

Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test Instructions for Use



For prescription use only

For in vitro diagnostic use only

For use under the Emergency Use Authorization (EUA) only

INTENDED USE

The Qorvo Biotechnologies 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 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 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.

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Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test Instructions for Use



SUMMARY AND EXPLANATION OF THE TEST

SARS-CoV-2 is a large enveloped, single-stranded RNA virus of the family Coronaviridae, genus Beta coronavirus, identified in December 2019. All coronaviruses share similarities in the organization and expression of their genome. The symptoms of the virus are similar to other viral respiratory diseases and include cough, fever and shortness of breath. The median incubation time is around 5 days with symptoms expected to be present within 12 days after infection.

The Qorvo Omnia SARS-CoV-2 Antigen test is an automated Bulk Acoustic Wave (BAW) biosensor-based test for the qualitative detection of SARS-CoV-2 directly from direct anterior nasal swabs without viral transport media.

PRINCIPLES OF THE PROCEDURE

The Qorvo Omnia SARS-CoV-2 Antigen test is to be run on the Qorvo Omnia instrument. Time to test result from is ~20 minutes from the start of the test in the instrument.

To perform the Qorvo Omnia SARS-CoV-2 Antigen test, a nasal swab specimen is processed using a lysis buffer to disrupt the virus and expose the internal viral nucleocapsid protein. The processed specimen is added to the cartridge and the cartridge is inserted into the instrument. The instrument moves fluid from the sample port and various reagents from the cartridge carousel across the biosensor contained within the cartridge. On the surface of the biosensor an enzyme-enhanced immune reaction takes place: antibodies to SARS-CoV-2 nucleocapsid protein on the resonator surface capture the specific antigens to SARS-CoV-2. An enzyme-conjugated anti-nucleocapsid antibody binds to the immobilized SARS-CoV-2 antigens. The reaction causes a change in resonance frequency which is detected by the instrument. There is a direct relationship between the concentration of SARS-CoV-2 viral antigens in the sample and the frequency shift detected by the sensor. Results are then reported in Arbitrary Units/mL (AU/mL) and designated as “positive” with an AU/mL equal to or greater than the cut-off value set at 1.0, or “negative” with an AU/mL less than 1.0.

Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test Instructions for Use



For additional information on system and assay technology, refer to the Qorvo Biotechnologies Omnia System Operator Manual.

MATERIALS PROVIDED

Catalogue # QPR8302 is a box that consists of the following materials.

- 20 cartridges individually sealed in aluminum foiled pouch with a humidity indicator and desiccant.
- 20 vials of lysis buffer (300uL each)
- 20 dropper caps
- 20 nasal swabs
- 1 Device instruction for use (IFU)
- 1 Device quick start guide (QSG)

Each test requires one cartridge, one vial of lysis buffer with dropper cap and one disposable swab. The desiccant and humidity indicator packaged with the cartridge may be discarded with the pouch.

MATERIALS REQUIRED BUT NOT PROVIDED

Qorvo Biotechnologies Omnia System (Catalog number # QPR9002)

Qorvo Biotechnologies Omnia SARS-CoV-2 External Control (Catalog # QPR8302.QC). The control kit contains vials with sufficient volume for a total of 60 tests and 60 disposable pipettes.

Qorvo Biotechnologies Omnia Transport Tubes (Catalog # QPR8302.TT)

TEST CARTRIDGE

Cartridge Content

The Qorvo Omnia SARS-CoV-2 Antigen cartridge is a single use disposable test cartridge that consists of two preassembled parts: resonators and a reagent carousel.

Resonators

- Resonators are pre-coated with mouse monoclonal antibodies to SARS-CoV-2 nucleocapsid protein in phosphate buffered saline.

Reagent carousel

- Consists of conjugate, wash buffers and substrate.
 - o Conjugate: Biotinylated anti-nucleocapsid protein (rabbit monoclonal) in HEPES based buffer with surfactant. Proclin-300 at 0.05% is used as a preservative.

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Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



- Enzyme Enhancer: Streptavidin conjugated to alkaline phosphatase in HEPES based buffer with surfactant. Proclin-300 at 0.05% is used as a preservative.
- Wash Buffers: HEPES buffer based with detergent.
- Substrate: AMP buffer based with a precipitating substrate` and detergent. Proclin-950 at 0.05% is used as a preservative.

Cartridge handling and storage

- Store cartridges and lysis buffer at refrigerated temperature between 2-8°C (36– 46°F). Do not use cartridges stored outside this temperature.
- Do not freeze the cartridges.
- Each cartridge pouch contains a humidity exposure indicator. Upon opening the cartridge pouch, the indicator must be assessed to confirm the cartridge has not been exposed to excess humidity.
- Do not use any cartridge if the desiccant packet is missing from cartridge pouch.
- Do not use any cartridge if the pouch has been punctured or previously opened.
- Each cartridge is for single use only – discard according to facility requirements after use.
- Do not use the test beyond the expiration date printed on the pouch. Always check expiration date prior to testing.

CHEMICAL HAZARD AND SAFETY INFORMATION

- The reagents in the cartridge carousel contain less than 0.1% sodium azide.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit please refer to the Safety Data Sheets (SDS) located at <https://www.qorvo.com/innovation/biotechnologies>.

INSTRUMENT

For a detailed description of instrument operating procedures, refer to the Qorvo Biotechnologies Omnia System Operator Manual. Instrument must be maintained as indicated in the Manual for reliable use.

Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



WARNINGS AND PRECAUTIONS

Warnings

- For use under Emergency Use Authorization Only.
- For prescription use only.
- For *in vitro* diagnostic use only.
- Read all instructions completely and carefully and follow all instructions. Failure to follow all instructions may result in inaccurate test results.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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 Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.
- Use appropriate precautions in the collection, handling and storage of patient samples. Refer to CDC Interim Guidelines for Collection, Handling and Transportation of clinical specimens from persons with Coronavirus Disease 2019 (COVID-19) at <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>, and to WHO's Interim guidance for Laboratory testing for coronavirus disease (COVID-19) in suspected human cases at <http://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117>, as amended and supplemented. Refer to the WHO website for additional publications.
- Used swabs must be treated as infectious waste.
- All samples, even after the extraction procedure, and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents; accordingly samples, reagents and the waste must be handled with utmost care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country.
- Do not use the kit contents beyond the expiration date.

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Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
- Strict adherence to the Qorvo Omnia SARS-CoV-2 assay instructions is necessary to obtain accurate results.
- Extraction buffer supplied with the kit should not be separated from the cartridges as testing (including extraction) is expected to be performed by trained laboratory personnel.

Safety Precautions

- 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 in a biohazard waste container. Proper handling and disposal methods should be established according to local regulations.
- Avoid splashing or aerosolization of samples or reagents as droplets are a means of transmission of SARS-CoV-2 virus. All drops and spills must be wiped up with an appropriate disinfectant such as a sodium hypochlorite solution with 0.5% active chlorine, and all soiled materials must be disposed of as infectious waste.

SPECIMEN COLLECTION AND PREPARATION

Patient Preparation

No special patient preparation is necessary.

Specimens Recommended

The Qorvo Omnia SARS-CoV-2 Antigen assay is validated for use with direct anterior nasal swab specimens only.

Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



Specimen Collection

- The Qorvo Omnia SARS-CoV-2 Antigen test kit includes swabs for direct anterior nasal specimen collection.
- 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 one 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.
- Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
- Withdraw the swab from the nasal cavity.
- Store the swab in a clean tube - Transport Tubes are available separately from Qorvo (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.

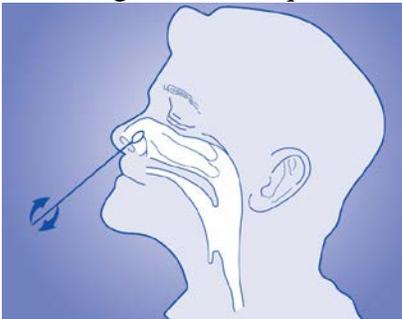


Figure 1: Nasal specimen collection

Specimen Processing

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

- Remove one vial of extraction reagent, one dropper cap and one Qorvo Omnia SARS-CoV-2 Antigen test cartridge.
- Label the lysis buffer vial and cartridge for each specimen or control to be tested.
- Remove and discard the cap from the lysis buffer tube (Figure 2a).
- 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).
- Remove the swab while squeezing the walls of the tube to extract the liquid from the swab tip (Figure 2c).

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Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



- 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).
- The processed sample is ready to be assayed on the Omnia SARS-CoV-2 Antigen test.

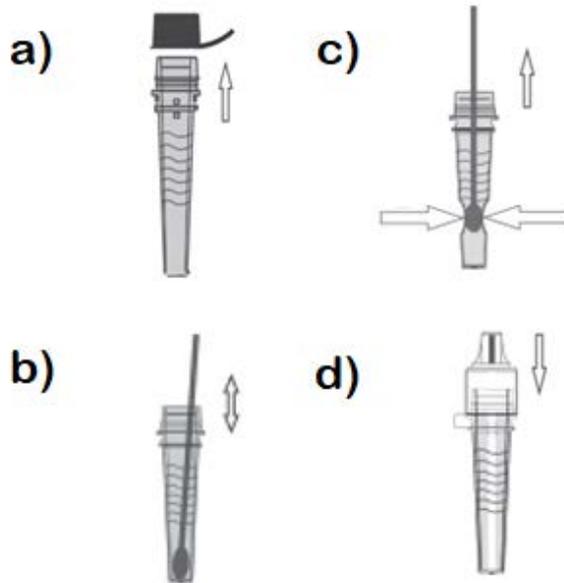


Figure 2: Specimen processing

Specimen Handling and Storage Conditions

- Nasal swabs must be tested within one hour of collection or frozen.
- Test the processed specimens according to the test procedure below.
- Processed samples in lysis buffer may be stored refrigerated or at room temperature for up to 24 hours prior to testing.

Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test Instructions for Use



TEST PROCEDURE

Operating Instructions

1. Power up the Instrument by pressing the power button on the lower right side of front panel.
2. Wait for power-up screen to complete.
3. Login using user credentials.
4. Press “Start New Test.” from the Main Menu.
5. Enter patient information and the associated sample type.
6. Press “Next.”
7. Prepare the cartridge following the on-screen instructions
 - o Select cartridge labeled SARS-CoV-2 Antigen
 - o Remove cartridge from pouch (discard pouch, humidity indicator and desiccant) The cartridge can be used directly from refrigerated storage and does not require time to equilibrate to room temperature.
 - o Place cartridge on flat surface

Once removed from the pouch the cartridge should be used immediately but may be held at room temperature for up to four hours.

8. Use the dropper cap to dispense 5 drops of processed sample into sample port (Figure 3). The sample will enter the cartridge by capillary action. Allow sufficient time for the leading edge of the sample to draw level with the “Sample Fill” line on the cartridge label.

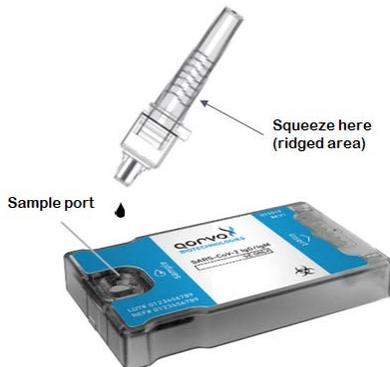


Figure 3: Specimen loading

9. Enter “Next”

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Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



10. Insert the cartridge into instrument by gently pushing the cartridge into the Cartridge Receiver until the instrument accepts and draws in the cartridge. Cartridge direction is according to the arrow on the cartridge.
11. Press “confirm” and the test will run automatically.
12. After the test is complete, the cartridge will be ejected from the instrument and results (AU/mL and positive/negative) will be displayed on the screen.
13. Dispose of the cartridge after it has been ejected according to facility instructions.
14. Results will be displayed. If an external printer is connected to the instrument, select “Print Results”.

Assay

The Qorvo Omnia SARS-CoV-2 Antigen test cartridge is ready for use. No additional preparation is necessary.

Calibration

The Qorvo Omnia SARS-CoV-2 Antigen test cartridge is factory calibrated. No additional calibration is necessary.

Quality Control

The Qorvo Omnia SARS-CoV-2 Antigen test cartridge has a built-in quality control. An internal positive control resonator is included in the test that binds the conjugate and confirms that the cartridge ran correctly.

External positive control is sold separately by Qorvo Biotechnologies. The positive control is a solution of recombinant nucleocapsid antigen that is applied directly to the test cartridge.

A sterile nasal swab is provided with the Qorvo Omnia SARS-CoV-2 Antigen test kit and is intended to be used as an external negative control. This is processed according to the instructions above.

External positive and negative controls should be tested consistent with good laboratory practice to confirm the test procedure and to verify proper test performance. It is recommended external controls are assayed at least once for each different test cartridge lot, for each new operator and additionally to comply with internal quality control procedures, Local, State and Federal regulations, or accreditation requirements.

Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



RESULT

Calculation

Results are automatically calculated by the instrument for each cartridge run. AU/mL (Arbitrary Units) is calculated by the instrument. Results are reported as “Positive” when the resonator in the test cartridge is read ≥ 1.0 AU/mL. Results are reported as “Negative” when the resonator in the cartridge is read < 1.0 AU/mL. Internal control must be valid for the test results to be reported. Invalid internal control will display results as “INVALID” and no result will be reported.

Interpretation of results

Internal Control	Nucleocapsid AU/mL	Displayed result	Test Result Interpretation
Invalid	Not displayed	INVALID	Invalid Test. Test again with a new specimen and new cartridge
Valid	< 1.0	NEGATIVE	Presumptive Negative for SARS-CoV-2 (no antigen detected)
Valid	≥ 1.0	POSITIVE	Positive for SARS-CoV-2 (antigen present)

Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



LIMITATIONS OF THE PROCEDURE

Limitations

- Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- Performance has not been established for use with specimens other than direct nasal swabs. Other specimen types have not been evaluated and should not be used with this assay. Performance in fresh specimens has not been established and may differ.
- Only qualitative results should be reported. Semi-quantitative numerical results have not been clinically or analytically validated and may not correlate with patient disease status, duration of illness or severity of illness. Semi-quantitative results have not been demonstrated to correlate with the success or failure of any therapeutic interventions and should not be used to guide clinical management.
- Test results should be considered in the context of all available clinical and diagnostic information, including patient history and other test results.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 2020 and February 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection.
- A false negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.

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Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. In this case, direct testing for the SARS-CoV-2 virus (e.g. PCR testing) should be considered.
- Positive results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.

Conditions of authorizations for the laboratories

The Qorvo Omnia SARS-CoV-2 Antigen test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-useauthorizations# covid19ivd>. However, to assist clinical laboratories using the Qorvo Omnia™ SARS-CoV-2 Antigen test (“your product” in the conditions below), the relevant Conditions of Authorization are listed below:

- A. Authorized laboratories* using the Qorvo Omnia SARS-CoV-2 Antigen test must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using the Qorvo Omnia SARS-CoV-2 Antigen test must use the product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

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Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test Instructions for Use



- C. Authorized laboratories that receive the Qorvo Omnia SARS-CoV-2 Antigen test must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- D. Authorized laboratories using the Qorvo Omnia SARS-CoV-2 Antigen test must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories must collect information on the performance of the Qorvo Omnia SARS-CoV-2 Antigen test and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Qorvo Biotechnologies (<https://www.qorvo.com/go/biotech>) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of the Qorvo Omnia SARS-CoV-2 Antigen test of which they become aware.
- F. All laboratory personnel using the Qorvo Omnia SARS-CoV-2 Antigen test must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
- G. Qorvo Biotechnologies, authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests” as “authorized laboratories.”

PERFORMANCE CHARACTERISTICS

CLINICAL PERFORMANCE

The performance of the Qorvo Omnia SARS-CoV-2 Antigen test was established by testing 89 direct nasal swabs collected prospectively from 89 patients suspected of SARS-CoV-2 infection within 6 days from onset of symptoms.

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Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



Nasal swabs were collected from both nostrils. Specimens were frozen immediately after collection and stored until tested. The performance of the Qorvo Omnia SARS-CoV-2 Antigen test was compared to results of a concurrently collected nasopharyngeal swab stored in 3 mL of viral transport media and tested with an EUA approved, high sensitivity real time PCR molecular test for detection of SARS-CoV-2. Final data analysis is presented below:

Omnia SARS-CoV-2 Antigen Results	Comparator Method		
	Positive	Negative	Total
Positive	51 ¹	0	51
Negative	6 ¹	32	38
Total	57	32	89

¹ Four (4) positive results enriched this study with different yet comparable RT-PCR Comparative Methods to ensure required testing of low positive specimens.

