

Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test

FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY

FOR IN VITRO DIAGNOSTIC USE ONLY

FOR PRESCRIPTION USE ONLY

FOR PROFESSIONAL USE ONLY

INTENDED USE

The Qorvo Biotechnologies Omnia SARS-CoV-2 Antigen Test comprising the Qorvo Biotechnologies Omnia System instrument and Qorvo Biotechnologies Omnia SARS-CoV-2 Antigen Test reagent cartridges is a bulk acoustic wave (BAW) biosensor-based immunoassay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for use in direct anterior nasal (nares) swab samples collected by the healthcare provider from individuals who are suspected of COVID-19 within the first six (6) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests. 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, 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.

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 protein antigen which is generally detectable in direct anterior nasal (nares) specimens during the acute phase of infection. Positive results indicate the presence of the nucleocapsid protein antigen, but clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are 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 such as isolating from others and wearing masks. Negative results should be considered in the context of an individual'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 healthcare professionals or operators who are proficient in performing tests in point of care settings. The Qorvo Omnia SARS-CoV-2 Antigen test is only for *in vitro diagnostic* use under the Food and Drug Administration's Emergency Use Authorization. The test has not been FDA cleared or approved.

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 (nares) swabs without viral transport media.

PRINCIPLES OF THE PROCEDURE

The Qorvo Omnia SARS-CoV-2 Antigen test uses automated bulk acoustic wave (BAW) biosensor- and immunoassay-based technology to detect the nucleocapsid antigen of SARS-CoV-2 directly from direct anterior nasal swabs without viral transport media. The Qorvo Omnia SARS-CoV-2 Antigen test is to be run on the Qorvo Omnia

System instrument. Time from the start of the test in the instrument to test result is approximately 20 minutes.

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 generated in Arbitrary Units/mL and reported as "positive" if the result is greater than or equal to the cut-off value or "negative" if the result is less than the cut-off value.

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

Note: Before you start testing, if you are new to the Qorvo Omnia Instrument, you must read the Qorvo Omnia System Operator Manual and the Qorvo Omnia SARS-CoV-2 Antigen test Instructions for Use (this document).

MATERIALS PROVIDED

Catalog # QPR8302 contains the following materials.

- 20 cartridges individually sealed in aluminum foiled pouch with a humidity indicator and desiccant.
- 20 vials of lysis buffer (450uL each)
- 20 dropper caps
- 20 sterile 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 Antigen Positive Control (Catalog # QPR8302.QC).

The control kit contains vials with sufficient volume for a total of 60 tests.

OPTIONAL MATERIALS

- Qorvo Biotechnologies Omnia Transport Tubes (Catalog #QPR8302TT)

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
 - Conjugate: Biotinylated anti-nucleocapsid protein (rabbit monoclonal) in HEPES based buffer with surfactant. Sodium azide and Proclin™-300 at ≤ 0.05% are used as a preservative.
 - Enzyme Enhancer: Streptavidin conjugated to alkaline phosphatase in HEPES based buffer with surfactant. Sodium azide and Proclin™-300 at ≤ 0.05% are used as a preservative.
 - Wash Buffers: HEPES buffer based with detergent and 0.05% sodium azide and/or 0.05% Proclin™-300 as a preservative.
 - Substrate: AMP buffer based with a precipitating substrate and detergent. Proclin™-950 at 0.05% is used as a preservative.

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STORAGE AND STABILITY

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. For the most current expiration dates of this test, please refer to: <https://www.fda.gov/covid-tests>
- 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.

INSTRUMENT

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

WARNINGS AND PRECAUTIONS

Warnings

- Read all instructions completely and carefully before performing the test and follow all instructions. Failure to follow all instructions may result in inaccurate test results.
- For use under Emergency Use Authorization Only.
- For prescription use only.
- For in vitro diagnostic use only.
- In the USA, this product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization. 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- 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.
- If the patient has had symptoms longer than 6 days, consider testing at least three times over five days with at least 48 hours between tests.

- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- 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; samples, reagents and 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.
- Once opened, the test cartridge should be used within 4 hours (240 minutes).
- Do not use the kit contents beyond the expiration date.
- Test components are single use. Do not reuse any kit components.
- Do not open the test cartridge until ready for immediate use.
- Discard and do not use if any of the test kit contents or packaging is damaged; or dropped test cartridges or other materials.
- Do not touch the swab tip.
- 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 Antigen test Instructions for Use is necessary to obtain accurate results. Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
- The test cannot be visually interpreted; the Qorvo Omnia System must be used to generate results.
- Lysis buffer supplied with the kit should not be separated from the cartridges as testing (including extraction) is expected to be performed by trained personnel.
- For more information on EUAs please visit:
<https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- For the most up to date information on COVID-19, please visit:
www.cdc.gov/COVID19
- Avoid contact with skin, eyes, nose or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose or mouth, flush with large amounts of water. **If irritation persists, seek medical advice.**
<https://www.poisonhelp.org> or 1-800-222-1222.

Chemical Name	GHS Code for Each Ingredient	Concentration
Sodium Azide	Acute Toxicity- Cat 3 (Oral) – H301 Acute Toxicity- Cat 2 (Dermal) – H310 Irritant- Cat 1 (Eye) - H318	≤ 0.05%
Proclin™ 300	Acute toxicity – Cat 4 (Oral) – H302 Skin Corrosion – Cat 1B – H314 Serious eye damage – Cat 1 – H318 Skin sensitization – Cat 1 – H317	≤0.05%
Proclin™ 950	Acute toxicity – Cat 4 (Oral) – H302 Skin Corrosion – Cat 1A – H314 Serious eye damage – Cat 1 – H318 Skin sensitization – Cat 1 – H317	≤0.05%

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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 test is validated for use with direct anterior nasal swab specimens only, using the swabs provided with the test kit and collected by the health care provider.

Specimen Collection

- The Qorvo Omnia SARS-CoV-2 Antigen test kit includes swabs for direct anterior nasal specimen collection. Use only the swabs provided with this test kit for specimen collection.
- Insert the swab into one nostril. 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.
- The sample should be processed immediately or stored 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.

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 lysis buffer, one dropper cap and one Qorvo Omnia SARS-CoV-2 Antigen test cartridge.
- Label the lysis buffer vial for each specimen or control to be tested.
- Remove 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).
- 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 Qorvo Omnia SARS-CoV-2 Antigen test.

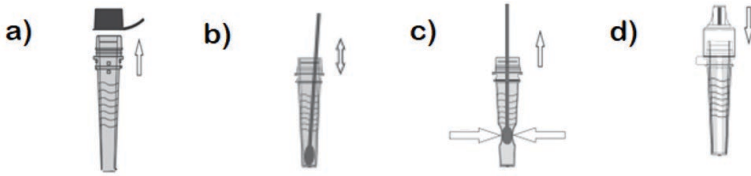


Figure 2: Specimen processing

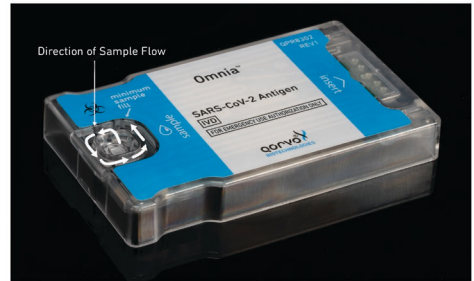
Specimen Handling and Storage Conditions

- Nasal swabs must be tested within one hour of collection or otherwise frozen for long term storage and subsequent testing.
- 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. Samples exceeding this duration (per these storage conditions) should be discarded.

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
 - Select cartridge labeled “SARS-CoV-2 Antigen”
 - 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. 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 7 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. *** Do not use less than 7 drops.** *This test should be performed with 7 drops of sample added to the sample*



part of the test cassette. Use of less than the stated 7 drops may result in an invalid test result.

9. Press “Next”.
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 arrow on cartridge.
11. If prompted, select the sample type.
12. Press “Confirm” and the test will run automatically.
13. After the test is complete, the cartridge will be ejected from the instrument and results (Positive, Negative, or Invalid) will be displayed on the screen.
14. Dispose of the cartridge after it has been ejected according to facility instructions.
15. 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, part number QPR8302.QC. 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.

