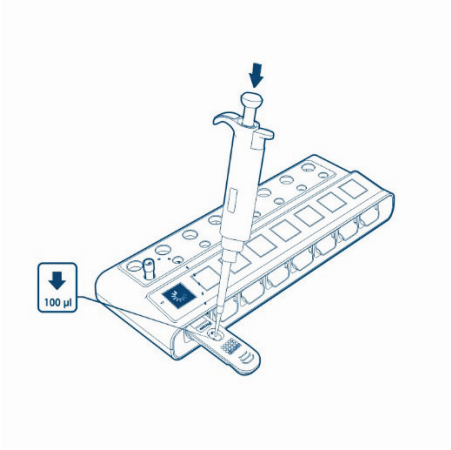
7. Add the patient TM sample to the Processing Tube containing the CoV2 Ag Diluent Buffer.



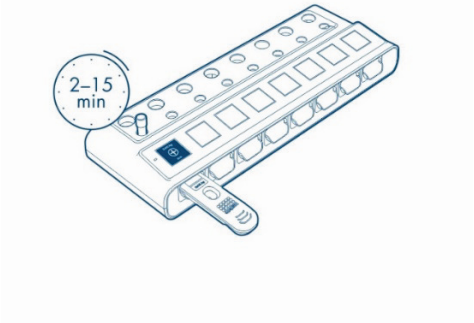
8. Mix the contents of the Processing Tube by pipetting up and down at least 4 times. Take care to not introduce foam while pipetting.



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



10. The test will start automatically following sample addition, signaled by a countdown timer on the display. This may take 30–60 seconds after the sample is added to the sample port. 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.

Results Analysis and Test Interpretation

The standard time from eStick sample detection to test result is 2–15 minutes. The time to result will be less than 15 minutes for positive samples containing high concentrations of SARS-CoV-2 antigen. The time to result will be displayed on the QIAreach eHub alongside the sample result. CoV2 Ag raw data is analyzed on the eStick firmware, which determines a positive or negative CoV2 Ag result based on an internal algorithm. The result is transmitted to the QIAreach eHub, which displays the result. Once the result is displayed, the result is retained on the eStick, and it can be removed from the QIAreach eHub. The retained result can be retrieved from the eStick by re-inserting into the QIAreach eHub. If the optional QIAreach Software is used, the QIAreach eHub can be used to transfer the test result to a computer for data transfer, backup, and report printing.

Quality control of test

All CoV2 Ag 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 not supplied with this kit. Laboratories or healthcare professionals wanting to test external positive and negative controls should do so consistent with good laboratory practice and local regulations.

If the test is invalid, an error code will be displayed on the eHub. The test should be repeated. See Technical Information for the list of CoV2 Ag error codes.

Interpretation of results

CoV2 Ag results are interpreted using the following criteria:

Table 1. Interpretation of CoV2 Ag results

CoV2 Ag result	Report/interpretation
Positive	SARS-CoV-2 infection likely
Negative	SARS-CoV-2 infection NOT likely

CoV2 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

The amount of antigen in a sample may decrease as the duration of illness increases. Negative results from specimens collected from patients with extended elapsed time between symptom onset and diagnosis should be treated as presumptive and confirmation with a molecular assay should be considered.

All test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test 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 and should be confirmed with an FDA authorized molecular 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.

False positive results for CoV2 Ag may occur due to cross-reactivity from high prevalence disease agents and normal or pathogenic flora that are reasonably likely to be encountered in the upper respiratory specimen or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a molecular assay.

Clinical performance was established on frozen specimens collected in BD Universal Viral Transport (UVT) media and Remel M4RT transport media.

The contents of this kit are for qualitative detection of SARS-CoV-2 antigens from nasopharyngeal swabs collected from the following **compatible** transport media only:

- BD Universal Viral Transport Media
- Remel M4RT Transport Media
- Copan Diagnostic Universal Transport Media (UTM-RT™)

- Thermo Fisher/Life Technologies Viral Transport Media (VTM)
- Hardy Diagnostics VTM
- Teknova VTM (CDC formulation)
- Bartels FlexTrans Transport Media
- CDC's formulation of VTM or
- Gibco Phosphate Buffered Saline (PBS)

The following transport media are **not compatible** with the CoV2 Ag test:

- PrimeStore MTM (molecular transport medium)
- Ruhof Inactivate, product code 354CVTK
- Transport media containing guanidine thiocyanate compound
- Molecular medium marketed to inactivate virus and preserve RNA/DNA
- Liquid Amies transport medium
- BD Eswabs,
- Aptima Swab Transport Media (STM), and
- Lee BioSolutions Saline

Important: Swabs with calcium alginate tips, swabs with preservatives, and swabs with wooden shafts must not be used in patient sample collection.