Statistic	Estimate
Sensitivity (Positive Percent Agreement)	51/57 (89.47%) (95% CI 78.88%-95.09%)
Specificity (Negative Percent Agreement)	32/32 (100%) (95% CI 89.28%-100%)
Positive Predictive Value (PPV)	51/51 (100%) (95% CI 93.00%-100%)
Negative Predictive Value (NPV)	32/38 (84.21%) (95% CI 68.58%-92.56%)
<i>PPV: proportion of positive device results that are true positive</i>	
<i>NPV: proportion of negative device results that are true negative</i>	

Days from Onset	Cumulative Omnia SARS-CoV-2 Antigen Positive	Cumulative RT-PCR Positive	PPA
0	1	1	100.0%
1	6	6	100.0%
2	13	15	86.7%
3	24	28	85.7%
4	43	49	87.8%
5	45	51	88.2%
6	51	57	89.5%

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Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

The Limit of Detection (LoD) for the Qorvo Omnia SARS-CoV-2 Antigen test was established using limiting dilutions of gamma-irradiated SARS-CoV-2 isolate USA-WA1/2020 (BEI Resources NR-52287). NR-52287 stock specimens were provided at a concentration of 2.8×10^6 TCID₅₀/mL (1.75×10^9 genome equivalents/mL) and diluted to respective concentrations with negative pooled nasal wash matrix. For each test, 50 μ L of sample was absorbed onto a flocked swab and the swab was tested per the above specimen processing instructions.

Limit of Detection – Initial Assessment

An initial LoD study was performed using a 5-fold serial dilution of the characterized inactivated SARS-CoV-2 virus into pooled negative human nasal matrix. A total of 4 dilutions were tested in triplicate with the starting concentration being 15,625 TCID₅₀/mL. The lowest concentration at which all replicates (3 of 3 replicates) were positive, 625 TCID₅₀/mL, was treated as the tentative LoD for each test.

SARS-CoV-2 Initial LoD Assessment

TCID ₅₀ /mL of Tested SARS-CoV-2 Sample	Positive Test Results
15,625	3/3
3,125	3/3
625	3/3
125	2/3

A refined LoD study was then performed using small step wise dilutions of the characterized inactivated SARS-CoV-2 virus into pooled negative nasal matrix starting with the tentative LoD. This study was performed in triplicate and the final LoD of this system was determined to be the lowest concentration resulting in positive detection of a minimum of 19 out of 20 replicates. To establish reliable assay sensitivity, 20 replicates were tested on the two lowest concentrations that returned 3/3 initial positive readings. Based on the results from this evaluation, the final LoD for this system was determined to be 200 TCID₅₀/mL (125,000 genome equivalents/mL).

Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



SARS-CoV-2 Refined LoD Assessment and Confirmation

TCID ₅₀ /mL of Tested SARS-CoV-2 Sample	Positive Test Results
625	3/3
312	3/3
250	20/20
200	20/20
156	2/3

Cross-reactivity (Analytical Specificity) And Microbial Interference

Cross-reactivity of the Qorvo Omnia SARS-CoV-2 Antigen test to a panel of related pathogens and micro-organisms and pooled human nasal wash was evaluated. Each organism was prepared individually in the absence and presence of SARS-CoV-2 at 3x LoD concentration. Both the cross-reactivity and microbial interference studies were conducted in triplicate. No cross-reactivity or interference was seen with the following organisms when tested at the concentration shown in the table below.

Cross-Reactivity and Microbial Interference: Omnia SARS-CoV-2 Antigen Test– Wet Testing

Organism	Concentration
Human coronavirus 229E	1.51 x 10 ⁶ TCID ₅₀ /mL
Human coronavirus OC43	5.01 x 10 ⁵ TCID ₅₀ /mL
Human coronavirus NL63	1.41 x 10 ⁵ TCID ₅₀ /mL
MERS-CoV	1.70 x 10 ⁵ TCID ₅₀ /mL
Adenovirus (C1 Ad. 71)	1.02 x 10 ⁸ TCID ₅₀ /mL
<i>Bordetella pertussis</i>	1.13 x 10 ¹⁰ CFU/mL
<i>Candida albicans</i>	6.27 x 10 ⁸ CFU/mL
<i>Chlamydia pneumoniae</i>	1.75 x 10 ⁶ IFU/mL
Enterovirus	1.26 x 10 ⁶ U/mL
<i>Haemophilus influenzae</i>	2.27 x 10 ⁹ CFU/mL
Human Metapneumovirus (hMPV)	3.80 x 10 ⁶ TCID ₅₀ /mL
Influenza A H1N1	3.55 x 10 ⁵ TCID ₅₀ /mL
Influenza A H3N2	3.55 x 10 ⁵ U/mL

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Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



Influenza B	4.17 x 10 ⁵ TCID ₅₀ /mL
<i>Legionella pneumophila</i>	1.88 x 10 ¹⁰ CFU/mL
<i>Mycoplasma pneumoniae</i>	3.16 x 10 ⁸ CFU/mL
Parainfluenza virus 1	3.39 x 10 ⁷ TCID ₅₀ /mL
Parainfluenza virus 2	1.51 x 10 ⁶ TCID ₅₀ /mL
Parainfluenza virus 3	8.51 x 10 ⁷ TCID ₅₀ /mL
Parainfluenza virus type 4A	1.38 x 10 ⁷ TCID ₅₀ /mL
Parainfluenza virus type 4B	1.17 x 10 ⁷ TCID ₅₀ /mL
<i>Pneumocystis jirovecii</i> - <i>S. cerevisiae</i> Recombinant	1.56 x 10 ⁷ CFU/mL
Pooled human nasal wash	100%
Respiratory syncytial virus type A	3.16 x 10 ⁶ U/mL
Respiratory syncytial virus type B	1.26 x 10 ⁶ TCID ₅₀ /mL
Rhinovirus	4.17 x 10 ⁵ U/mL
<i>Staphylococcus aureus</i>	5.5 x 10 ⁹ CFU/mL
<i>Staphylococcus epidermidis</i>	9.27 x 10 ⁹ CFU/mL
<i>Streptococcus pneumoniae</i>	2.26 x 10 ⁹ CFU/mL
<i>Streptococcus pyogenes</i>	1.64 x 10 ⁹ CFU/mL

In-silico analysis using Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology and likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet-testing.

- SARS-CoV-1: BLAST results showed high homology between the nucleocapsid of SARS-CoV-1 reference isolates TW11 and BJ01 and SARS-CoV-2. Alignment results for isolate TW11 Sequence ID AAR87518.1 (Query Cover: 100%, Percent Identity: 90.76) and isolate BJ01 Sequence ID AAP30037.1 (Query Cover: 100%, Percent Identity: 90.52%) means cross-reactivity cannot be ruled out.
- Human Coronavirus HKU1: BLAST results showed 36 sequence IDs, all nucleocapsid protein, showing homology. The top two alignment scores were Sequence ID AXT92485.1 (Query Cover: 82%, Percent Identity: 36.74%) and Sequence ID AGW27840.1 (Query Cover: 76%, Percent Identity: 39.10%). Homology is relatively low, but cross-reactivity cannot be ruled out.

Endogenous Interference Substances

The following substances, either naturally present in respiratory specimens or artificially introduced into the nasal passage, were evaluated with the Qorvo Omnia SARS-CoV-2 Antigen test at the concentrations listed below. Each material was prepared individually in the absence and presence of

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Qorvo Biotechnologies

Omnia™ SARS-CoV-2 Antigen

Test Instructions for Use



SARS-CoV-2 at 3x LoD concentration. None of these substances were found to interfere with assay performance. Testing was performed in replicates of 3.

Substance	Concentration
Whole Blood	4%
Mucin	0.5%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
CVS Nasal Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
CVS Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	1:10 dilution
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Tamiflu (Oseltamivir Phosphate)	5 mg/mL
Biotin	3.5 µg/mL

High-dose Hook Effect

No high dose hook effect was observed up to 2.8×10^6 TCID₅₀/mL of gamma irradiated SARS-CoV-2 with the Qorvo Omnia SARS-CoV-2 Antigen test.

References

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2. Zhu N, Zhang D, Wang W, et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. N Engl J Med 2020;382(8):727-733.
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4. World Health Organization. Coronavirus disease (COVID-19) technical guidance: Laboratory testing for 2019-nCoV in humans page. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>. Accessed April 27, 2020

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Qorvo Confidential & Proprietary Information

Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test Instructions for Use



Version Information

Qorvo part number QPR8302-PK075

Version B

January, 2021

Qorvo Biotechnologies Omnia™ SARS-CoV-2 External Control

FOR IN VITRO DIAGNOSTIC USE ONLY

FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY

INTENDED USE

The Qorvo Omnia SARS-CoV-2 Antigen Positive Control is intended for use as an external quality control sample to monitor the performance of the Qorvo Omnia SARS-CoV-2 Antigen test with direct anterior nasal swabs.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner.

SUMMARY AND EXPLANATION OF THE TEST

Negative control testing is performed by using a new and unused sterile nasal swab with the Qorvo Omnia SARS-CoV-2 Antigen test.

Positive control testing is performed by using the Qorvo Omnia SARS-CoV-2 Antigen Positive Control. The Qorvo Omnia SARS-CoV-2 Antigen Positive Control is a liquid quality control reagent that provides the user assurance that the Qorvo Omnia SARS-CoV-2 Antigen test is performing as intended.

It is recommended that controls are run once for each Qorvo Omnia SARS-CoV-2 Antigen test cartridge lot, for each new operator and/or as deemed necessary by internal quality control procedures, and in accordance with local, state and federal regulations or accreditation requirements.

It is the responsibility of each laboratory or healthcare setting using the Qorvo Omnia SARS-CoV-2 Antigen test to establish an adequate quality assurance program.

INSTRUCTIONS FOR USE

WARNINGS AND PRECAUTIONS

- For prescription use only
- For use under an Emergency Use Authorization Only
- For in vitro diagnostic use.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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 Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.
- Sample shall be collected following the manufacturer's instructions for use and the COVID-19 standard of care.
- Observe the normal precautions required for handling all laboratory reagents.
- Dispose of all waste material in accordance with local guidelines.

SAFETY PRECAUTIONS

- The reagents in the cartridge carousel contain less than 0.1% sodium azide.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit please refer to the Safety Data Sheets (SDS) located at <https://www.qorvo.com/innovation/biotechnologies>.

STORAGE AND STABILITY

Store controls between 2°C and 8°C.

Unopened controls that are stored between 2°C and 8°C can be used until the expiration date. Do not use kits or components beyond the expiration date given on the label.

Once opened, the vial has a 14 day expiry. After each use recap and store the vial in the original container at 2-8°C.

TEST PROCEDURE

Materials Provided

Catalogue # QPR8302.QC is a box that consists of the following materials.

- Six vials of SARS-CoV-2 Antigen Positive Control
- 60 disposable transfer pipettes
- 1 package insert

Materials Required but Not Provided

Qorvo Omnia SARS-CoV-2 Antigen test kit

Qorvo Omnia Instrument

Operating Instructions

Store the Qorvo Omnia SARS-CoV-2 Antigen Positive Control upright at 2-8°C.

Positive Control

1. Power up the Qorvo Omnia Instrument by pressing the power button on the lower right side of front panel
2. Wait for power-up screen to complete
3. Login using user credentials
4. Press "Start New Test" from the Main Menu
5. Fill in control information

INSTRUCTIONS FOR USE

6. Press "Next"
7. Prepare the cartridge following the on-screen instructions
 - o Select cartridge labeled Qorvo Omnia SARS-CoV-2 Antigen
 - o Remove cartridge from pouch
 - o Place cartridge on flat surface
8. Mix the control vial gently by rocking or inversion.
9. Use a disposable transfer pipette to dispense a minimum of 100 µL of Qorvo Omnia SARS-CoV-2 Antigen Positive Control into the sample port
10. Press "Next"
11. Insert the cartridge into instrument by gently pushing the cartridge into the cartridge receiver until the instrument accepts and draws in the cartridge; cartridge direction is according to arrow on cartridge end
12. When prompted, select the "Positive Control" sample type
13. Confirm and run the test
14. After the test is complete, the cartridge will be ejected from the instrument
15. Dispose the cartridge after the cartridge has been ejected
16. Print the results

Negative Control

1. Follow the test procedure in the Qorvo Omnia SARS-CoV-2 Antigen test IFU using an unused sterile nasal swab provided with the kit
2. When prompted select the "Negative Control" sample type

EXPECTED RESULTS

The Qorvo Omnia SARS-CoV-2 Antigen Positive Control should report a positive result. The Negative Control swab should report a negative result.

If the procedure does not perform as expected do not test further patient samples, and contact Qorvo Biotechnologies Customer Technical Support:

Toll Free: 1.833.384.1522
Email: OmniaCOVID19Test@qorvo.com

DOCUMENT NUMBER

Qorvo Part Number QPR8302-PK071
 Rev C
 March 2021

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

Specimen Recommended

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

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.



Figure

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

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 and cartridge for each specimen or control to be tested.
3. Remove and discard 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.

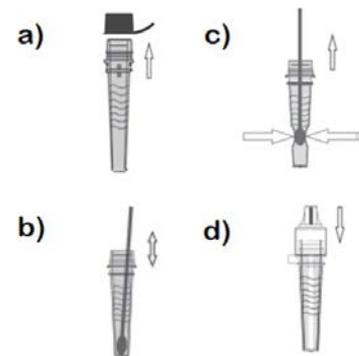


Figure 2

Qorvo 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

QUICK-START GUIDE



Antigen Cartridge Preparation



1. Remove the SARS-CoV-2 antigen test cartridge from the foil pouch and place on a flat surface. 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.

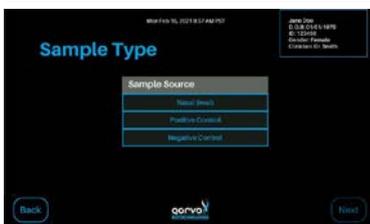
2. Use the dropper cap on the vial of Lysis Buffer and gently squeeze the ridged area of the vial to dispense 5 drops (~100 μ L) of sample into sample port. Allow sufficient time for the leading edge of the sample to draw level with the "Sample Fill" line on the cartridge label.



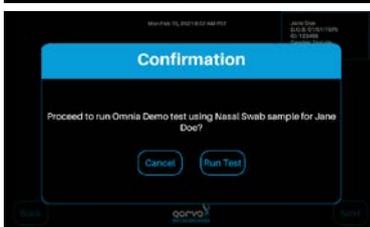
3. Press "Next" on the instrument.



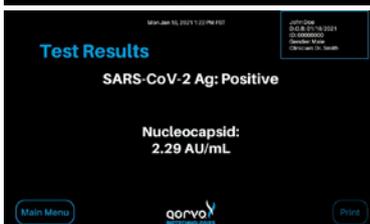
4. Insert the cartridge (the end that has the word Insert and arrow) into the instrument's cartridge receiver until the instrument draws it in.



5. If prompted, select the sample type.



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.

8. After testing is complete, the cartridge will be ejected from the instrument. Discard the cartridge and transfer pipette into a biohazard waste container.

Important Notes/Warnings/Precautions

- Store cartridges at refrigerated temperature between 2-8°C for the duration of the cartridge shelf life. Do not 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 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.

TECHNICAL SUPPORT

Toll-Free: 1.833.384.1522

Email: OmniaCOVID19Test@qorvo.com

DOCUMENT VERSION

Part Number

QPR8302-PK073

Version A

March 2021

Qorvo Biotechnologies® Omnia™ System Operator Manual

FOR EMERGENCY USE AUTHORIZATION ONLY



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 or high 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.

TABLE OF CONTENTS

OVERVIEW OF QORVO OMNIA SYSTEM.....	4
COMPONENTS IN THE BOX.....	4
WARNINGS.....	5
SYMBOLS AND LABELS.....	5
INSTRUMENT LABELS.....	5
SPECIMEN PRECAUTIONS.....	6
EXTERNAL QUALITY CONTROL.....	6
INSTRUMENT INSTALLATION.....	6
PRINTER INSTALLATION.....	6
USING THE TOUCH SCREEN.....	6
GRAPHIC USER INTERFACE.....	6
STARTING A NEW TEST.....	17
RUNNING A TEST.....	19
PERIODIC MAINTENANCE AND SERVICE.....	25
CLEANING THE OUTER CASE.....	25
CLEANING THE TOUCH SCREEN.....	25
REPLACING THE AIR FILTER.....	25
RETURNING THE INSTRUMENT FOR SERVICE.....	25
INSTRUMENT DISPOSAL.....	26
INSTRUMENT DIMENSIONS.....	26
POWER SUPPLY.....	26
INPUT/OUTPUT CONNECTIONS.....	26
OPERATING CONDITIONS.....	26
SHIPPING/STORAGE CONDITIONS.....	26
PROBLEM SOLVING.....	27
DOCUMENT INFORMATION.....	31

OVERVIEW OF QORVO OMNIA SYSTEM

The Qorvo Biotechnologies Omnia system is a device for measuring biomarker concentrations from a human sample. The Qorvo Omnia system consists of an instrument, on-board software, and single-use test cartridges. The instrument (Fig 1) contains all hardware, software, and mechanical components necessary for full automation of biomarker detection.



