QUICK START GUIDE

SARS-CoV-2 ANTIGEN TEST

qorvo BIOTECHNOLOGIES

Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test

FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY

FOR IN VITRO DIAGNOSTIC USE

Refer to the Qorvo Omnia SARS-CoV-2 Antigen Test Instructions for Use for more complete information.

The Qorvo Omnia SARS-CoV-2 Antigen test is an integrated system of instrument and reagent cartridges using immunoassay principles for the qualitative detection of nucleocapsid viral antigens from SARS-CoV-2 in direct anterior nasal (NS) swab specimens without transport media from individuals who are suspected of COVID-19 by their healthcare provider within the first 6 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 or high complexity tests.

The Qorvo Omnia SARS-CoV-2 Antigen test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is detectable in direct anterior nasal 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 Qorvo Omnia SARS-CoV-2 Antigen test is intended for use by trained clinical laboratory personnel specifically instructed and trained in in vitro diagnostic procedures and proper infection control procedures. In the United States, the Qorvo Omnia SARS-CoV-2 Antigen test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Specimens Recommended
The Qorvo Omnia SARS-CoV-2 Antigen assay is validated for use with direct anterior nasal swabs.

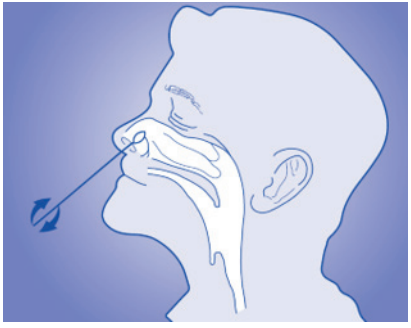


Figure 1

Specimen Collection

1. The Qorvo Omnia SARS-CoV-2 Antigen test kit includes swabs for direct anterior nasal specimen collection.
2. Insert the swab into one nostril of the patient. The swab tip should be inserted until resistance is felt at the level of the turbinates (less than 1 inch into the nostril). Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected (Figure 1). Take approximately 15 seconds to collect the specimen.
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity.
5. Store the swab in a clean tube (Do not use viral transport medium with the nasal swab specimen. The specimen should be processed within one hour, or immediately frozen for long term storage and subsequent testing.

If using a dry frozen swab, allow the swab to warm to room temperature for 20 minutes; then follow the specimen processing procedure below.

Specimen Processing

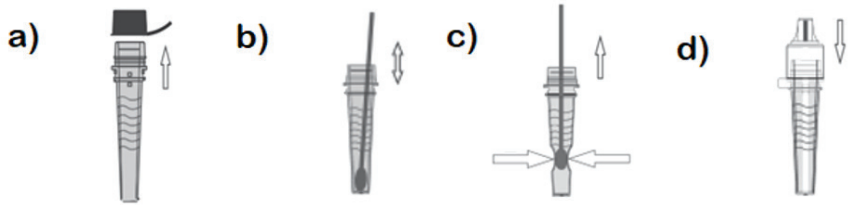
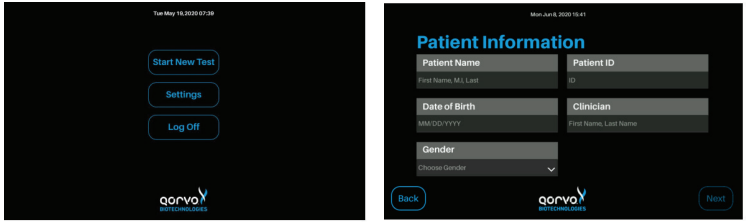


Figure 2

1. Remove one vial of lysis buffer, one dropper cap and one Qorvo Omnia SARS-CoV-2 Antigen test cartridge.
2. Label the lysis buffer vial for each specimen or control to be tested.
3. Remove the cap from the lysis buffer tube (Figure 2a).
4. Insert the swab into the tube and plunge up and down for a minimum of 30 seconds, taking care not to splash the contents out of the tube (Figure 2b).
5. Remove the swab while squeezing the walls of the tube to extract the liquid from the swab tip (Figure 2c).
6. Press firmly to attach the dropper cap onto the tube containing the processed sample. Threading or twisting the cap is not required. Mix thoroughly by swirling or flicking the bottom of the tube (Figure 2d).
7. The processed sample is ready to be assayed on the Qorvo Omnia SARS-CoV-2 Antigen test.