RESULTS

Test Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

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. Individuals who test positive with the SARS-CoV-2 Omnia Antigen Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of

false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results are presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

Invalid

Test again with residual processed sample and new cartridge if the test is invalid.

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	Display Result	Test Result Interpretation
Invalid	Not displayed	INVALID	Invalid Test. Test again with residual processed sample and new cartridge.
Valid	Not displayed (Less than cut-off)	NEGATIVE	Presumptive Negative for SARS-CoV-2 (no antigen detected)
Valid	Not displayed (Equal to or greater than cut-off)	POSITIVE	Positive for SARS-CoV-2 (antigen present)

LIMITATIONS OF THE PROCEDURE

- Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
- This test should be performed with 7 drops of sample added to the sample port of the test cassette. Use of less than the stated 7 drops may result in an invalid 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.
- The test has not been validated for use with viral transport media (VTM) or universal transport media (UTM). Usage of the test with samples prepared using VTM or UTM may cause false positive, false negative, or invalid results.
- 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 August 2021 and October 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.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- 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.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.

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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>. However, to assist clinical laboratories using the Qorvo Omnia SARS-CoV-2 Antigen test, 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 the product are not permitted.
- 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 the 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 (OmniaCOVID19Test@Qorvo.com) 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 the Qorvo Omnia SARS-CoV-2 Antigen test 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, 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" as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

Clinical Performance

Prospective OTC study⁵

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARSCoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive. At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule. Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test. Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of

testing. Performance of the antigen test with serial testing in individuals is described in the Table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive/ PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 76.2%	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result.

2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.

3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test. Day 0 is the first day of documented infection with SARS-CoV-2.

Omnia SARS-CoV-2 Clinical Performance

The performance of the Qorvo Omnia SARS-CoV-2 Antigen test was established by testing 383 direct nasal swabs collected prospectively from 383 patients suspected of SARS-CoV-2 infection within 6 days from onset of symptoms and from asymptomatic patients reporting exposure to an individual confirmed with COVID-19.

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

Performance for Symptomatic Subjects

Omnia SARS CoV 2 Antigen Results	Comparator Method		
	Positive	Negative	Total
Positive	35	0	35
Negative	6	72	78
Total	41	72	113

Statistic	Estimate
Sensitivity (Positive Percent Agreement)	85.37% (35/41) (95% CI 70.83%-94.43%)
Specificity (Negative Percent Agreement)	100% (72/72) (95% CI 95.01%-100%)

Positive Results Broken Down by Days Since Symptom Onset

Days from Onset	Cumulative Omnia SARS CoV 2 Antigen Positive	Cumulative RT PCR Positive	PPA
0	1	1	100.0%
0-1	10	11	90.91%
0-2	16	20	80.00%
0-3	20	25	80.00%
0-4	29	35	82.86%
0-5	34	40	85.00%
0-6	35	41	85.37%

Total Subjects Stratified by Age

Age Group	Total enrolled subjects
2 to 13 Years of Age	9
14 to 23 Years of Age	11
24 to 64 Years of Age	88
65+ Years of Age	5

Invalid Analysis

The initial invalid test rate for symptomatic subjects for this study is 4.42% (5/113); 100% (5/5) of initial invalid tests were resolved with retesting with residual processed

sample.

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 flocced 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). Based upon the testing procedure for this study the LoD of 200 TCID₅₀/mL equates to 10 TCID₅₀/swab. 50ul of solution was spiked onto the swab for contrived samples during this study.

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

Omicron Testing

The performance of the Qorvo Omnia SARS-CoV-2 Antigen Test in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx[®]) initiative. The clinical specimens used to prepare this dilution series were not identical to the previous specimen pools prepared and tested by RADx to assess performance with the Omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA-authorized RT-PCR method, the Qorvo Omnia SARS-CoV-2 Antigen Test detected 100% of live Omicron samples at a Ct value of 25.8 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct values greater than 27.4) were not detected by the Qorvo Omnia SARS-CoV-2 Antigen Test in this study.