Figure 1



Figure 2

The test cartridge (Fig 2) consists of two preassembled parts: a main cartridge body and a reagent carousel. All the liquid reagents required for the test are contained in the reagent carousel. The liquid reagents on the carousel are automatically moved in an interface between the cartridge and instrument. During a test, the sample is added to the cartridge sample port to the fill line and the user inserts the cartridge into the instrument following the indicator arrow on the cartridge. When inserted, the instrument recognizes the test type and other relevant cartridge information by reading a Radio Frequency Identification (RFID) tag permanently affixed to the cartridge. The user follows the prompts on the screen to initialize the test.

For detailed instructions on running a test, refer to the Instructions for Use for each assay.

COMPONENTS IN THE BOX

- Instrument (1)
- Power Supply (1)
- Operator Manual (1)
- Quick Start Guide (1)
- Replacement Air Filters (5)

OPERATOR MANUAL

WARNINGS

Read these instructions completely before using the product.

1. For in vitro diagnostic use.
2. The Qorvo Omnia System is FOR EMERGENCY USE AUTHORIZATION ONLY
3. Read all instructions completely and carefully follow all instructions. Failure to follow all instructions may result in inaccurate test results.

SYMBOLS AND LABELS

The following symbols are found on the Qorvo Omnia system and cartridges:

Symbol	Explanation
	Protect instrument from moisture
	User to consult the instructions for use
	Indicates the temperature range for use/storage
	Indicates serial number so that the device can be identified
	Indicates the manufacturer's catalogue number so the device can be identified
	Indicates the date after which the cartridge is not to be used (expiration date)
	Indicates that the cartridge is intended for single use
	Indicates possible biological risk
	In-Vitro Diagnostic Medical Device
	Underwriter Labs Approved
	For prescription use only

INSTRUMENT LABELS

The instrument has a label on the bottom. The label contains information specific to each instrument (serial number), part number and information related to instrument storage and use environments.

SPECIMEN PRECAUTIONS

1. Specimens may be infectious. Use Universal Precautions when performing any testing on the Omnia system.
2. 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.
3. 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.
4. Wash hands thoroughly after handling specimens and used cartridge.

EXTERNAL QUALITY CONTROL

External quality control solutions are used to demonstrate that the test cartridge and Qorvo Omnia System are operating properly. The use of external quality controls after installation are recommended where appropriate. Refer to the Quality Control section of each test cartridge's Instructions for Use for specific guidance.

INSTRUMENT INSTALLATION

1. The instrument should be placed in a clean, well-ventilated area. The instrument has a small footprint (10"x9"x5") with minimal space required.
2. At least a 30cm circumference surrounding the instrument should be maintained to allow for enough ventilation.
3. Remove the instrument from its box and place on a level surface.
4. Attach the DC power cable to the back of the instrument. **Use only the Qorvo Omnia system power supply – any other power supply may damage the instrument and void the warranty.**
5. Plug the grounded AC power cable into the provided DC power supply and then into a grounded electrical outlet. Do not plug the instrument into a power-strip or surge protector??
6. To power up the instrument, press the power button on the top of the instrument. It takes approximately five minutes to reach required internal temperature (37°C / 99°F). Once operating temperature is reached, the start-up screen will be visible. It is recommended to leave the instrument on for the period of the working day. To power down the instrument, press the power button again (for a minimum of three seconds).

PRINTER INSTALLATION

The Qorvo Omnia system is compatible with the Dymo[®] LabelWriter[®] 450 printer. The printer is connected to the Qorvo Omnia system via the USB port.

Label type: DYMO LabelWriter Address Printer Labels, 1 1/8" x 3 1/2"

Dymo label part number: 30252

USING THE TOUCH SCREEN

1. Do not rest your hand on the touch screen.
2. Tap screen gently.
3. Never touch the screen with a sharp or abrasive object.

GRAPHIC USER INTERFACE

The graphic interface on the Qorvo Omnia system guides the user through the process of entering the required information for each cartridge, preparing the cartridge and running the test. After the instrument is powered up it takes about five minutes for the required internal temperature to be reached. The start-up screen (Figure 3) will be present until the operating temperature is reached.



Figure 3

Logging in and Main Menu

After initialization, the Log In screen will appear (Figure 4). At the Log In screen, enter your credentials. If you are setting up an instrument for the first time, the username “admin” and user password “admin” (both lower case) credentials will be needed to log in. After login, 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. New user credentials may be created by pressing “Settings” at the Main Menu, and then “Admin”. After creating the user logins, log out and log back in as one of the newly created users.

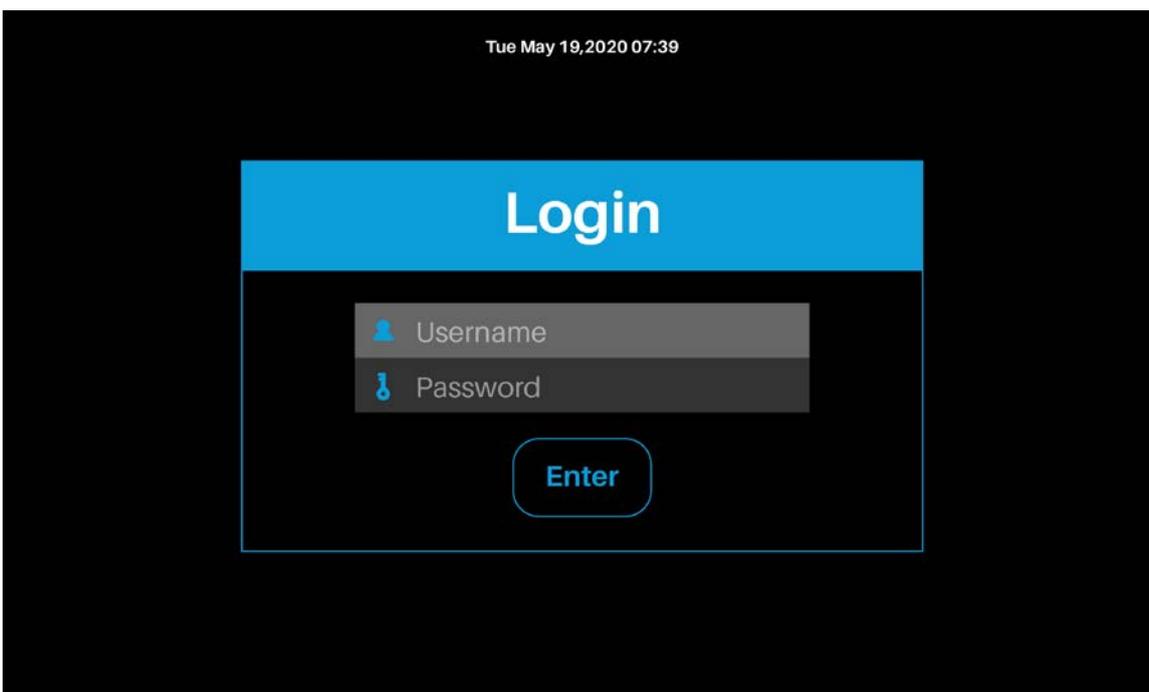


Figure 4

After Log In, the Main Menu will appear (Figure 5). From the Main Menu, the operator may select “Start New Test,” to begin a new diagnostic test; “Settings,” to manage instrument and network settings; or “Log Off.”

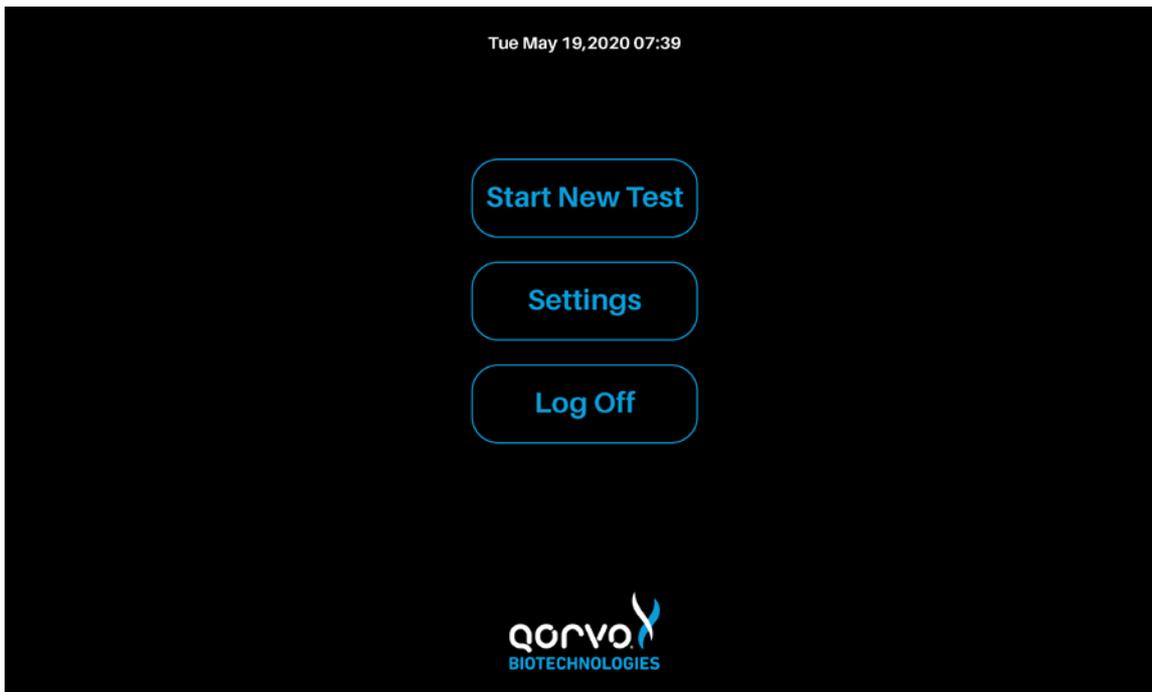


Figure 5

The instrument is now installed, powered up and the user is logged in. Operation of the instrument is described in sections below.

1. Settings – this section describes how to set up the instrument’s System Settings such as Display, Data & Time, Event Log, Printer, Reports and more.
2. Starting a New Test - this section walks the user through cartridge preparation, performing a test and printing the results.
3. Log out.

Settings

By selecting the *Settings* button, the operator will be presented with one of two settings screens, depending on whether the operator is an administrator or a user.

If the operator is an administrator, the following screen will appear (Figure 6a).

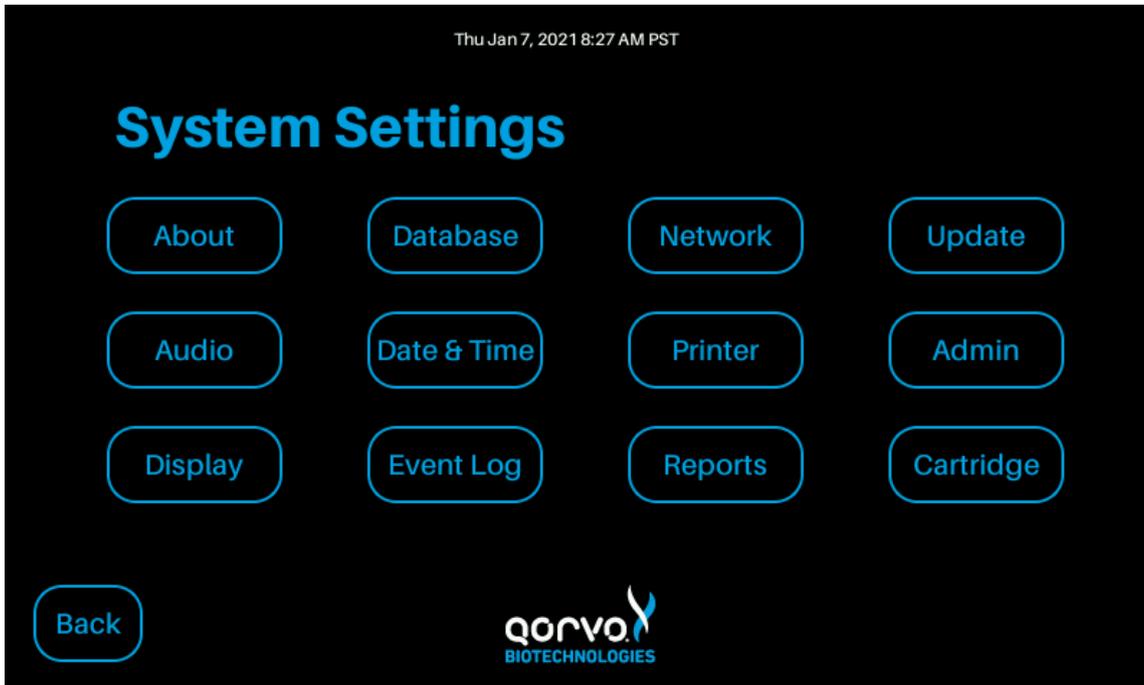


Figure 6a

If the operator is a user without administration credentials, the following screen is visible (see Figure 6b).

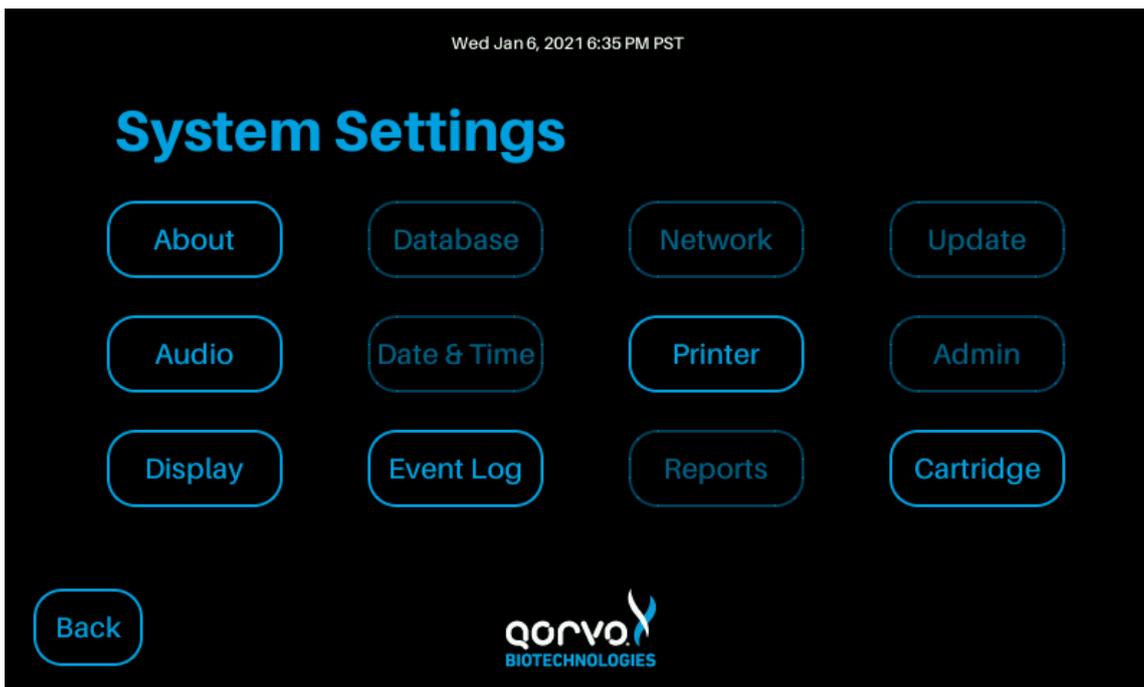


Figure 6b

Settings screens for users without administrator privileges

First, the Settings screen for non-administrator users will be described.