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

Performance Characteristics

Clinical performance

Sensitivity

Sensitivity was estimated by evaluating health care professional-collected nasopharyngeal swab samples in BD Universal Viral Transport (UVT) (cat. no. 220527) and Remel M4RT (cat. no. R12552) transport media from study subjects with RT-PCR-confirmed symptomatic SARS-CoV-2 infection at the time of sampling. A total of 30 previously collected (banked) samples from 30 subjects were tested using the CoV2 Ag system.

Table 2 describes the clinical sensitivity at initial CoV2 Ag testing and after the discordant sample testing (testing with a second RT-PCR) and removal of 1 false negative sample that did not agree with the reference method result.

Table 2. Clinical sensitivity

	Number of samples tested	Number of CoV2 Ag positive results	Positive percent agreement	95% confidence interval
At initial testing	30	27	90.00%	73.47–97.89%
After discordant sample testing	29	27	93.10%	77.23–99.15%

Table 3 shows the SARS-CoV-2 gene Ct values from false negative sample reference method testing. All the false negative samples (3/3) had reference method Ct values greater than 31.

Table 3. Reference method Ct values for false negative samples

	Reference method		
		Ct values	
Sample count	Result	N1	N2
1	Pos	37.7	38.4
2	Pos	31.9	35.1
3	Pos	37.2	37.8

All discordant samples (n=3) received further testing using a SARS-CoV-2 RT-PCR test.

Table 4 shows the results of discordant sample testing.

Table 4. Comparison of CoV2 Ag results to reference method and discordant method results for false negative samples

	Discordant method	
	Positive	Negative
	Reference method	
CoV2 Ag	Positive	Positive
Negative	2	1

One of the 3 false negative samples tested negative by the discordant method, resolving its initial status as a false negative and excluding it from the calculation of sensitivity after discordant sample testing. The post discordant sample testing sensitivity was 93.10% (95% confidence interval: 77.23–99.15%).

Sensitivity by Ct value range

For all reference method positive samples, the clinical sensitivity of the CoV2 Ag was stratified below by cycle threshold (Ct) value range for the SARS-CoV-2 N1 and N2 genes (across both Ct values for each subject).

Table 5. Clinical sensitivity by reference method Ct value range

	Number of positive results		
Ct value range	**Reference method**	**CoV2 Ag**	**Sensitivity**
<11	1	1	100.00%
11 ≤ Ct <21	13	13	100.00%
21 ≤ Ct <31	9	9	100.00%
≥31	6*	4*	66.67%

* Before the exclusion of the 1 false negative sample, the sensitivity of CoV2 Ag is 57.14% (4 CoV2 Ag positive samples agree with the 7 reference method positive samples whose Ct values are ≥31).

Specificity

Specificity was estimated by evaluating health care professional-collected nasopharyngeal swab samples in BD Universal Viral Transport (UVT) (cat. no. 220527) and Remel M4RT (cat. no. R12552) transport media from RT-PCR-confirmed negative study subjects collected after and prior to the start of the SARS-CoV-2 pandemic (on or after December 1, 2019 and before December 1, 2019, respectively). A total of 30 previously collected (banked) samples from 30 subjects were tested using the CoV2 Ag system. The following table shows the clinical specificity.

Table 6. Clinical specificity

Number of samples tested	Number of CoV2 Ag negative results	Negative percent agreement	95% confidence interval
30	30	100%	88.43–100.00%

Analytical performance

Limit of Detection (Analytical sensitivity)

The limit of detection (LoD) for the CoV2 Ag system was determined by limiting dilution studies using heat-inactivated SARS-CoV-2. The virus is a preparation of SARS-CoV-2, isolate USA-WA1/2020, that has been inactivated by heating at 65°C for 30 minutes. The material was supplied frozen at a concentration of 1.15×10^7 $TCID_{50}$/mL.