Summary Results:

Omicron Pool 2 Live Dilution		Assay #1	Assay #2	Company Assay
	Ct N2 Ave.	Percent Positive (n 5)	Percent Positive (n 5)	Percent Positive (n 5)
Dilution 1	19.8	100	100	80
Dilution 2	20.8	100	100	100
Dilution 3	21.5	100	100	60
Dilution 4	22.7	100	100	100
Dilution 5	23.6	100	0	100
Dilution 6	24.0	60	0	100
Dilution 7	24.8	0	0	100
Dilution 8	25.8	0	0	100
Dilution 9	27.4	0	0	0
Dilution 10	28.1	0	0	0
Dilution 11	29.1	0	0	0

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	1.51×10^6 TCID ₅₀ /mL
Human coronavirus OC43	5.01×10^5 TCID ₅₀ /mL
Human coronavirus NL63	1.41×10^5 TCID ₅₀ /mL
MERS-CoV	1.70×10^5 TCID ₅₀ /mL
Adenovirus (C1 Ad. 71)	1.02×10^8 TCID ₅₀ /mL
Bordetella pertussis	1.13×10^{10} CFU/mL
Candida albicans	6.27×10^8 CFU/mL
Chlamydia pneumoniae	1.75×10^6 IFU/mL
Enterovirus	1.26×10^6 TCID ₅₀ /mL
Haemophilus influenzae	2.27×10^9 CFU/mL
Human Metapneumovirus (hMPV)	3.80×10^6 TCID ₅₀ /mL
Influenza A H1N1	3.55×10^5 TCID ₅₀ /mL
Influenza A H3N2	3.55×10^5 TCID ₅₀ /mL
Influenza B	4.17×10^5 TCID ₅₀ /mL
Legionella pneumophila	1.88×10^{10} CFU/mL
Mycoplasma pneumoniae	3.16×10^8 CFU/mL
Parainfluenza virus 1	3.39×10^7 TCID ₅₀ /mL
Parainfluenza virus 2	1.51×10^6 TCID ₅₀ /mL
Parainfluenza virus 3	8.51×10^7 TCID ₅₀ /mL
Parainfluenza virus type 4A	1.38×10^7 TCID ₅₀ /mL
Parainfluenza virus type 4B	1.17×10^7 TCID ₅₀ /mL
Pneumocystis jirovecii - S. cerevisiae Recombinant	1.56×10^7 CFU/mL

Staphylococcus epidermidis	9.27 x 10 ⁹ CFU/mL
Streptococcus pneumoniae	2.26 x 10 ⁹ CFU/mL
Streptococcus pyogenes	1.64 x 10 ⁹ CFU/mL
Pooled human nasal wash	100%
Respiratory syncytial virus type A	3.16 x 10 ⁶ TCID ₅₀ /mL
Respiratory syncytial virus type B	1.26 x 10 ⁶ TCID ₅₀ /mL
Rhinovirus	4.17 x 10 ⁵ TCID ₅₀ /mL
Staphylococcus aureus	5.5 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.

Interfering 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 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 2.8×10^8 TCID₅₀/mL of gamma irradiated SARS-CoV-2 with the Qorvo Omnia SARS-CoV-2 Antigen test.

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TECHNICAL SUPPORT

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MANUFACTURER INFORMATION:

QORVO BIOTECHNOLOGIES

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PLYMOUTH, MN 55447

Qorvo Biotechnologies Omnia[™] SARS-CoV-2 Antigen Test

FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY

FOR IN VITRO DIAGNOSTIC USE

FOR PRESCRIPTION USE ONLY

FOR PROFESSIONAL USE ONLY



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 comprising the Qorvo Biotechnologies Omnia System instrument and Qorvo Biotechnologies Omnia SARS-CoV-2 Antigen Test reagent cartridges is a bulk acoustic wave (BAW) biosensor-based immunoassay for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. The test is authorized for use in direct anterior nasal (nares) swab samples collected by the healthcare provider from individuals who are suspected of COVID-19 within the first six (6) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests. 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, 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.