The *About* screen provides information on the instrument and associated software. The total time the system has been on and number of cartridges run by the instrument are also captured (See Figure 7)

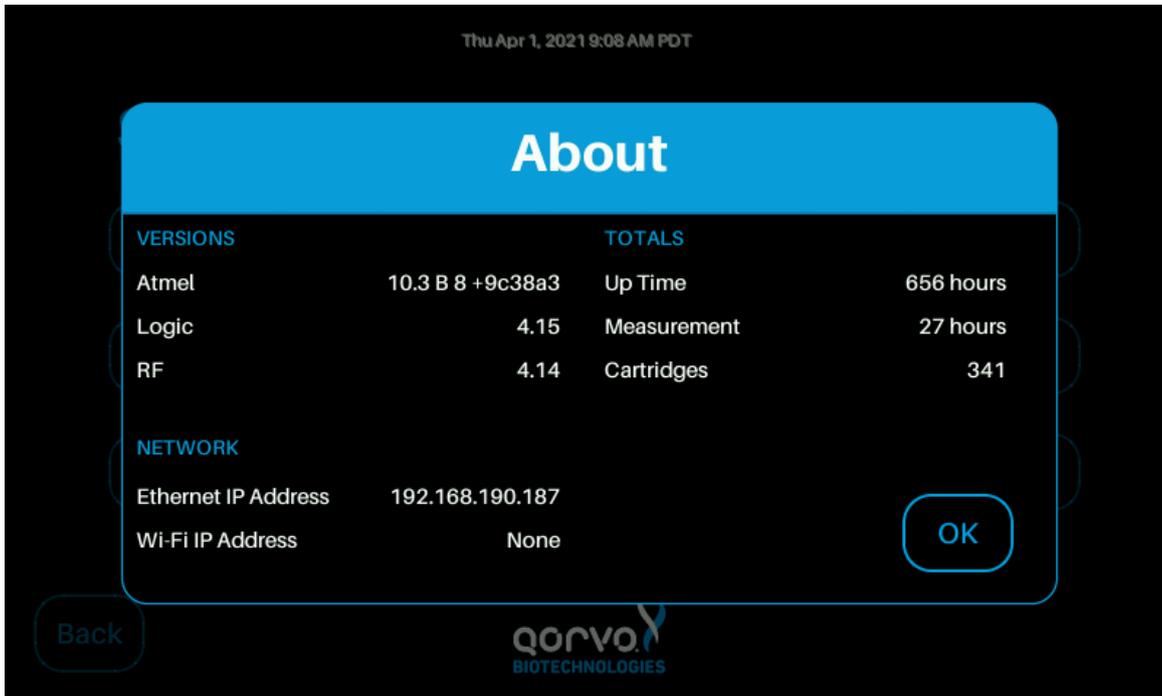


Figure 7

The *Audio* screen permits the user to adjust the tone volume at the completion of each cartridge that is run (see Figure 8).

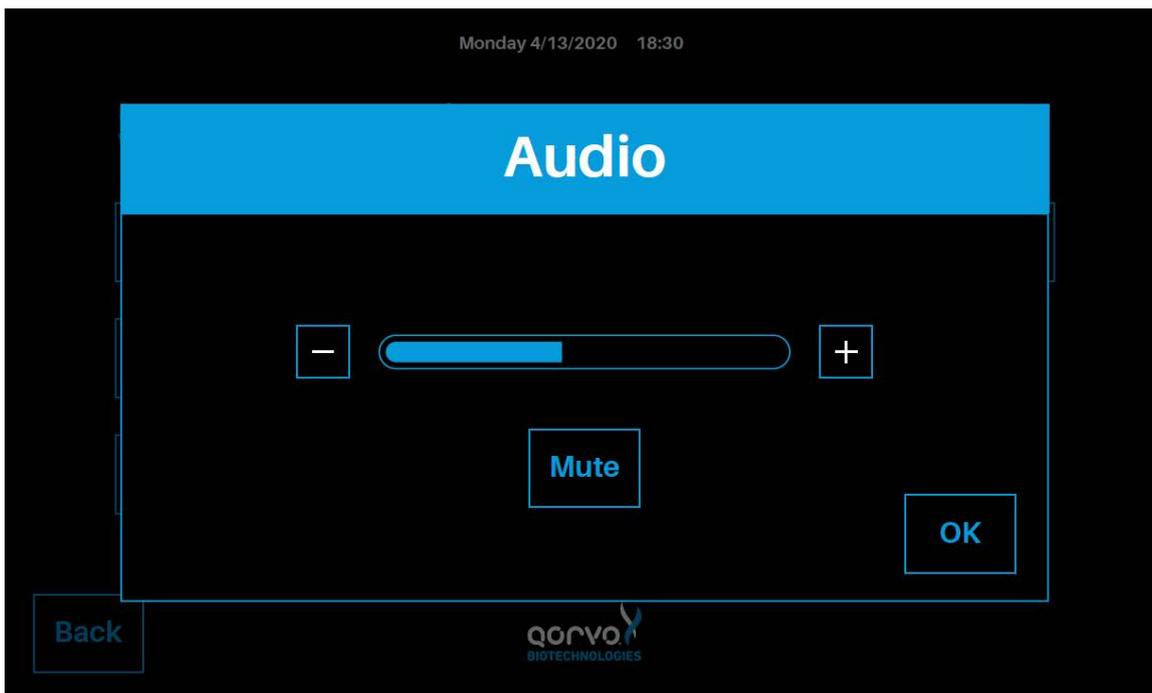


Figure 8

The backlight of the display can be adjusted through the *Display* option (see Figure 9).

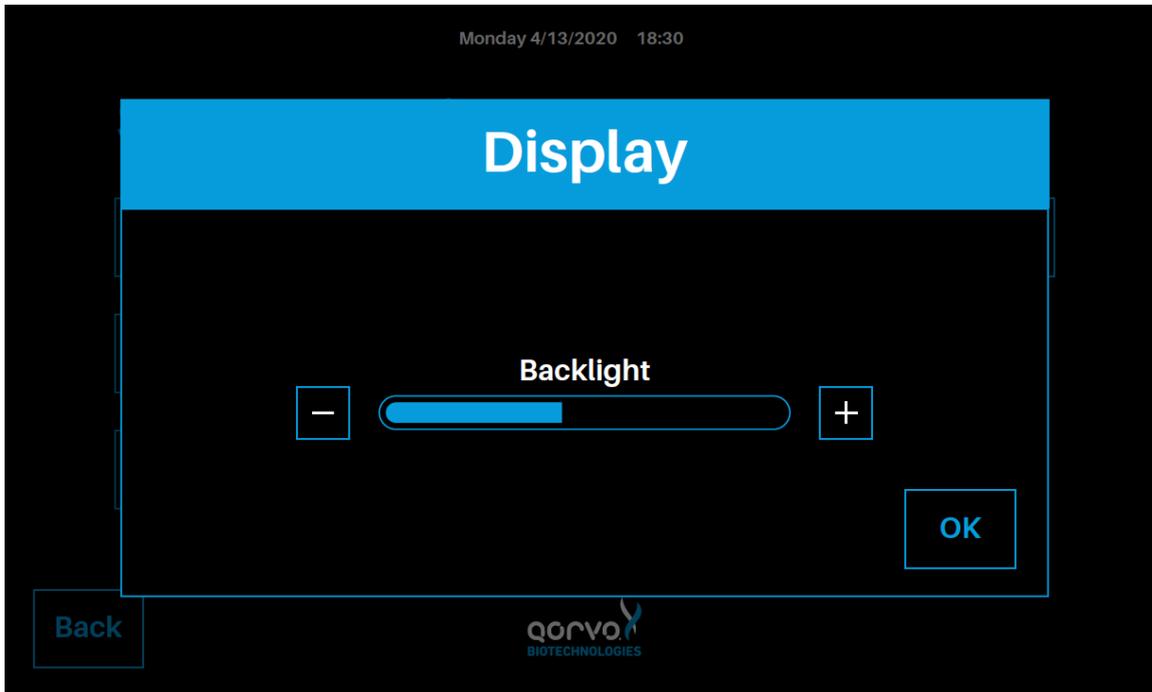


Figure 9

The *Event Log* screen (Figure 10) permits the user to view and download internal information about instrument operation. This may be useful for customer support cases.

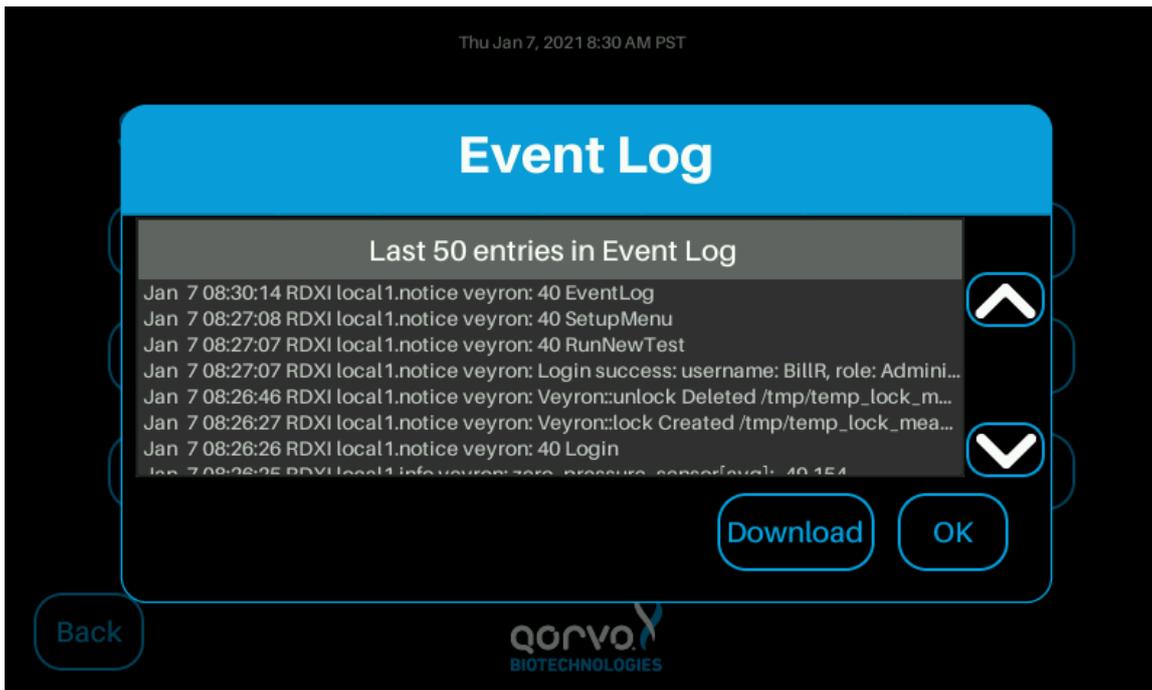


Figure 10

The *Printer* screen permits the user to configure print results automatically (See Figure 11). If “Auto-Print Results” is turned On, test results will be printed automatically following the test completion, provided a printer is connected.

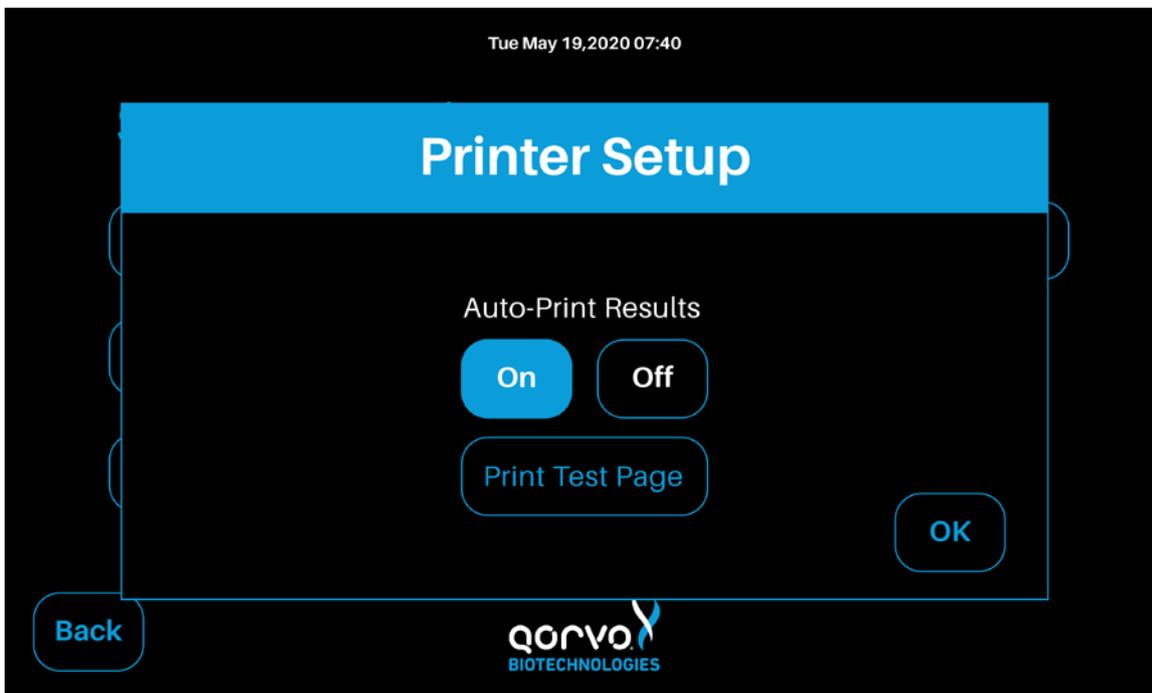


Figure 11

The user can print a test page after setting up the printer (Figure 12).

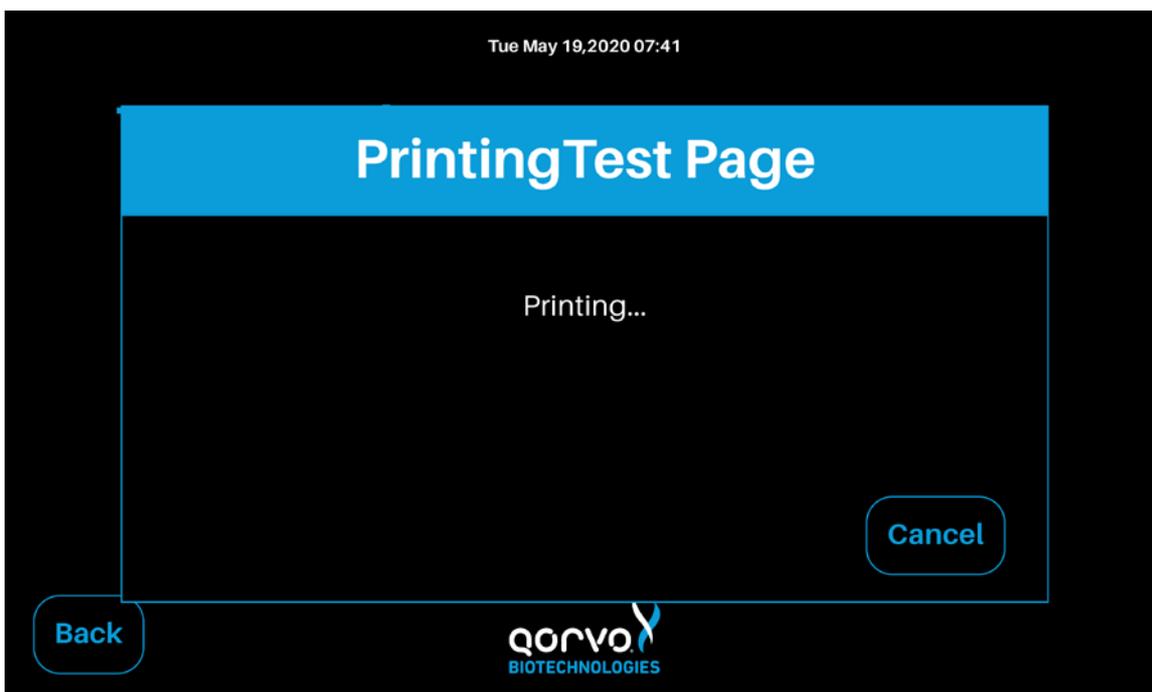


Figure 12

The *Cartridge* screen (Figure 13) allows the user to insert a cartridge and read its test type, lot code, and status. In this way, the user may determine if a cartridge has already been used, without going through the process of setting up a new test.