LoD screening

An initial LoD screening study was performed with CoV2 Ag using a 10-fold dilution series (five dilutions in total) 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 viral transport media (VTM). Dilutions were tested in triplicate starting at a test concentration of 2×10^4 $TCID_{50}$/mL. The lowest concentration at which all (3/3) replicates were positive was chosen for LoD range finding.

The chosen LoD concentration was further refined using a limited dilution series (5 dilutions in total) of the heat-inactivated SARS-CoV-2 virus made in negative clinical matrix and tested with CoV2 Ag in five (5) replicates. The lowest detectable concentration demonstrating 100% positive results was set as the tentative LoD for confirmation.

LoD confirmation

The LoD of the CoV2 Ag system was confirmed by testing twenty (20) replicates from multiple concentrations at or slightly above the tentative LoD. The LoD was confirmed as 445 $TCID_{50}$/mL, demonstrating 100% (20/20) positive results (Table 7).

Table 7. LoD confirmation

SARS-CoV2 concentration	CoV2 Ag test result	% Positive
445 $TCID_{50}$/mL	20/20 Positive	100%

Cross-reactivity (analytical specificity) and microbial interference

CoV2 Ag 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 28 pathogenic microorganisms (16 viruses, 11 bacteria, 1 yeast/fungi) and 1 pooled human nasal wash, representative of normal respiratory microbial flora that may be present in the nasal cavity, were tested in triplicate in SARS-CoV-2 RT-PCR-confirmed negative clinical matrix either in the absence of inactivated SARS-CoV2 to assess the likelihood of a false-positive result or presence of the virus at 3x the LoD to assess the probability of a false negative result. Bacterial and viral pathogens were prepared to a target concentration of 1 x 10^6 CFU/mL or IFU/mL and 1 x 10^5 $TCID_{50}$/mL or EID_{50}/mL, respectively. If the stock concentration of pathogen was less than the target testing concentration, the maximum possible concentration was tested. No cross-reactivity or interference was observed with the microorganisms when tested at the listed concentrations presented (Table 8).

Table 8. Cross-reactivity and microbial interference summary for CoV2 Ag

Pathogen	Concentration tested	Cross-reactive (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
SARS-coronavirus*	Clinically relevant concentration*†	3/3	3/3
Human coronavirus HKU1†	*in silico*	n/a	n/a
Adenovirus C1 Ad. 71	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Human Metapneumovirus (hMPV)	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Parainfluenza virus 1	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Parainfluenza virus 2	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Parainfluenza virus 3	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Parainfluenza virus 4	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Influenza A	1 x 10^5 EID_{50}/mL	3/3	3/3
Influenza B	1 x 10^5 EID_{50}/mL	3/3	3/3
Enterovirus	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Respiratory Syncytial Virus (RSV)	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Rhinovirus	1 x 10^5 $TCID_{50}$/mL	3/3	3/3
Haemophilus influenzae	1 x 10^6 CFU/mL	3/3	3/3
Streptococcus pneumoniae	1 x 10^6 CFU/mL	3/3	3/3

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Table 8. Cross-reactivity and microbial interference summary for CoV2 Ag (cont'd)

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

* SARS-coronavirus was tested at a 5 fold dilution of a clinically relevant concentration (Ct value: 25–28 by PCR test per the vendor)

† *in silico* analysis was performed.

The *in-silico* cross reactivity test 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).
- *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 fully ruled out.

Endogenous interference

A total of 17 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 CoV2 Ag Test. The effect of potentially interfering substances on CoV2 Ag was evaluated by spiking interfering substances and testing at concentrations as listed in Table 9, either in the presence of heat-inactivated SARS-CoV-2 at 3x the LoD concentration to assess the likelihood of a false negative result, or in the absence of virus to assess the probability of a false positive result. Testing was performed in five (5) replicates per substance in SARS-CoV-2 RT-PCR-confirmed negative clinical matrix. No interference was observed for all potential interfering substances at the tested concentrations except for Mupirocin, which showed possible interference at 10 mg/mL (Table 9).

