QIAreach® Anti-SARS-CoV-2 Total Test
Quick Reference Guide

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
- Plasma collection or serum tubes

Minimum collection volume 1ml

Pre-analytical Steps

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

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

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

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

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

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

Summary of Limitations:
- QIAreach 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.

Note: Refer to the QIAreach 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 QIAreach Anti-SARS-CoV-2 Total Test, use the QIAreach 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 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.