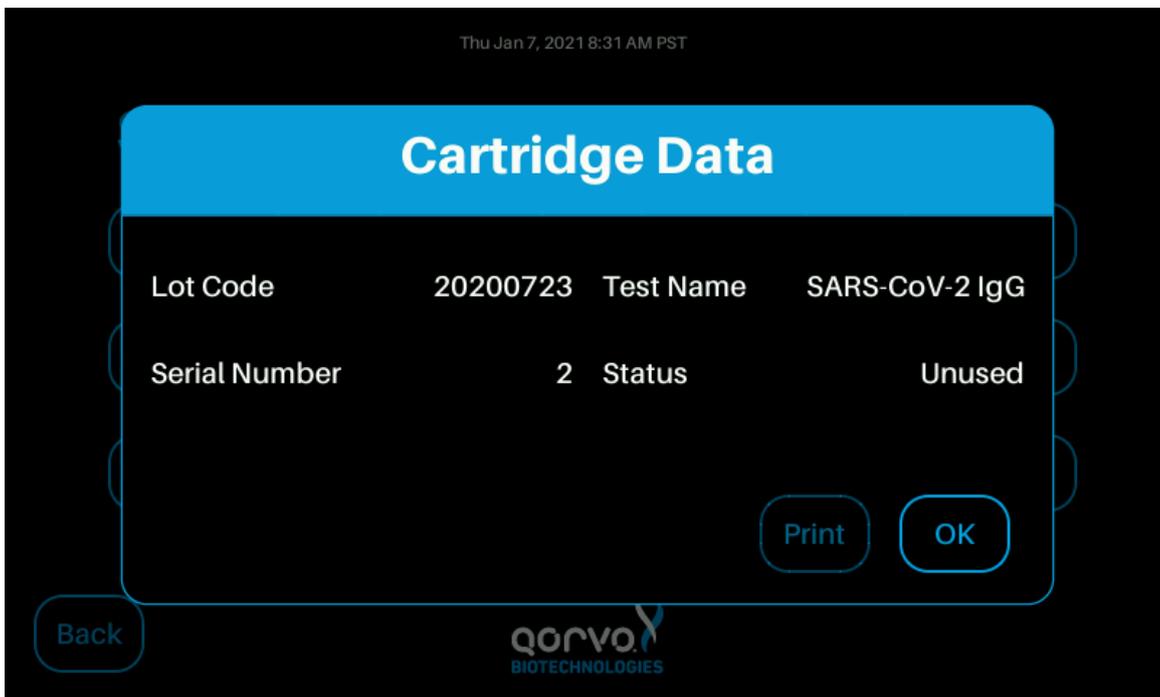


Figure 13

Settings screens for users with administrator privileges

Several other items in the Settings screen permit an operator with administrator credentials to perform certain restricted functions.

The *Date and Time* screen allows the user to set the current date and time (see Figure 14).

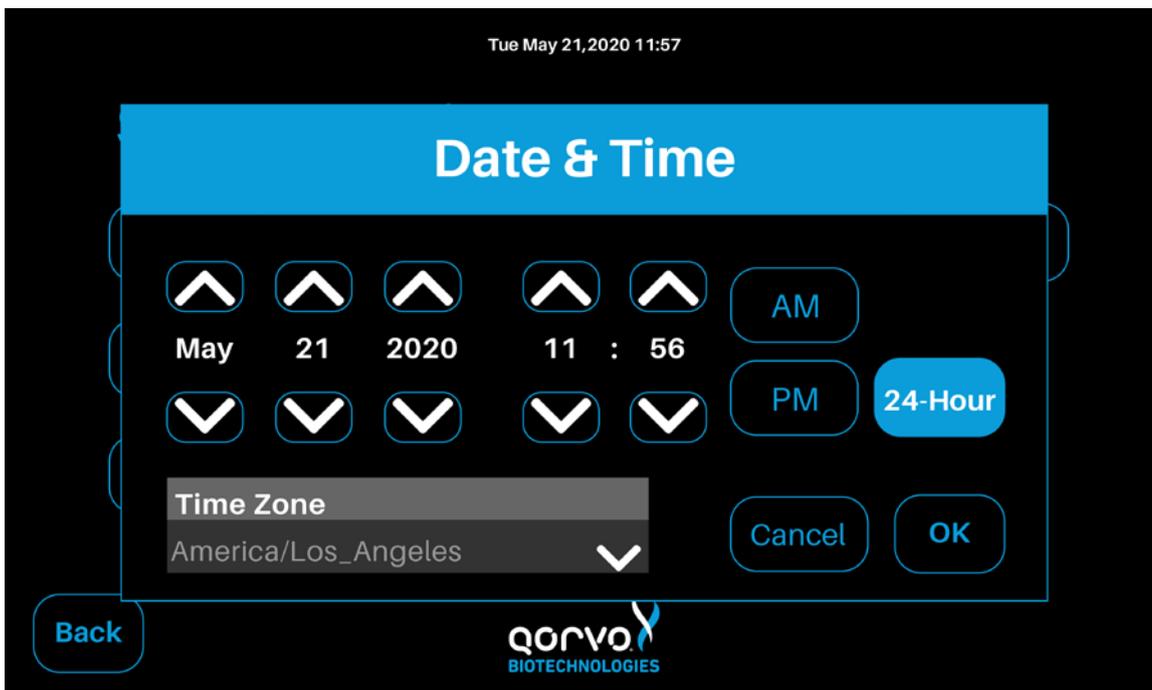


Figure 14

The *Reports* button brings up the Configure Report screen that enables the user to select the items to be included in the printed report (see Figure 15).

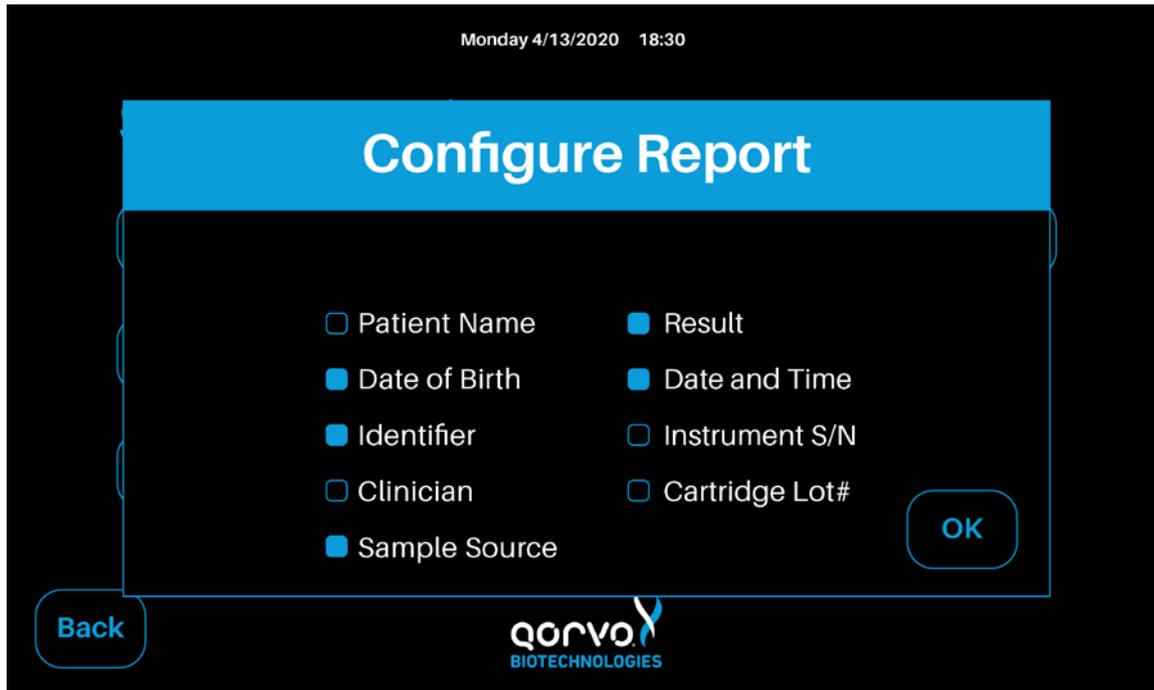


Figure 15

The Qorvo Omnia system may be connected to the internet via Ethernet or Wi-Fi. The Qorvo Omnia system is Wi-Fi enabled. To configure Wi-Fi access, use the *Network* screen. *Changing* the network settings required administrator credentials (see Figure 16).

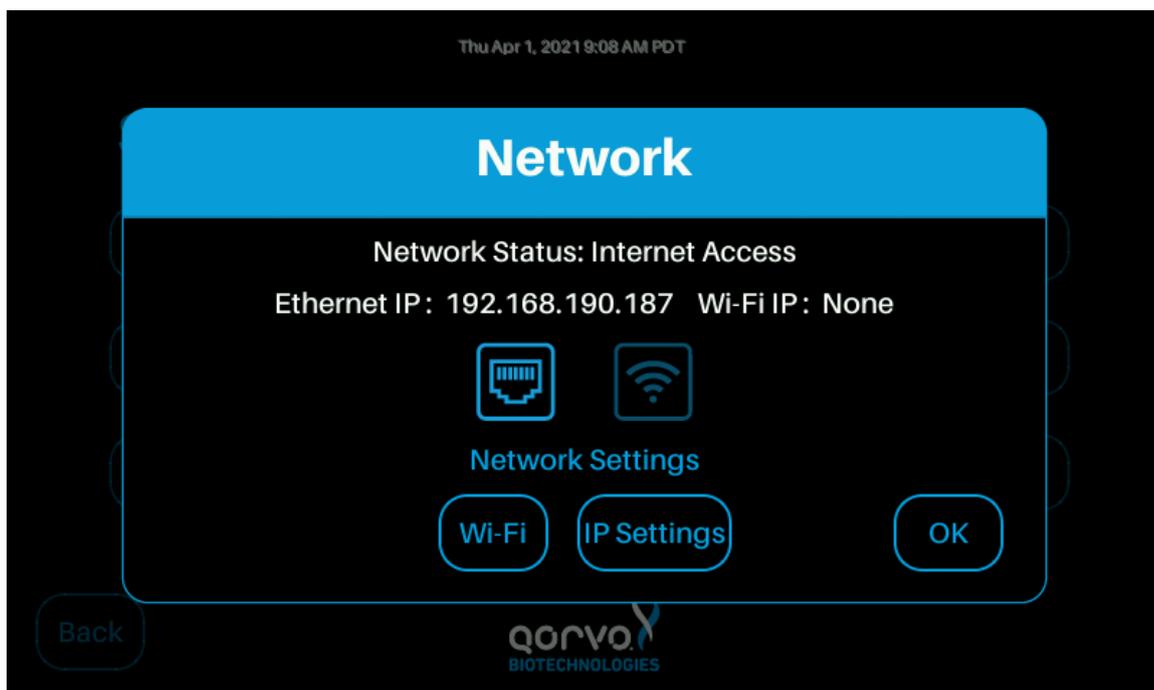


Figure 16

The *Update Button* brings up the Software Update screen (Figure 17) that enables updates of the system software by those with administrator privileges.

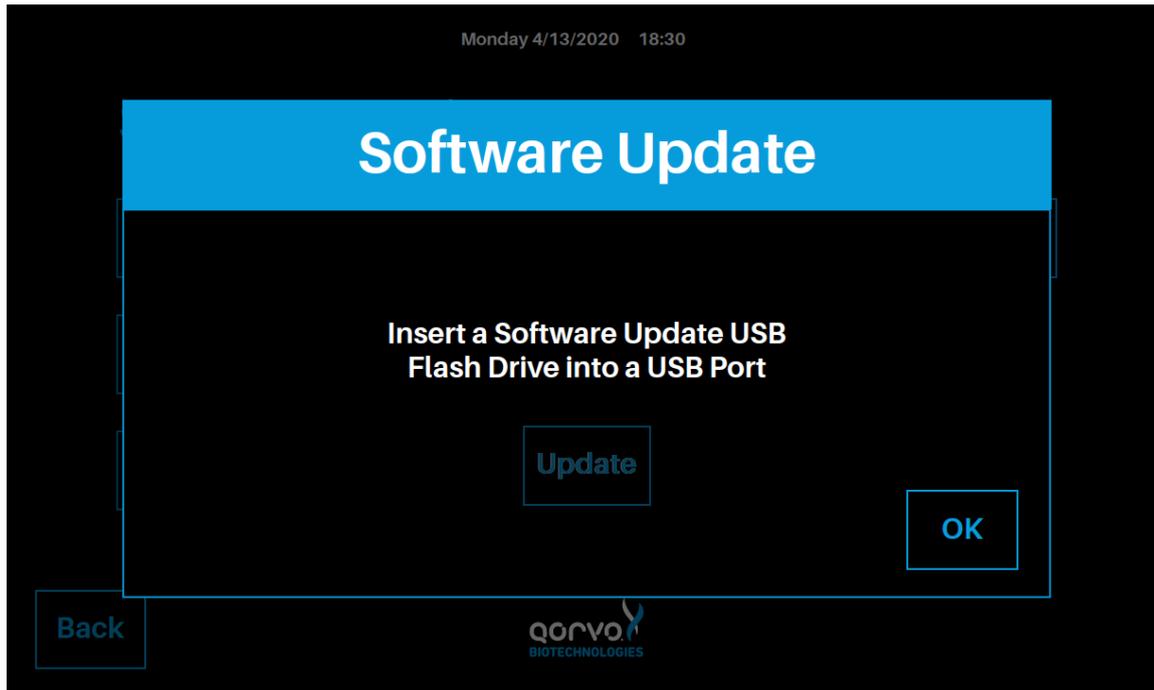


Figure 17

The *Admin* button will bring up the Admin screen (Figure 18), permitting an operator with administrator credentials to add or remove users.

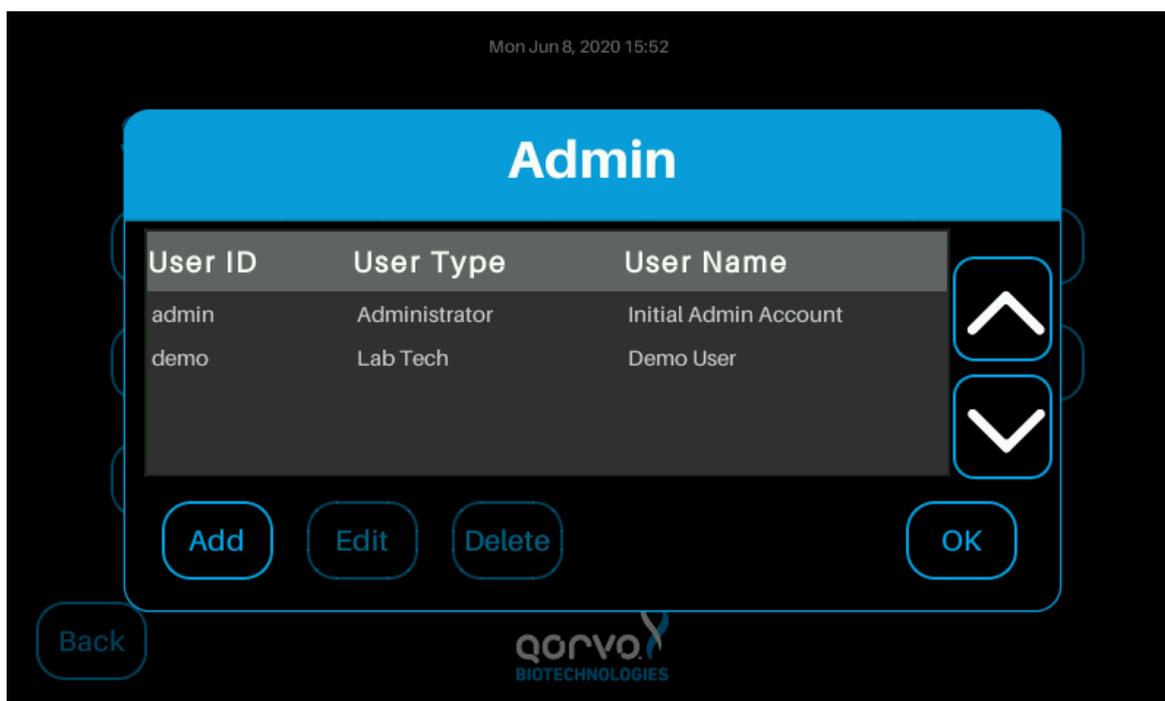


Figure 18

Pressing the “Add” button will bring up the Add/Edit User screen (Figure 19). The controls in this screen may be used to add a new user or remove a user. The User Type may be a user with administrator rights or a normal user.