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 protein antigen which is generally detectable in direct anterior nasal (nares) specimens during the acute phase of infection. Positive results indicate the presence of the nucleocapsid protein antigen, but clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are presumptive and confirmation with a molecular assay if necessary for patient management, may be performed. Negative results do not rule out SARSCoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions such as isolating from others and wearing masks. Negative results should be considered in the context of an individual'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 healthcare professionals or operators who are proficient in point of care settings. The Qorvo Omnia SARS-CoV-2 Antigen test is only for *in vitro diagnostic* use under the Food and Drug Administration's Emergency Use Authorization. The test has not been FDA cleared or approved.

Specimens Recommended

The Qorvo Omnia SARS-CoV-2 Antigen assay is validated for use with direct anterior nasal swabs. The test can be performed with swabs collected by a health care provider.

Specimen Collection

1. The Qorvo Omnia SARS-CoV-2 Antigen test kit includes swabs for direct anterior nasal specimen collection. Use only the swabs provided with this test kit for specimen collection.
2. Insert the swab into one nostril. 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 1

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

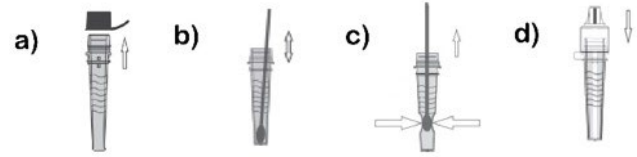


Figure 2

Omnia Instrument Preparation

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



Antigen Cartridge Preparation



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



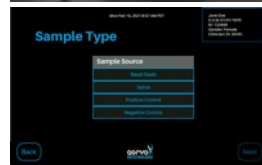
2. Use the dropper cap on the vial of lysis buffer and gently squeeze the ridged area of the vial to dispense 7 drops of sample into sample port. **Do not use less than 7 drops.** The sample will flow counterclockwise through a channel around the sample port. Allow sufficient time for the leading edge of the sample to draw level with the "Sample Fill" line on the cartridge label.



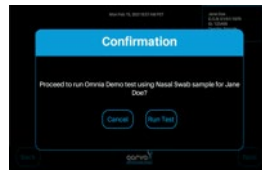
3. Press "Next" on the instrument.



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



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



6. Confirm by selecting "Run Test".



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

Important Notes/Warning Precautions

- Read all instructions completely and carefully before performing the test and follow all instructions. Failure to follow the instructions may result in inaccurate test results.
- For use under Emergency Use Authorization Only.
- For prescription use only.
- For in vitro diagnostic use only.
- 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.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- 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; samples, reagents and 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.
- Discard and do not use if any of the test kit contents or packaging is damaged; or dropped test cartridges or other materials.
- Do not touch the swab tip.
- 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 Antigen test Instructions for Use is necessary to obtain accurate results. Inadequate or inappropriate sample collection, storage, and transport can result in incorrect results.
- The test cannot be visually interpreted; the Qorvo Omnia System must be used to generate results.
- Lysis buffer supplied with the kit should not be separated from the cartridges as testing (including extraction) is expected to be performed by trained personnel.

- Avoid contact with skin, eyes, nose or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose or mouth, flush with large amounts of water. **If irritation persists, seek medical advice.** <https://www.poisonhelp.org> or 1-800-222-1222.

Chemical Name	GHS Code for Each Ingredient	Concentration
Sodium Azide	Acute Toxicity- Cat 3 (Oral) – H301 Acute Toxicity- Cat 2 (Dermal) – H310 Irritant- Cat 1 (Eye) - H318	≤ 0.05%
Proclin™ 300	Acute toxicity – Cat 4 (Oral) – H302 Skin Corrosion – Cat 1B – H314 Serious eye damage – Cat 1 – H318 Skin sensitization – Cat 1 – H317	≤0.05%
Proclin™ 950	Acute toxicity – Cat 4 (Oral) – H302 Skin Corrosion – Cat 1A – H314 Serious eye damage – Cat 1 – H318 Skin sensitization – Cat 1 – H317	≤0.05%

ProClin is a trademark of The Dow Chemical Company or an affiliated company of Dow

- Do not use less than 7 drops in the sample application. This test should be performed with 7 drops of sample added to the sample port of the test cassette. Use of less than the stated 7 drops may result in an invalid test result.
- After receipt, store cartridges at refrigerated temperature between 2-8°C for the duration of the cartridge shelf life. Don't freeze the cartridge. For the most current expiration dates of this test, please refer to: <https://www.fda.gov/covid-test>
- 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 reuse any kit components.
- Do not open the test cartridge until ready for immediate use; Once opened, the test cartridge should be used within 4 hours (240 minutes).

