

Qorvo Biotechnologies Omnia™ System Quick-Start Guide

FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY

FOR IN VITRO DIAGNOSTIC USE ONLY

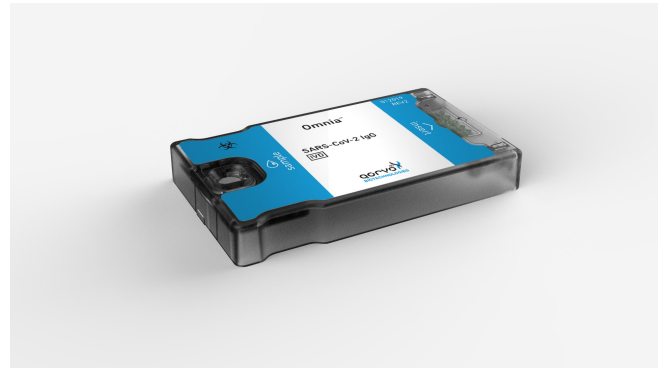
Read these instructions completely before using the product. Follow the instructions carefully, as not doing so may result in inaccurate test results. For in vitro diagnostic and laboratory professional use. This instrument has been authorized for use with the Qorvo Biotechnologies Omnia SARS-CoV-2 Antigen Assay only.

QORVO OMNIA SYSTEM

The Omnia immunoassay system consists of a portable, reusable instrument and a single-use assay-specific cartridge.



Instrument



Cartridge

Step 1: Unpacking

1. Remove the instrument, power converter, and AC power cable from the shipping box.
2. Place the instrument on a clean, level work surface.

Step 2: Instrument Setup Check List

1. Connect the AC power cable to the power converter.
2. Connect the AC power cable to a grounded electrical outlet.
3. Connect the power converter to rear of the instrument.
4. If using Ethernet, connect the Ethernet cable (not supplied) to the socket at the rear of the instrument. Connect the other end of Ethernet cable to an active Ethernet socket. If using Wi-Fi rather than Ethernet, see the Qorvo Biotechnologies Omnia System Operating Manual for detailed instructions on connecting with Wi-Fi.
5. If using an external printer, connect the printer power converter to the rear of the printer and to main power. Connect the printer USB cable from printer to either USB port on the instrument side.
6. Power up the instrument by pressing the power button on the lower right side of front panel.
7. Wait for power-up screen to complete.
8. This completes the instrument setup checklist.

Step 3: Logging in and Main Menu

1. At the log in screen, enter your user credentials. If you are setting up the instrument for the first time, the username “admin” and user password “admin” (both lower case) credentials will be needed to log in.
2. After logging in with the admin/admin credentials, the system will require you to create a new password for the admin user name.
3. After you enter the new password, the system will return you to the Main Menu.
4. From the Main Menu, press “Settings” and then “Admin” to bring up the administrator panel where you may create new user names and passwords. Be sure to create user credentials for each expected operator of the system and record those credentials. The initial admin/admin login credentials do not permit the operator to run tests
5. After creating the user logins, log out and log back in as one of the newly created users.
6. From the Main Menu, select “Start New Test” to begin a new diagnostic test.
7. From the Main Menu, Press “Settings” to manage instrument and network settings.
8. NOTE: Changing certain settings may require Administrator credentials.

Step 4: Running a Test

1. Press “Start New Test” from the Main Menu.
2. Enter patient data at the Patient Information screen.
3. Press “Next”.
4. Follow screen prompts to prepare a cartridge and run the test. Detailed instructions may be found in “Instructions for Use” for individual tests.
5. After sample is loaded, press “Next”.
6. Follow screen prompts to run the test.
7. After the test is complete, the instrument will eject the cartridge, and the cartridge should be disposed of in accordance with biological waste disposal regulations.
8. Results will be automatically displayed after the test is complete.
9. Test results will automatically print if there is a connected printer and the “Auto-Print Results” option is enabled in the Printer Setup Menu. If this option is not enabled, you may print the results manually from the results display screen.

Step 5: Logging Out

1. User may Log Off from the Main Menu.

Maintenance

1. Cleaning the Outer Case: Wipe the outer case using a soft cloth, dampened with a mild, non-abrasive detergent or cleaning solution. Do not spray any detergents or solutions directly on the outer case.
2. Cleaning the Touch Screen: Use a soft, lint free cloth dampened with glass-cleaning fluid.
3. Replacing the Air Filter (perform monthly): refer to section Replacing the Air Filter in the Qorvo Omnia System Operator Manual.

Warnings and Precautions

1. For in vitro diagnostic use only.
2. Handle all specimens and related materials as if capable of transmitting infectious agents.
3. It is recommended to follow your institution’s requirements for decontamination procedures or if spills occur. See Qorvo Omnia System Operator Manual for instrument cleaning.
4. Dispose of used materials as biohazardous waste in accordance with federal, state and local requirements.
5. Please refer to the package insert for detailed assay instructions, cautions, limitations, and warnings.

QUICK-START GUIDE

TECHNICAL SUPPORT

Qorvo Biotechnologies® is committed to the highest standards of customer service. You can get support or additional guidance by contacting us at:

Toll-Free: 1.833.384.1522

E-mail: OmniaCOVID19Test@qorvo.com

This guide is a supplement. For additional information, please consult the detailed system instructions and the Troubleshooting Guide contained in the separate Qorvo Omnia System Operator's Manual that came with your system.

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 is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

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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