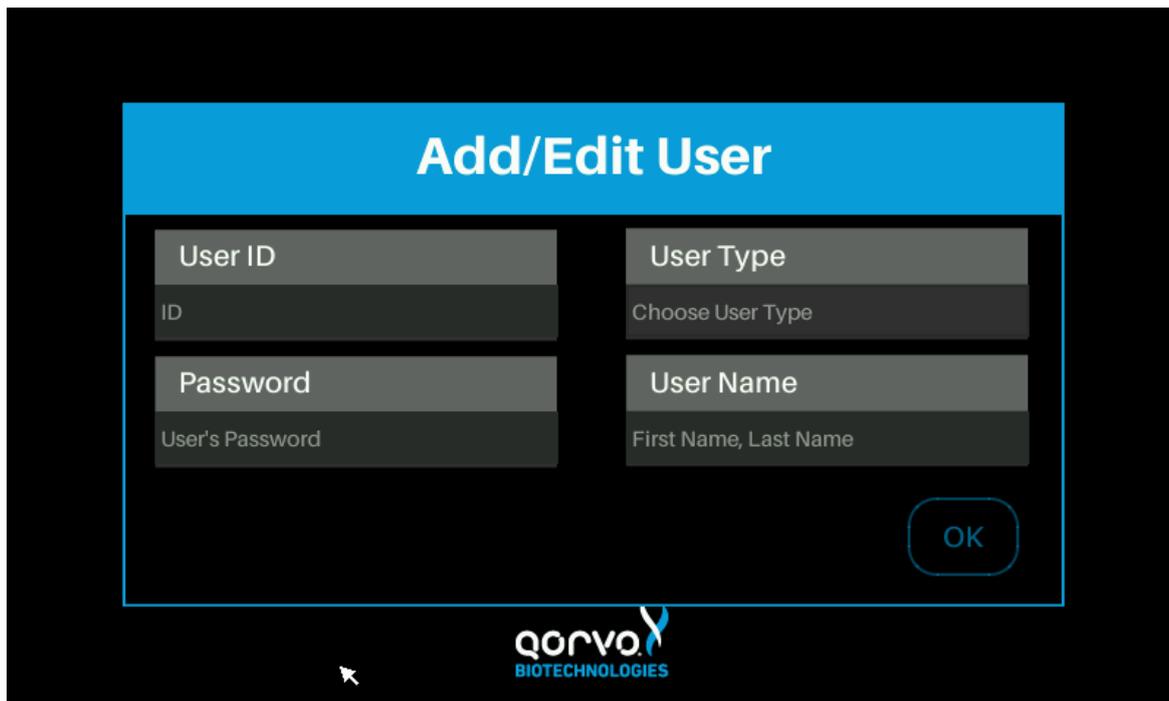


Figure 19

The following image (Figure 20) shows an example after entering the user information.

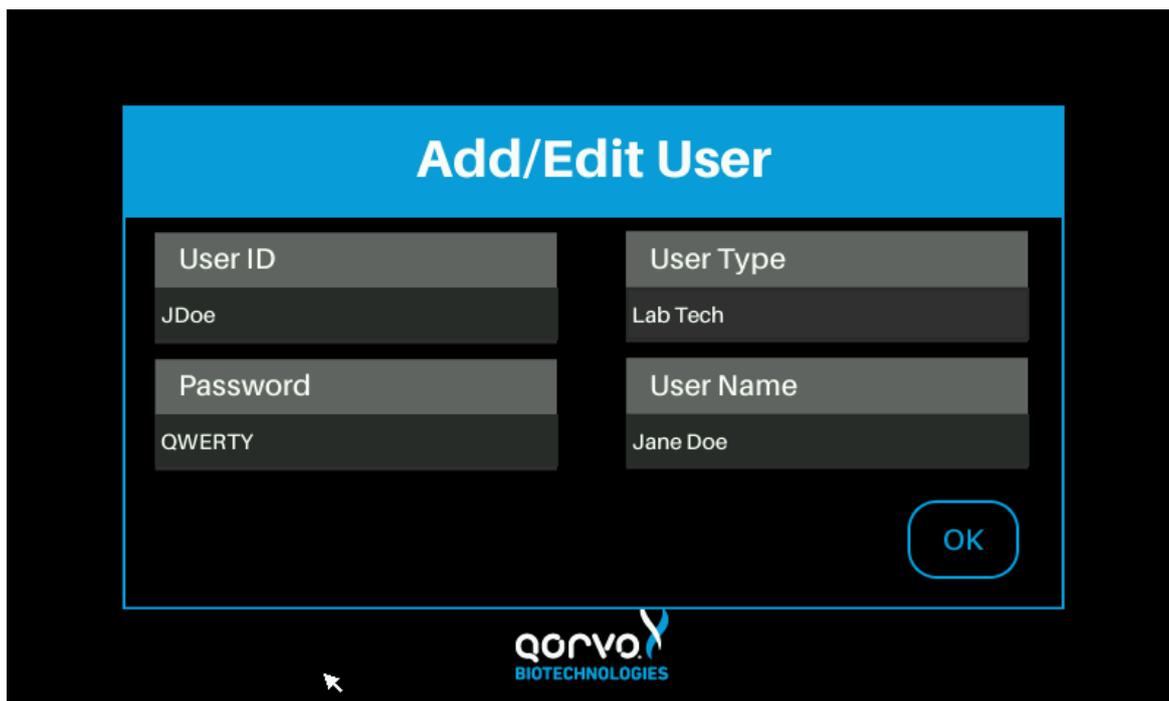


Figure 20

After the user information is entered, press the OK button. The interface will return to the Admin screen (Figure 21) and the new user and user type will appear.

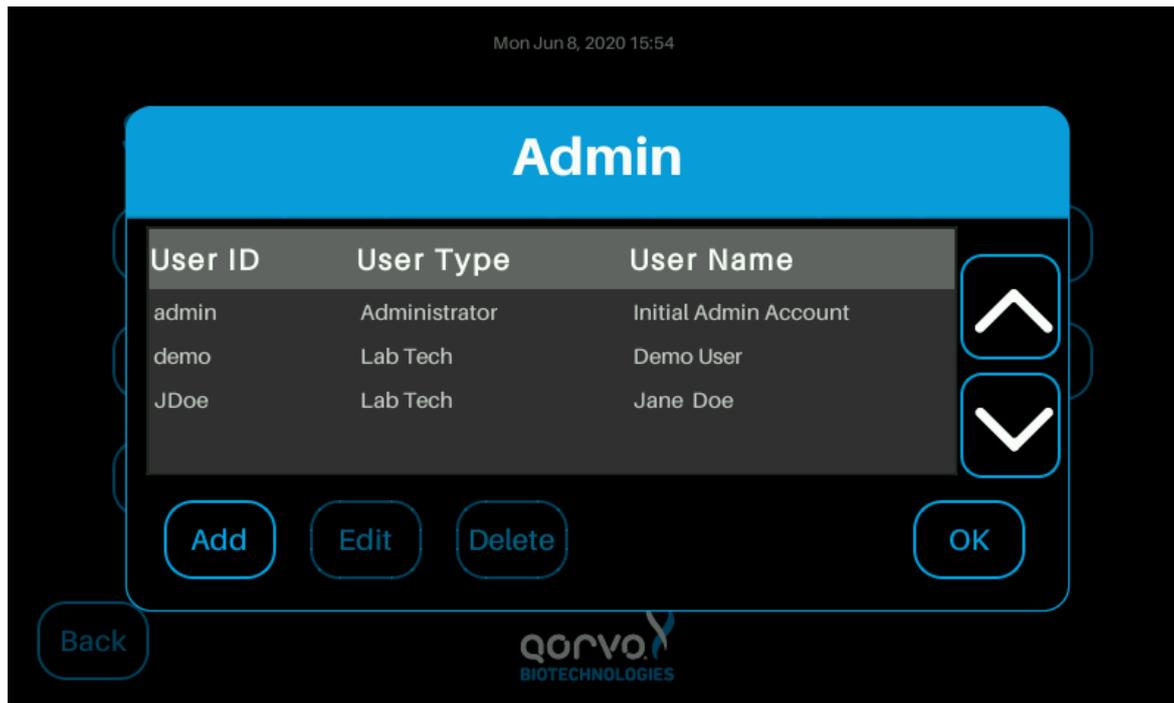


Figure 21

This concludes the description of items selectable from the Settings screen.

STARTING A NEW TEST

From the Main Menu press "Start New Test." Patient Information screen appears, and the following patient information associated with the sample must be entered (Figure 22a):

1. Patient Name
2. Patient ID
3. Date of Birth
4. Clinician
5. Gender

Mon Jun 8, 2020 15:41

Patient Information

Patient Name First Name, M.I., Last	Patient ID ID
Date of Birth MM/DD/YYYY	Clinician First Name, Last Name
Gender Choose Gender	

Back  Next

Figure 22a

Figure 22b shows the Patient Information screen after the fields have been filled in with example patient information.

Mon Jun 8, 2020 15:42

Patient Information

Patient Name John Jones	Patient ID 00000-00
Date of Birth 05/10/2016	Clinician Dr. Smith
Gender Male	

Back  Next

Figure 22b

RUNNING A TEST

Note: The workflow between Qorvo Biotechnologies Omnia cartridges is similar. More detailed instructions for individual tests may be found in the Instructions for Use for each test.

Note: Cartridges are single-use, assay-specific with the assay name clearly marked on the cartridge pouch label and the cartridge label. The cartridge pouch should not be opened unless it will be used in a test. The following steps must be performed to ensure accurate sample analysis: confirm that cartridge has not expired by reviewing the Expiration Date on the pouch label.

The following instructions will guide you in how to prepare the cartridge and run the test.

1. From the Patient Information screen, press “Next.”
2. The Prepare Cartridge screen appears (Figure 23).

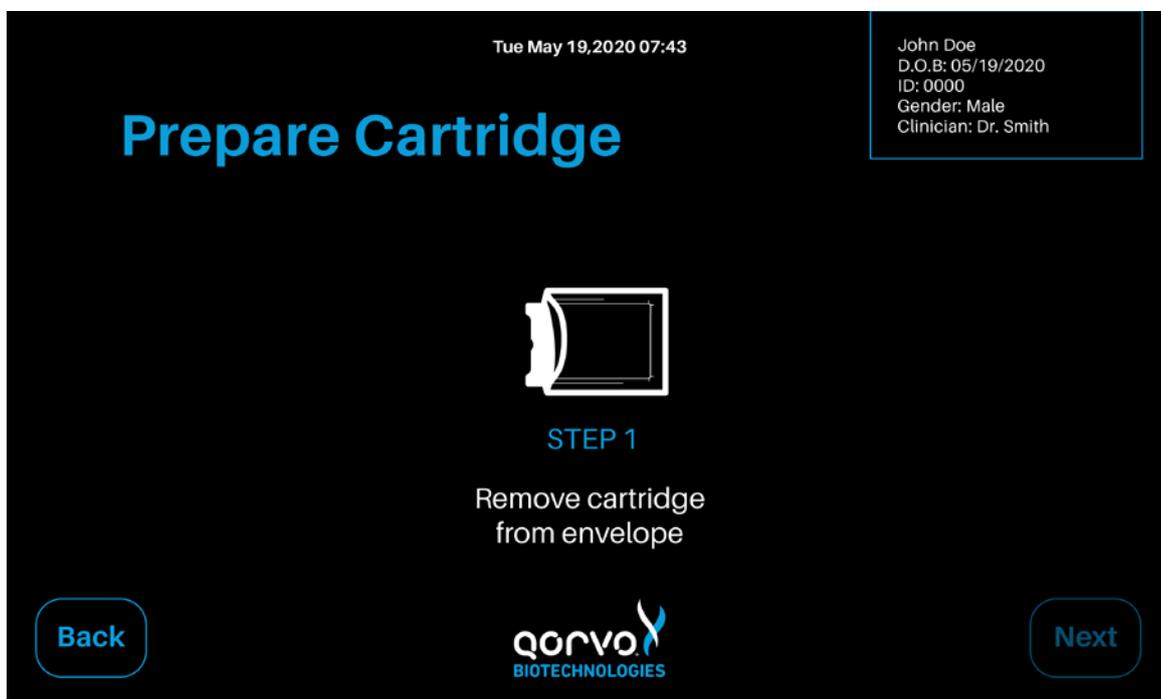


Figure 23

3. Remove cartridge from pouch (pouch also contains a humidity indicator and a desiccant pouch that can be disposed of as normal waste).
4. Place cartridge on flat surface.
5. Press “Next” when ready to proceed. The screen in Figure 24 will appear.

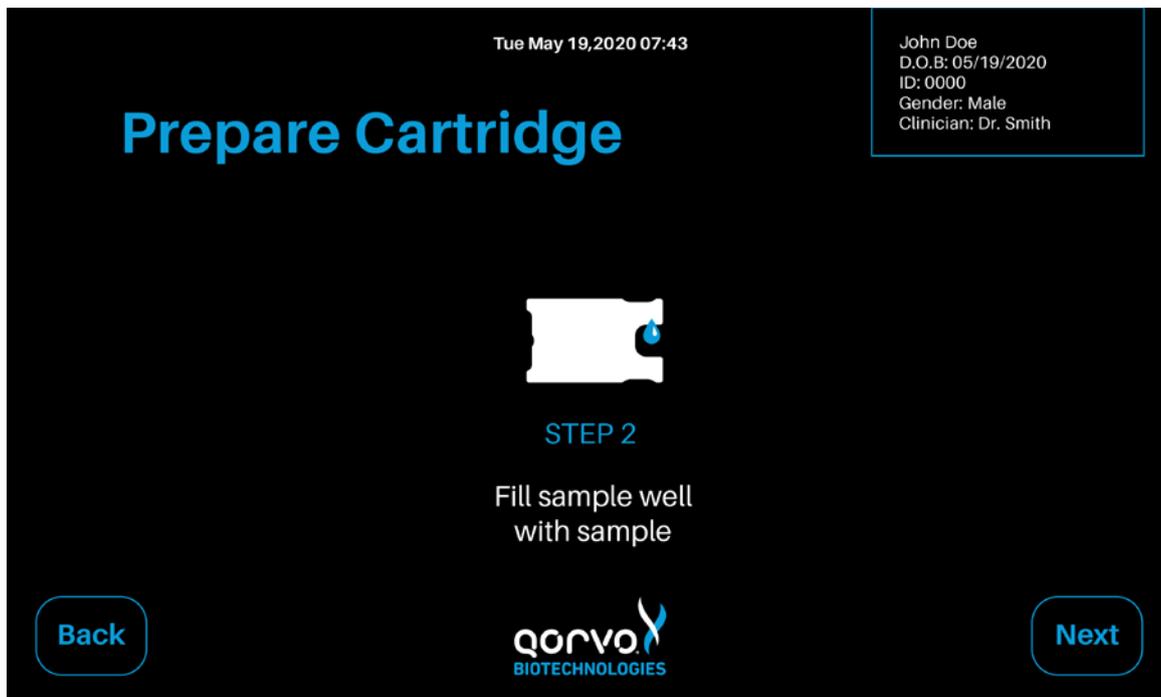


Figure 24

6. Follow IFU instructions to dispense sample into sample port. Each Qorvo Omnia test kit provides the necessary ancillary equipment to safely and accurately load the specimen.
7. Ensure all sample has been absorbed into the sample port and the sample has reached the “fill” line. After the cartridge has been prepared, press “Next” Figure 25.

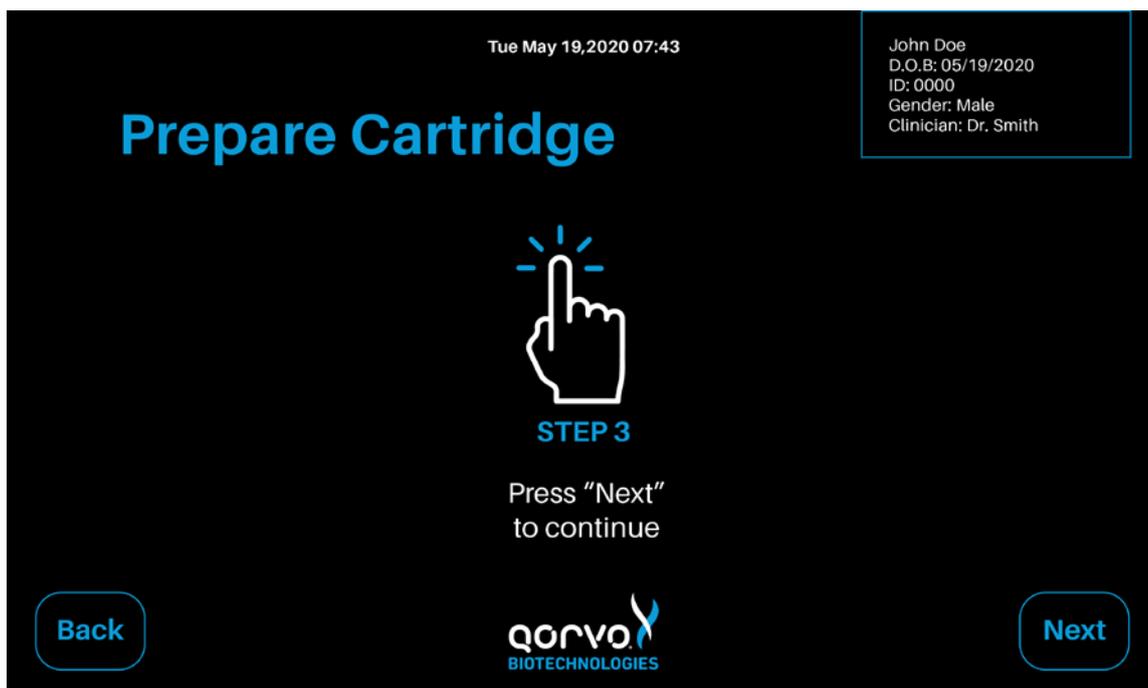


Figure 25

8. Place the cartridge into instrument by holding the sample-port end with the cartridge label facing up and following the arrow-indicated insert direction displayed on the cartridge label (Figure 26). Gently push the cartridge into the Cartridge Receiver until the instrument accepts and draws in the cartridge.