- Do not use the test beyond the expiration date printed on the pouch. Always check expiration date prior to testing.
- Specimens may be infectious. Use Universal Precautions when performing this assay.
- Use routine laboratory precautions. Do not eat, drink, or smoke in the area where samples are being handled and testing is being conducted. Avoid any contact between hands, eyes or mouth during sample collection and testing.
- Wear personal protective equipment (PPE) in accordance with laboratory and institutional policies such as laboratory coats, disposable gloves, and eye protection when handling patient samples.
- Wash hands thoroughly after handling specimens and used cartridge.
- Dispose of used cartridge, nasal swab and lysis buffer vial in a biohazard waste container. Proper handling and disposal methods should be established according to local regulations.
- Please refer to the package insert for detailed assay instructions, cautions, limitations, and warnings.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between August 2021 and October 2021. Clinical performance has not been established with 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If the patient has had symptoms longer than 6 days, consider testing at least three times over five days with at least 48 hours between tests.**
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If the patient continues to have symptoms of COVID-19, and both their first and second tests are negative, they may not have COVID-19, however additional follow-up may be needed.
- For more information on EUAs please visit: <https://www.fda.gov/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

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.

In the USA, this product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization. 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. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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OMNIA SYSTEM OPERATOR MANUAL

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, 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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OVERVIEW OF 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 (Figure 1) contains all hardware, software, and mechanical components necessary for full automation of biomarker detection.



Figure 1



Figure 2

The test cartridge (Figure 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 interface between the cartridge and instrument. During a test, the sample is added to the cartridge sample port up 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 diagnostic test, refer to the Instructions for Use for each diagnostic assay.

COMPONENTS IN THE BOX

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












WARNINGS

Read these instructions completely before using the product.

1. For in vitro diagnostic and Laboratory Professional use.
2. The 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 Qorvo 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 the 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 5 cm (2 inches) 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 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.
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

BARCODE SCANNER

A USB barcode scanner may be used to enter text.

Recommended Scanner: Motorola/Zebra DS4308-HD7U2100AZW

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.

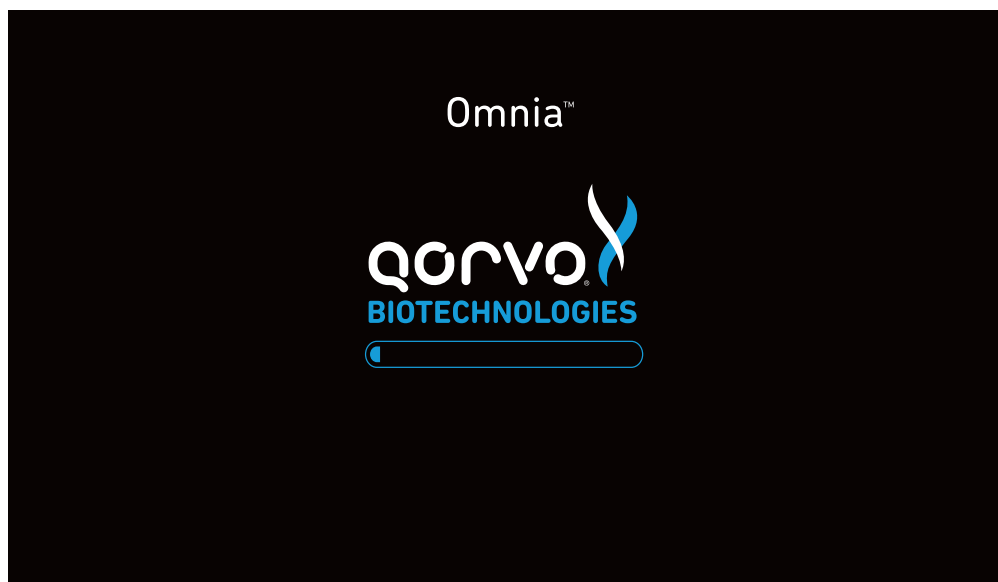


Figure 3

Logging in and Main Menu

After initialization, the Log In screen will appear (Figure 4). At the Log In screen, enter your 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 logging in with the admin/admin credentials, the system will require you to create a new password for the admin user name. After you enter the new password, the system will return you to the Main Menu. 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. 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.

