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

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

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

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

Negative results should be treated as presumptive, and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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

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

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

This QIAreach SARS-CoV-2 Antigen Test has been authorized only for the detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal and nasal swab specimens, not for any other viruses or pathogens, and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1)of the Act, 21 U.S.C. § 360bbb-3 (b)(1), unless the declaration is terminated or authorization is revoked sooner.

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

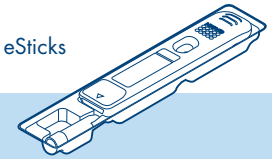
IVD **RX ONLY**

For use under Emergency Use Authorization (EUA) only

REF 646533

Test Kit Contents (REF 646533)

60 x QIAreach SARS-CoV-2 Antigen eSticks

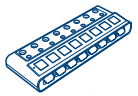


60 x QIAreach SARS-CoV-2 Antigen Processing Tubes

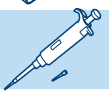
2 x 10ml QIAreach SARS-CoV-2 Antigen Diluent Buffer

Additional Components Required

QIAreach eHub

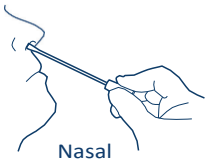


Adjustable Volume Pipettes + tips
Volume/s required: 100µl, 400µl

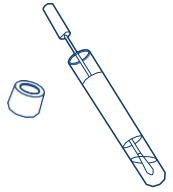


Swab and transport media (Copan UTM®)
Minimum collection volume 1ml

Pre-analytical Steps



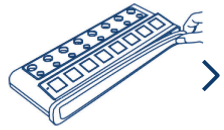
Patient sample collected through Nasal or Nasopharyngeal swab. For Nasal and Nasopharyngeal swab collection, follow swab manufacturer instructions and CDC guidelines.



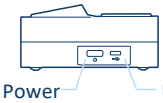
Patent sample stored in viral transport media (Copan UTM) to Manufacturer's instructions. Please refer to IFU for further details.

QIAreach eHub Setup

Remove QIAreach eHub from its packaging.



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



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

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

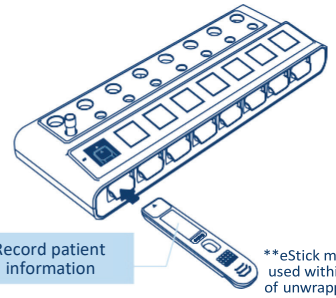
www.qiagen.com
800-344-3631
Technical support: techservice-na@qiagen.com

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

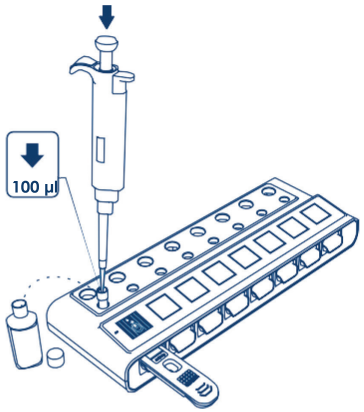
Test Procedure

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

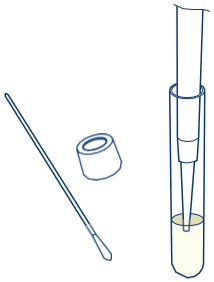
1 Ensure that the QIAreach eHub is turned on, then insert the QIAreach Processing Tube and eStick.



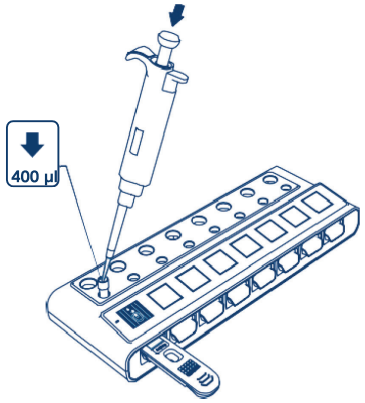
2 Transfer 100 µl of QIAreach Diluent Buffer solution into the QIAreach Processing Tube.



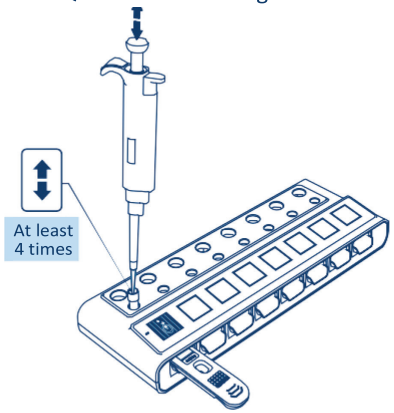
3 Draw 400 µl of patient sample from transport media (Copan UTM).
Refer to IFU for further detail.



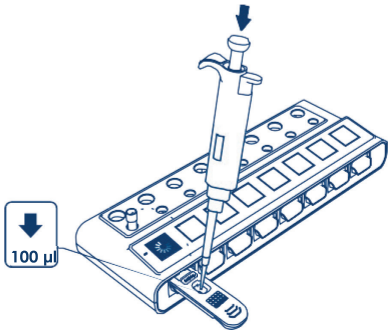
4 Transfer the sample to the QIAreach Processing Tube.



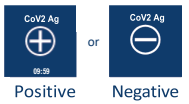
5 Mix the contents at least 4 times to mix the sample in the QIAreach Processing Tube.



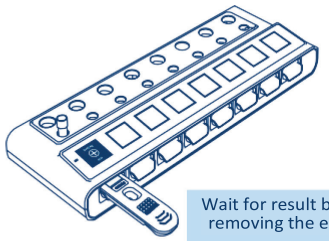
6 Transfer 100 µl from the QIAreach Processing Tube to the eStick.



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



Positive Negative



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