Omnia Instrument Preparation

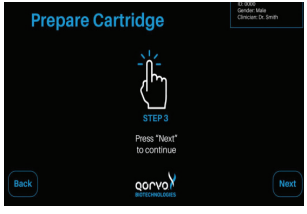


1. Power up the instrument using power button on the lower right side of front panel
2. Login using user credentials
3. Press “Start New Test” from the Main Menu
4. Enter patient information
5. Press “Next” and prepare test cartridge

Antigen Cartridge Preparation

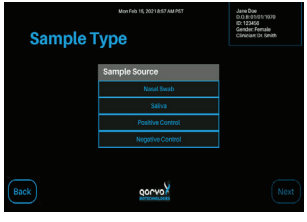
1. Remove the SARS-CoV-2 antigen test cartridge from the foil pouch and place on a flat surface. Label the cartridge with a pen if required, do not attach stickers or labels. Discard the desiccant. Check the integrity of the humidity indicator card. The test cartridge can be used directly from refrigerated storage and does not need additional time to equilibrate to room temperature before testing.

2. Use the dropper cap on the vial of lysis buffer and gently squeeze the ridged area of the vial to dispense 6-7 drops of sample into sample port. The sample will flow counter clockwise through a channel around the sample port. Allow sufficient time for the leading edge of the sample to draw level with the "Sample Fill" line on the cartridge label.

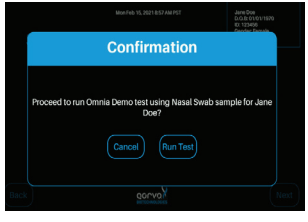


3. Press "Next" on the instrument.

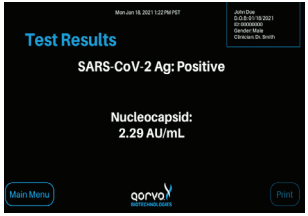
4. Insert the cartridge (the end that has the Insert and arrow) into the instrument's cartridge receiver until the instrument draws it in. Press Next.



5. If prompted, select the sample type. Press Next.



6. Confirm by selecting "Run Test".



7. The results will be available on the screen. You can also print the results if connected to an external printer. After testing is complete, the cartridge will be ejected from the instrument. Discard the cartridge into a biohazard waste container.

Important Notes/Warning Precautions

- Store cartridges at refrigerated temperature between 2-8°C for the duration of the cartridge shelf life. Don't freeze the cartridge.
- If desiccant packet is missing from cartridge pouch, DO NOT USE. Discard cartridge and use a new cartridge.
- Do not use any cartridge if the pouch has been punctured or previously opened.
- Each cartridge is for single use only.
- Do not use the test beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
- After receipt, store cartridges in a refrigerator that is maintained at 2-8°C (36-46°F).
- Specimens may be infectious. Use Universal Precautions when performing this assay.
- Use routine laboratory precautions. Do not eat, drink, or smoke in the area where samples are being handled and testing is being conducted. Avoid any contact between hands, eyes or mouth during sample collection and testing.
- Wear personal protective equipment (PPE) in accordance with laboratory and institutional policies such as laboratory coats, disposable gloves, and eye protection when handling patient samples.
- Wash hands thoroughly after handling specimens and used cartridge.
- Dispose of used cartridge, nasal swab and lysis buffer vial in a biohazard waste container. Proper handling and disposal methods should be established according to local regulations.
- Please refer to the package insert for detailed assay instructions, cautions, limitations, and warnings.

In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA,42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests.

This product has been authorized only for the detection of proteins from SARS-CoV-2 and not for any other viruses or pathogens; and, in the USA, 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 the virus that causes COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

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