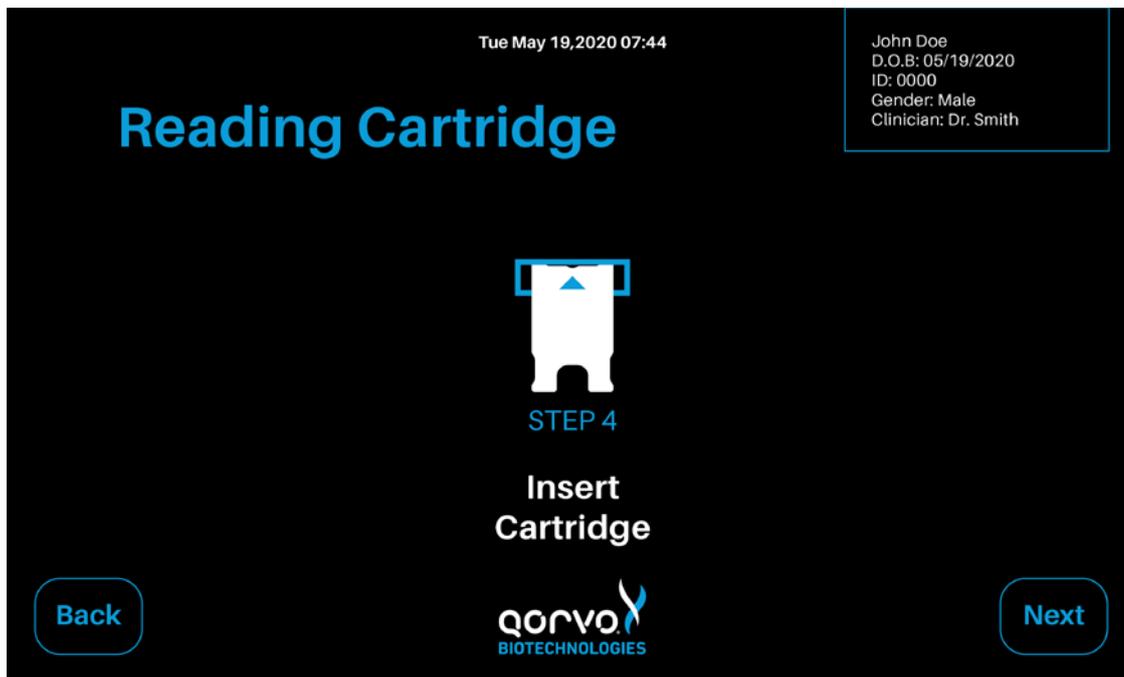


Figure 26

- Each cartridge contains a radio-frequency identification (RFID) tag that communicates with the instrument as to the cartridge type. The RFID tag informs the instrument which assay to run and informs the user which sample types are compatible with the selected cartridge (Figure 27).

Note: The assay information in Figure 27 is an example only. Refer to Qorvo Omnia test cartridge Instructions for Use for assay-specific information.

Note: If the cartridge has previously been used, the instrument will recognize that the cartridge is invalid and the cartridge will be ejected. The interface will return to the Patient Information Screen.

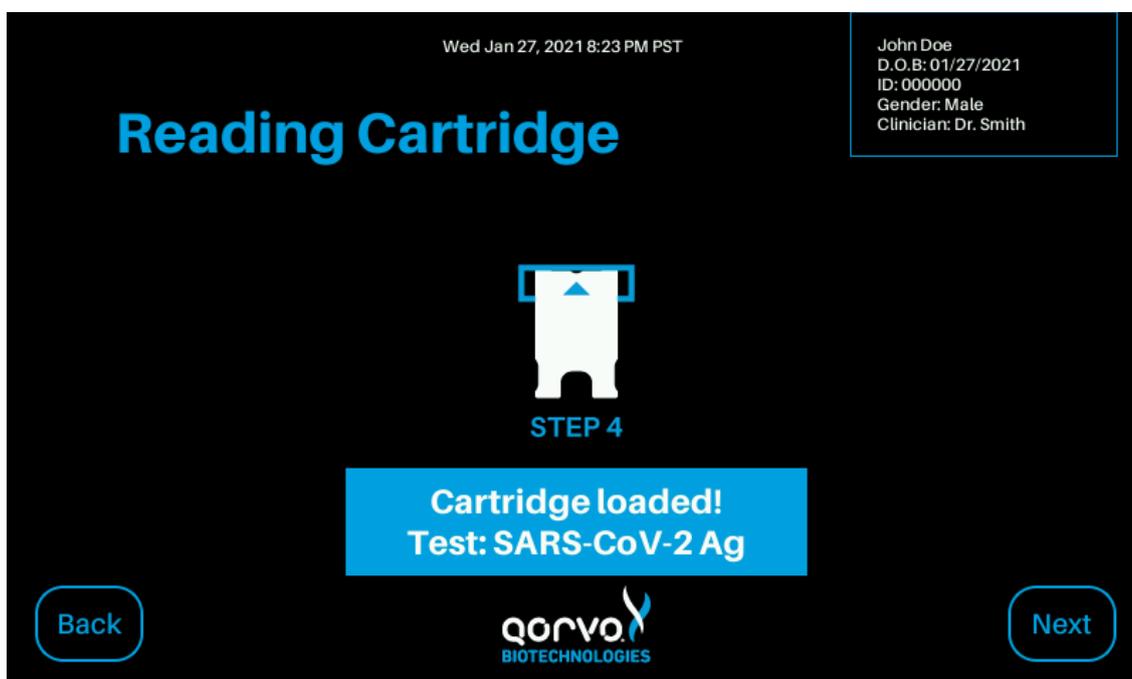


Figure 27

- Once the cartridge is read and identified, the user may be required to select the sample type as shown in Figure 28. Press "Select Source" or the down arrow to select the sample type from the pull-down display for the assay. For assays with one sample type this screen will not display?

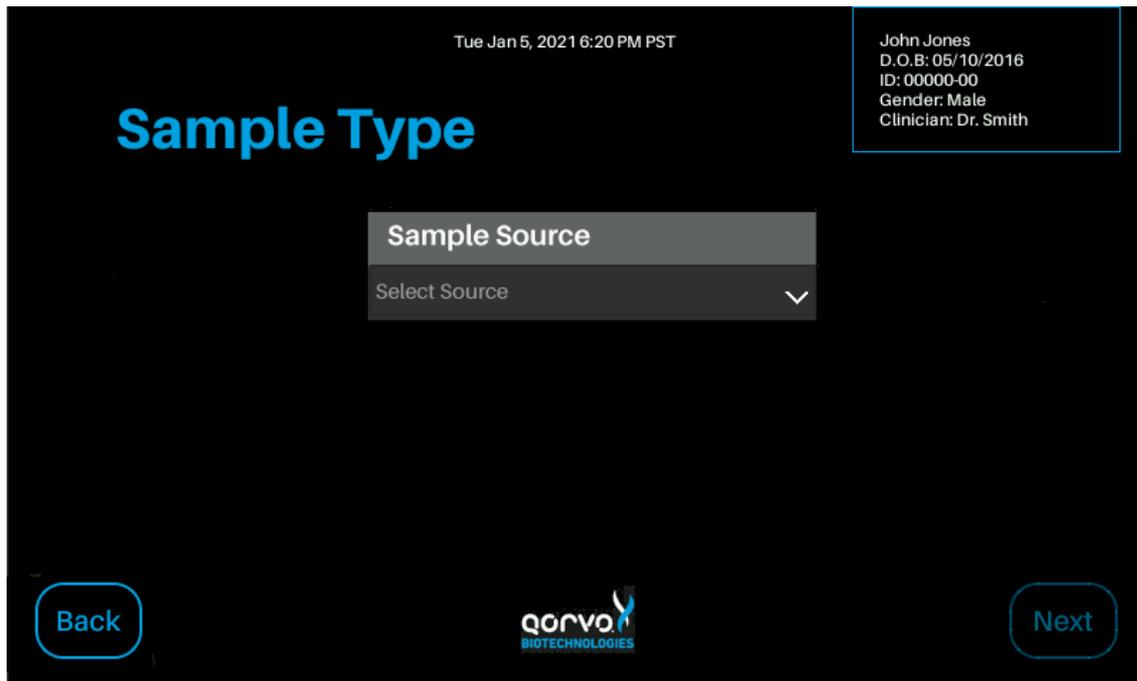


Figure 28

- Once the sample type is selected, press "Next".
- The user is then required to confirm and run the test (Figure 29).

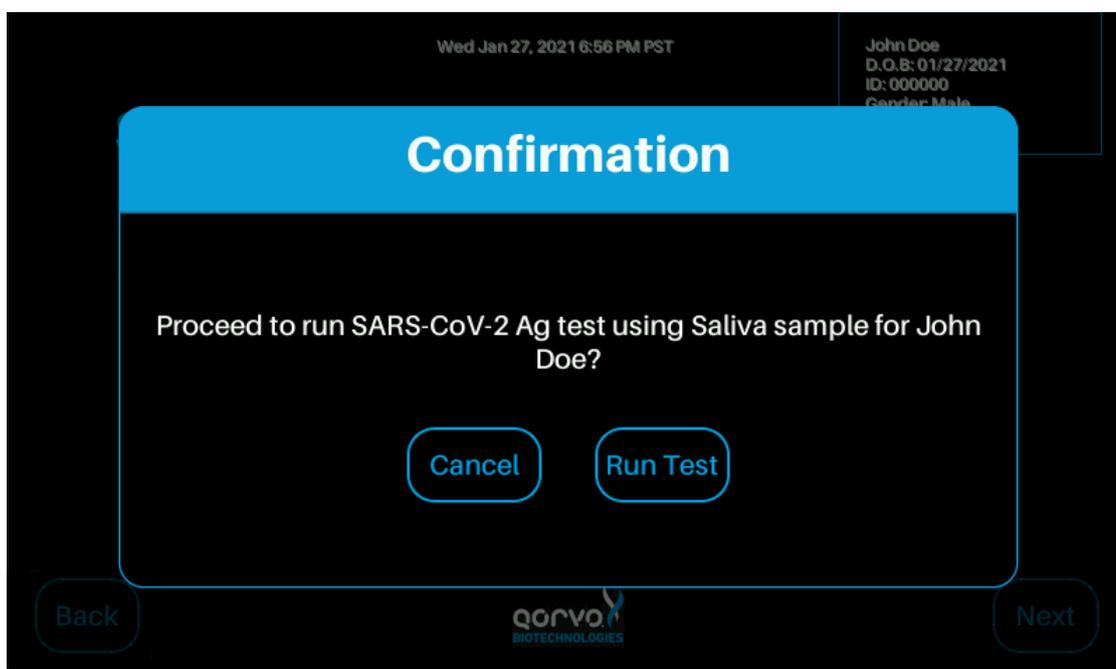


Figure 29

The screen will show the progress of the testing (Figure 30). After the test is complete, the cartridge will be ejected from the instrument. Dispose used cartridge and pipette as biological waste.

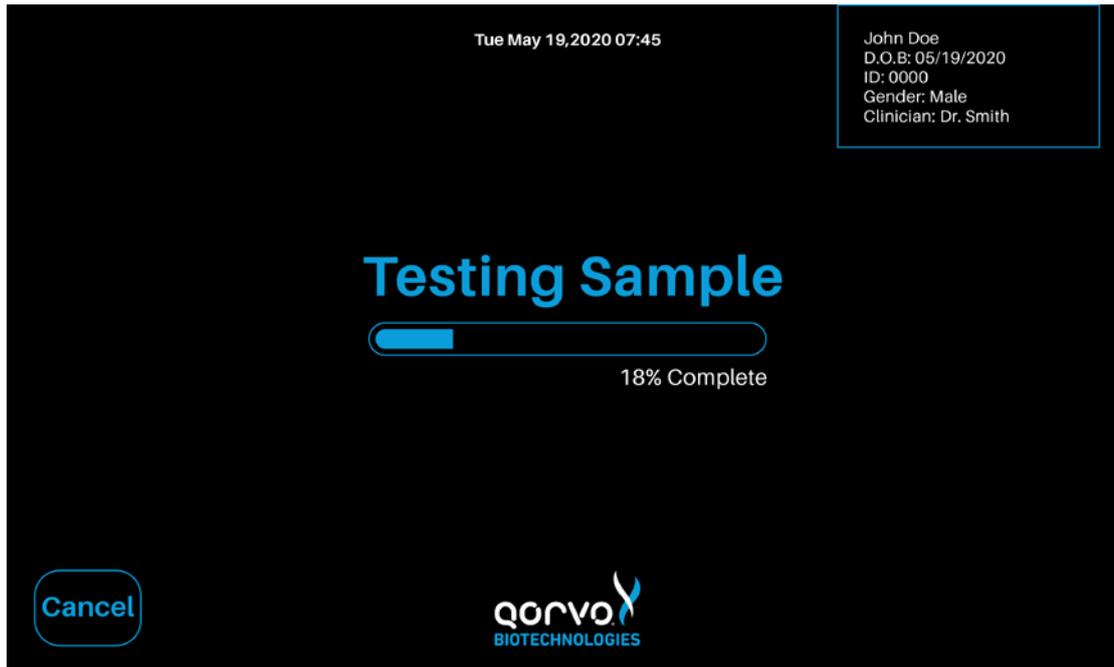


Figure 30

Test results will be displayed immediately after cartridge is ejected. Figure 31 is an example only. See Omnia system individual Instructions for Use for information on interpretation of results.

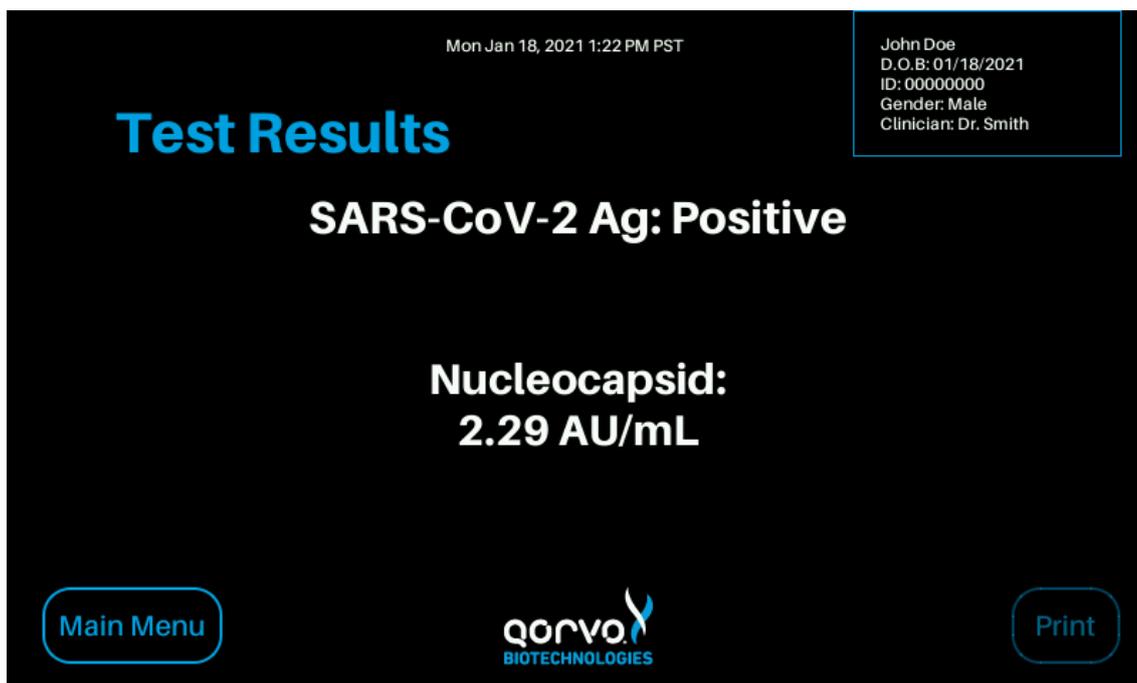


Figure 31

If automatic printing option is selected in Printer Setup, test results will be sent to the printer automatically. If automatic printing option is turned off, the user may press the Print button to send the results to the printer. While printing, a printing message will momentarily pop up (Figure 32).