Table 9. Summary of endogenous interfering substance testing

Interference substances	Concentration tested	Cross-reactivity (CoV2 Ag negative result/ total tested)	Interference (CoV2 Ag positive result/ total tested)
Whole blood	1% 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	4/5	5/5
Fluticasone Propionate	5% v/v	5/5	5/5
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	5/5	5/5
Ricola (Menthol)	1.5 mg/mL	5/5	5/5
Sucrets (Dyclonin/Menthol)	1.5 mg/mL	5/5	5/5
Fisherman's Friend	1.5 mg/mL	5/5	5/5

High dose hook effect

To evaluate the potential of high SARS-CoV-2 virus concentrations to create signal suppression, or "hook effect", resulting in false negative outcomes in the CoV2 Ag Test, increasing concentrations of heat-inactivated SARS-CoV-2 virus were tested.

High dose hook effect was not observed up to 4.45×10^5 $TCID_{50}$/mL of SARS-CoV-2.

Transport media compatibility (matrix equivalency)

Cov2 Ag performance was evaluated with six (6) different transport media matrices: COPAN Diagnostic Universal Transport Medium (UTM-RT™), Thermo Fisher/Life Technologies Viral Transport Media (VTM), Hardy Diagnostics VTM, Teknova VTM (CDC formulation), Bartels FlexTrans Transport Medium, and PBS 7.2. Positive samples were contrived by spiking low, medium, and high titers of SARS-CoV-2 (BEI Resources, cat. no. NR-52286) into either negative clinical matrix or transport media with human nasal fluid mimicking natural negative clinical matrix. The contrived positive samples were tested in parallel with uncontrived negative samples with 5 replicates at each concentration level. CoV-2 Ag test results were evaluated against the expected negative results for uncontrived samples and the expected positive results for low, medium, and high level contrived positive samples. For each matrix tested, the 100% overall agreement to the expected result across Negative, Low Positive, Medium Positive, and High Positive test panels for all 6 transport media is reported in Table 10.

Table 10. Transport media compatibility (matrix equivalency) test agreement to expected result

Transport media	Negative agreement (n=5)	Low positive agreement (n=5)	Med positive agreement (n=5)	High positive agreement (n=5)	Overall agreement (n=20)
COPAN UTM-RT	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (20/20)
Life Technologies VTM	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (20/20)
Hardy Diagnostics VTM	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (20/20)
Teknova VTM (CDC Formulation)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (20/20)
Bartels FlexTrans Transport Medium	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (20/20)
Gibco PBS pH 7.2	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (20/20)

Specimen stability

The specimens in transport media are stable at room temperature (15–30°C) up to 8 hours, at 2–8°C up to 72 hours, and frozen storage (≤–20°C). Freeze/thaw cycles should be minimized.

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	CoV2 Ag Positive: SARS-CoV-2 infection likely. The time shown is the time required for the positive result to be calculated.
	Negative	CoV2 Ag 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.

Error codes

The following table lists the error codes in CoV2 Ag:

Table 12. CoV2 Ag 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.
A-128	Frequency 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-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 color of sample*. 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	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 in processing tube prior to adding test sample. Discard and use new eStick.
B-17	High Frequency	Discard and use new eStick.
B-18	Frequency Out of Range	Discard and use new eStick.
B-19	Low Frequency	Ensure sample is mixed in processing tube prior to adding test sample. Discard and use new eStick.
B-21	Peak Data Failure	Check color of sample*. 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.

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

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 technical assistance and more information, please see our Technical Support Center at **www.qiagen.com/Support** (for contact information, visit **www.qiagen.com**).

CoV2 Ag troubleshooting

See Technical Information for the list of error codes

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, 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
	*in vitro* diagnostic
	Use by date
	Temperature limitation
	Catalog number
	Material number
	Manufacturer
	Protect from light
	Consult instructions for use
	Caution
	Do not open electrical unit
	Do not reuse

Ordering Information

Product	Contents	Cat. no.
QIAreach SARS-CoV-2 Antigen Test Kit	60 CoV2Ag eSticks / Processing Tubes 2 x 10 ml QIAreach CoV2 Ag Diluent Buffer	646533
Relative Products		
QIAreach eHub	QIAreach eHub, power adapter, and USB connector cable	9002969
QIAreach Software	n/a	1118894

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, November 2020	Initial release
R2, November 2020	Removed FDA authorization statements under Warnings and Precautions section

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