



# QIAreach<sup>®</sup> Anti-SARS-CoV-2 Total Test Quick Reference Guide



The QIAreach<sup>®</sup> Anti-SARS-CoV-2 Total 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. Testing of serum laboratories certified under CLIA that meet the requirements to perform moderate- or high-complexity tests.

The QIAreach Anti-SARS-CoV-2 Total Test has been authorized only for detecting the presence of total antibodies to SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Due to the risk of false-positive results, confirmation of positive results should be considered using a second, different total antibody assay. Please study the *QIAreach Anti-SARS-CoV-2 Total 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** 645033

[www.qiagen.com](http://www.qiagen.com)  
800-344-3631  
Technical support: [techservice-na@qiagen.com](mailto:techservice-na@qiagen.com)

Digital Detection Technology  
designed by and licensed from  
**ellume**  
[ellumehealth.com](http://ellumehealth.com)

## Test Kit Contents (REF 645033)

Note: Do not use the QIAreach Anti-SARS-CoV-2 Total Test beyond the expiration date displayed on the associated product labeling.

60 x QIAreach Anti-SARS-CoV-2 Total eSticks

60 x QIAreach Anti-SARS-CoV-2 Total Processing Tubes

3 x 10ml QIAreach Anti-SARS-CoV-2 Total Diluent Buffer



## Additional Components Required

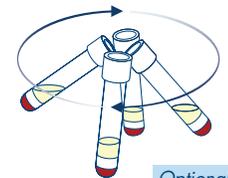
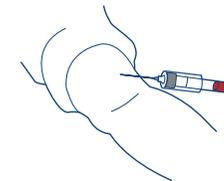
QIAreach eHub (REF 9003063)

Adjustable Volume Pipettes + tips  
Volume/s required: 50µl, 150µl, 300µl

Plasma collection or serum tubes  
Minimum collection volume 1ml



## Pre-analytical Steps

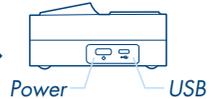
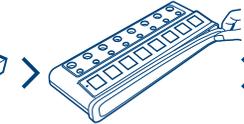


Optional Step

Draw patient sample using a plasma collection tube or standard serum tube - following phlebotomy best practice.

Centrifuge the sample per the collection tube manufacturer's specifications.

## 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) and turn on by pushing the power button.

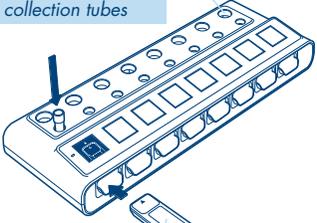
**NB:** Refer to QIAreach eHub User Manual for a complete guide to device operation and troubleshooting.

# Test Procedure

**Note:** Refer to the *QIArearch Anti-SARS-CoV-2 Total Test Instructions for Use (Handbook)* 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 QIArearch Anti-SARS-CoV-2 Total Test, use the QIArearch Anti-SARS-CoV-2 Controls product; this product is sold separately and is available from QIAGEN (Catalog Number 647030). External controls should be run as outlined in the procedure for testing the samples. Positive and negative controls are required to be tested each time when a new lot is used, when a new operator performs the test, or when the test is run in a new room/laboratory, etc. as a good laboratory practice to confirm the test procedure and to verify proper test performance.

1 Ensure the QIArearch eHub is turned on then insert the QIArearch Processing Tube and eStick. Samples and reagents must be brought to room temperature.

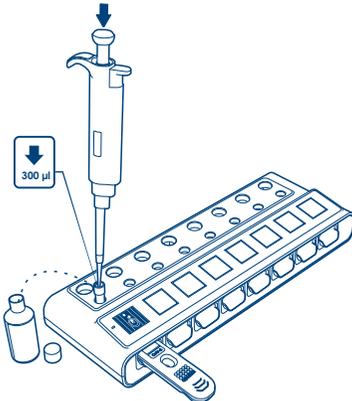
Allowance for 13 mm collection tubes



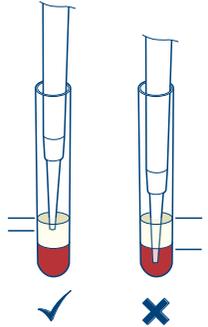
Record patient information

\*\*eStick must be used within 1hr of unwrapping\*\*

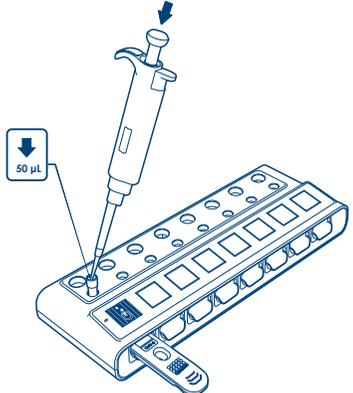
2 Transfer 300 µl of QIArearch Diluent Buffer solution into QIArearch Processing Tube.



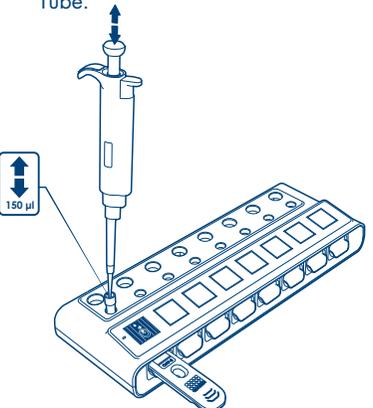
3 Draw 50 µl of serum or plasma sample from collection tube. Refer to the instructions for use for further detail.



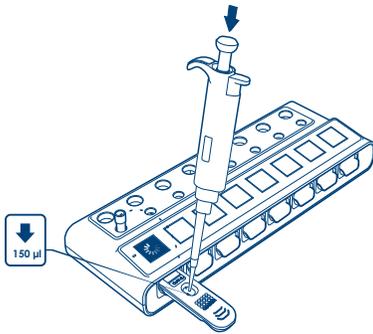
4 Transfer the plasma sample to QIArearch Processing Tube.



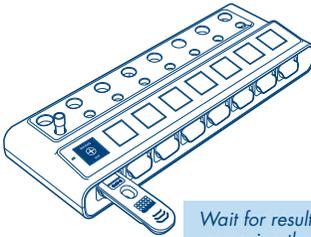
5 With the pipette set to 150 µl, mix the contents at least 4 times to mix the sample in the QIArearch Processing Tube.



6 Transfer 150 µl from the QIArearch Processing Tube to the eStick.



7 The test will run automatically and display a result within approximately 10 minutes.



Anti-CoV2 0959 **+** Positive or Anti-CoV2 **-** Negative

## Summary of Limitations:

- QIArearch Anti-SARS-CoV-2 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.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

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