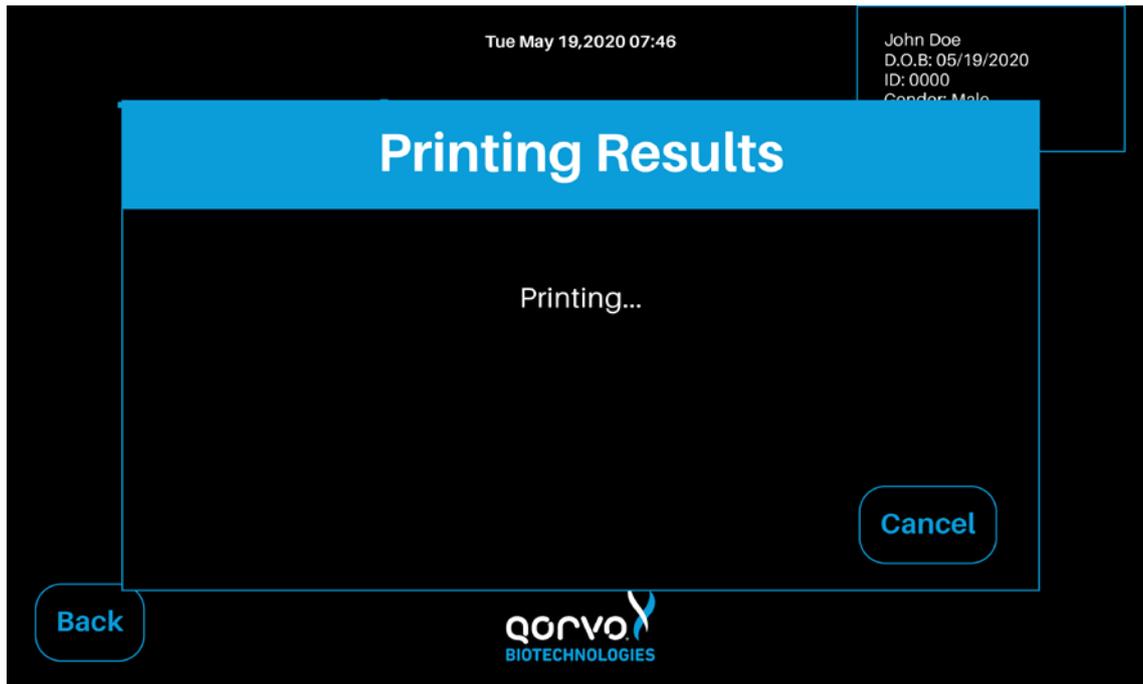


Figure 32

To Power Off, press and hold the Power button for 5 seconds (Figure 33).

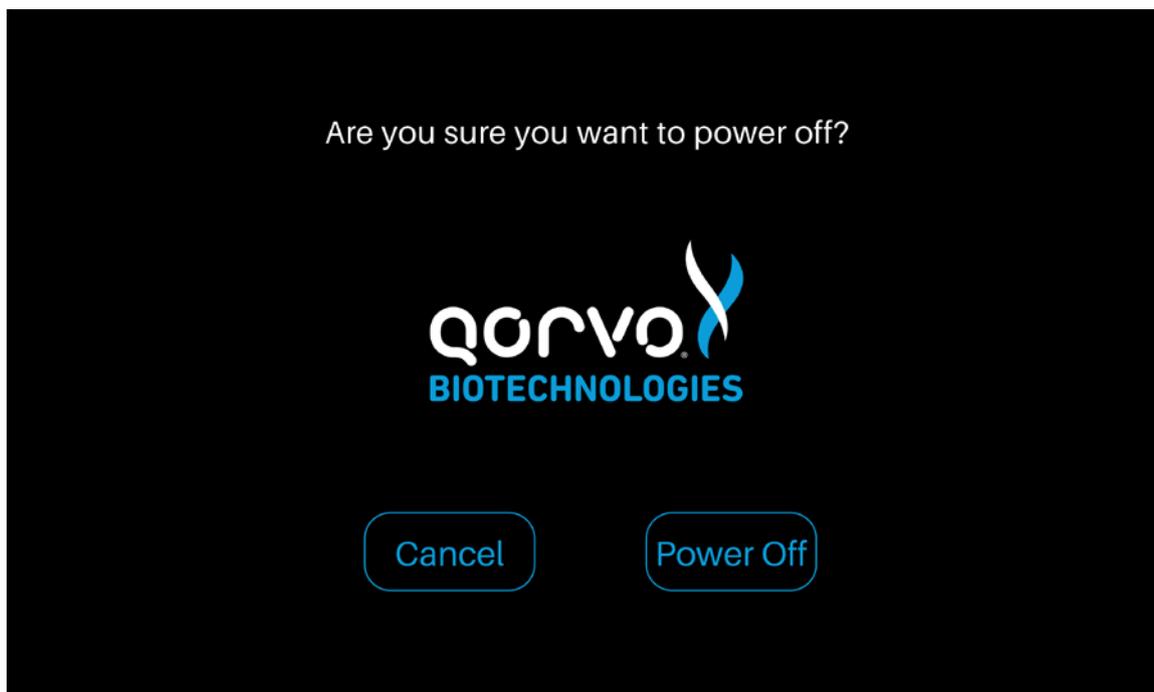


Figure 33

PERIODIC MAINTENANCE AND SERVICE

The instrument requires minimal maintenance.

CLEANING THE OUTER CASE

Do not spray or pour any detergents or solutions directly onto the outer case. Clean the outer case with a soft cloth, dampened with a mild, non-abrasive detergent or cleaning solution such as 10% bleach solution or a 30% isopropyl alcohol solution.

CLEANING THE TOUCH SCREEN

Clean the screen periodically using a soft, lint-free cloth dampened with glass-cleaning fluid.

REPLACING THE AIR FILTER

The air filter should be replaced monthly regardless of how often the instrument is used. As described below (Figure 34), the back of the instrument contains a fan filter (part number 151215) and retainer (part number 150615).

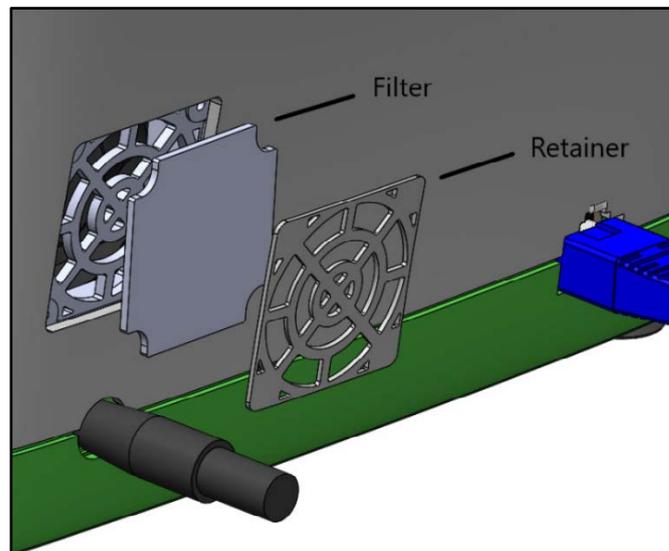


Figure 34

To service the filter, start by turning off the instrument and unplugging the DC power cable on the rear of the instrument. Remove the filter retainer with a flat-head screwdriver, taking care to ensure the retainer can be replaced in the same orientation. An up arrow is molded into the plastic of the retainer. After setting the retainer aside, use the same flathead screwdriver to remove the used filter. Discard the used filter in the trash and insert a new filter. The filter is symmetrical in shape and has no front or back. Once the new filter is in place, replace the retainer. Plug in the DC power cable into the receptacle at the rear of the instrument.

RETURNING THE INSTRUMENT FOR SERVICE

For support questions or if the instrument needs to be returned for service, please contact Qorvo Biotechnologies Customer Support by:

E-mail: OmniaCOVID19Test@qorvo.com

Toll-Free: 1.833.384.1522

OPERATOR MANUAL

INSTRUMENT DISPOSAL

When disposing of the instrument, please perform appropriate cleaning, and handle as industrial waste in accordance with local and federal regulations.

INSTRUMENT DIMENSIONS

1. Width: 10"
2. Depth: 9"
3. Height: 5"
4. Weight: approximately 7 lbs

POWER SUPPLY

1. SL Power Electronics, ME40A1803F01
2. Output rated: 18.0 volt, 2.22 amps, 40 watts
3. Input rated: voltage 100-240VAC, $\pm 10\%$, 47-63Hz, 1Ø
4. Current 115VAC: 1.2A, 230VAC: 01.6A

INPUT/OUTPUT CONNECTIONS

1. USB, RJ-45 and power

OPERATING CONDITIONS

1. Altitude: $\leq 10,000$ ft above sea level
2. Temperature: 15-30°C (59-80°F)
3. Humidity: 30-80%, non-condensing

SHIPPING/STORAGE CONDITIONS

1. Shipping temperature: -29-60°C (-20-140°F)
2. Storage temperature: 0-45°C (32-113°F)

PROBLEM SOLVING

Wireless Networks

The Qorvo Omnia system supports Wi-Fi network connectivity using the private network WPS2-PSK protocol. We have made every effort to establish compatibility with this protocol. However, due to the wide range of wireless routers available, if you have difficulty connecting to a wireless network, we offer the following suggestions to improve connectivity.

Note: Access to the Network settings via the main Settings Menu requires a login with administrator privileges.

1. Check network status

- a. Access the Network settings via the main Settings menu
- b. Is an address shown in the IP Address field? If yes, continue to step 1(c), otherwise proceed to step 3 if you are using a wired connection or step 4 if using a wireless connection.
- c. Does the network status say Connected? If yes, all should be good, otherwise, continue to step 2.

2. IP address assigned, but no Internet connection

- a. From a PC on the same network as the instrument, use the ping command to see if instrument can be reached. If the ping command indicates no response, contact your local IT department for assistance, otherwise continue to step 2(b).
- b. From a PDC on the same network, open a web browser and got to www.example.com. Do you see the "Example Domain" message? If yes, continue to step 2(c), otherwise, access to that web site may be blocked. Contact your local IT department for assistance.
- c. Does the local network require a proxy server for Internet access? If yes, contact your local IT support team and ask for a workaround, as the Omnia instrument does not support use of a proxy service, otherwise continue to step 2(d).
- d. Does the gateway router enforce MAC address filtering? If so, contact your local IT department and provide them with the MAC addresses shown on the label on the bottom of the instrument. (There will be two of them: one for the wired interface and one for the Wi-Fi interface.) If this does not solve the problem, contact your local IT department for assistance.
- e. End of troubleshooting section.

3. No IP address assigned – wired connection

- a. From the Network settings, press the Wi-Fi button and verify Wi-Fi is Off.
- b. From the Network settings, press the IP Settings button and verify Automatic IP is On.
- c. Examine the Ethernet connector on the rear of the instrument. Is the yellow LED on? If yes, continue with step 3(d), otherwise contact Qorvo Customer Support.
- d. Is the green LED on the Ethernet connector also on? If yes, verify the switch or hub the instrument is connected to is in turn connected to the DHCP server. Verify with your local IT department that a DHCP server is available on the network, or if not obtain a fixed IP address from them and use their IP Settings menu to enter the information. If the green LED is not on, verify the Ethernet cable is solidly plugged into the instrument on one end and the switch/hub on the other end. Check/replace the Ethernet cable.

4. No IP address assigned – wireless connection

- a. From the Network settings, press the Wi-Fi button and verify Wi-Fi is On.
- b. Verify you have selected the proper network and entered the correct passphrase.
- c. Turn Wi-Fi Off then back on. Reselect the desired wireless network and enter the passphrase. Confirm the Selected Network entry displays the network you selected.
- d. Return to the main Network menu to see if an IP address was assigned. If not, try connecting to the same Wi-Fi network with another device, such as a mobile phone or tablet/laptop. If the other device connects but the instrument still does not, contact your local IT department or Qorvo Technical Support.

Instrument Error Codes

These are error codes pertaining to the instrument and are not specific to individual tests.

Error Code	Error Name	Error Description
0050	Instrument is Tilted	The instrument cannot be tilted during measurement. Ensure the instrument is within 30 degrees of level. Repeat the test with a new cartridge. Contact Qorvo Technical Support if the error persists.
0060	Instrument Temperature is Too Hot	The instrument is too hot to perform a measurement. Check that the fan filter is clean and not blocked. Try placing the instrument in a cooler location. Repeat the test with a new cartridge. Contact Qorvo Technical Support if the error persists.
0100	Pressure Error	An error is detected with the Pump Head pressure. Try repeating the test with a new cartridge. Contact Qorvo Technical Support if the error persists.
0110	Thermal Error	An error is detected with an over or under temperature condition. Check that the fan filter is clean and not blocked. Ensure the instrument is in a location where the ambient temperature is within specified operating conditions. Repeat the test with a new cartridge. Contact Qorvo Technical Support if the error persists.
0120	Cartridge Error	The cartridge is not fully engaged. Try repeating the test with a new cartridge. Contact Qorvo Technical Support if the error persists.
0140	BAW Hardware Error	The BAW sensor is not functioning correctly. Try powering off the instrument and repeating the test with

Error Code	Error Name	Error Description
		new cartridge. Contact Qorvo Technical Support if the error persists.
0150	Software Corrupted	The instrument has detected that the software has unexpectedly changed. This may be due to a hardware error. Measurements cannot be performed. Turn the instrument power off and back on. Contact Qorvo Technical Support if the error persists.
0170	Conductivity Sensor Error	An error is detected with the conductivity sensor. Turn the instrument power off and back on. Contact Qorvo Technical Support if the error persists.
0180	Motor Error	An error occurred while running a motor. Repeat the test with a new cartridge. Contact Qorvo Technical Support if the error persists.
0220	Low Temp Error	The instrument was not able to warm-up to measurement temperature within five minutes. Turn the instrument power off and back on. Contact Qorvo Technical Support if the error persists.
0230	POST Error	The instrument detected an error during power-on self-test. Measurements cannot be performed. Turn the instrument power off and back on. Contact Qorvo Technical Support if the error persists.
0250	Data Send Error	The instrument was unable to transmit Diagnostics data. Verify the instrument has an Internet connection and the Diagnostics settings are correct.
0300	Login Error	Incorrect login credentials.

Cartridge Error Codes

These are error codes specific to individual tests.

Error Code	Error Name	Error Description
0010	Cartridge Cannot be Read	The RFID on the cartridge cannot be read. Insert a new cartridge. If the error persists, contact Qorvo Technical Support.

OPERATOR MANUAL

0020	Cartridge is Incompatible	The cartridge is not supported by this instrument. Insert a supported cartridge.
0030	Cartridge is Expired	The cartridge has expired and cannot be used for measurement. Insert an unexpired cartridge.
0040	Cartridge has been Used	The cartridge has been previously used and cannot be used for measurement. Insert an unused cartridge.
0080	Insufficient Sample	The cartridge did not have a sufficient sample amount. Test with a new cartridge. Confirm that the sample port is full (to the fill line) and sample is not overfilled (the sample is not pooled at the sample port). If the error persists, contact Qorvo Technical Support.
0130	Conductivity Error	Bad Solution Conductivity. Try repeating the test with a new cartridge. Contact Qorvo Technical Support if the error persists.
0270	Cartridge Error	The cartridge has an internal component failure. Try repeating the test with a new cartridge. Contact Qorvo Customer Technical if the error persists.
0280	Missing Carousel	The cartridge is missing the carousel or it is not in the proper position. Try repeating the test with a new cartridge. Contact Qorvo Technical Support if the error persists.

DOCUMENT INFORMATION

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Date: March, 2021

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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 only been authorized for use with the Omnia SARS-CoV-2 Antigen Assay only.

QORVO OMNIA SYSTEM

The Qorvo Omnia immunoassay analyzer system consists of a portable, reusable instrument and a one-time use test cartridge containing the assay.



Instrument



Test 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 Omnia System Operator Manual for detailed instructions on connecting with Wi-Fi.

QUICK-START GUIDE

5. If using a 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. After login, 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. New user credentials may be created by pressing "Settings" at the Main Menu, and then "Admin". After creating the user logins, log out and log back in as one of the newly created users.
2. From the Main Menu, select "Start New Test" to begin a new diagnostic test.
3. From the Main Menu, Press "Settings" to manage instrument and network settings.
4. 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

Cleaning and 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.

QUICK-START GUIDE

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.

TECHNICAL SUPPORT

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

E-mail: OmniaCOVID19Test@qorvo.com

Toll-Free: 1.833.384.1522

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 or high 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.

DOCUMENT VERSION

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Version B

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