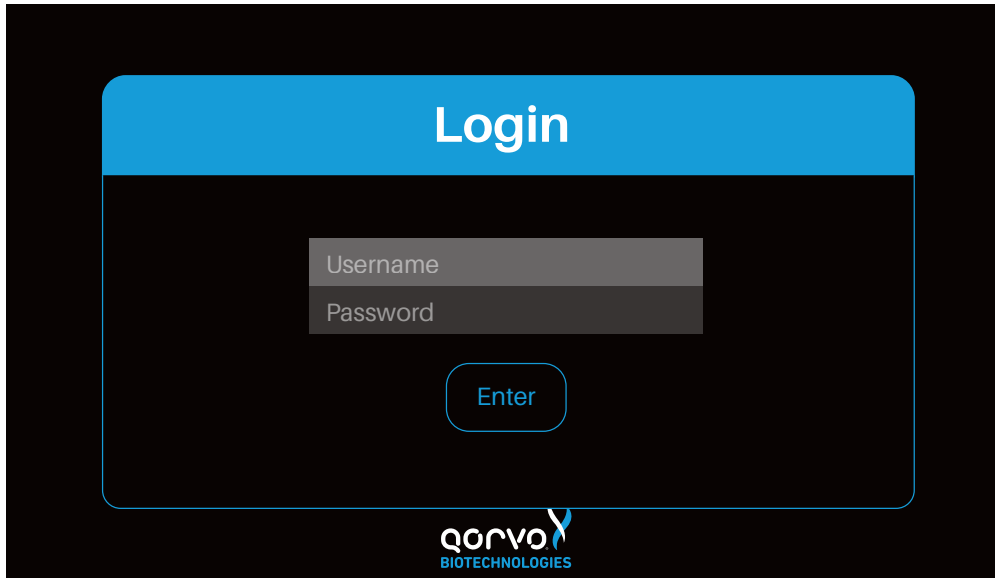


Figure 4

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 “Logout.”

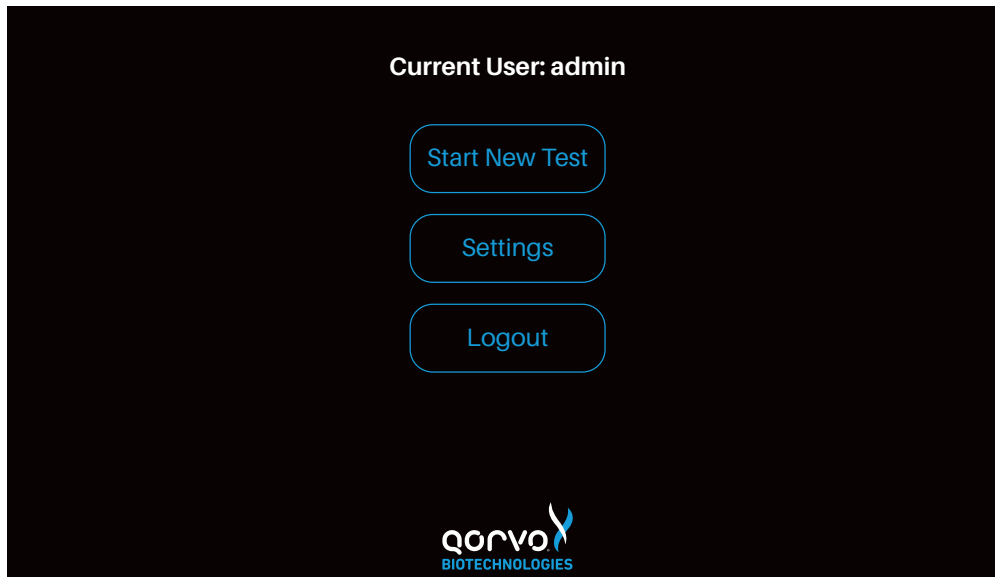


Figure 5

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).

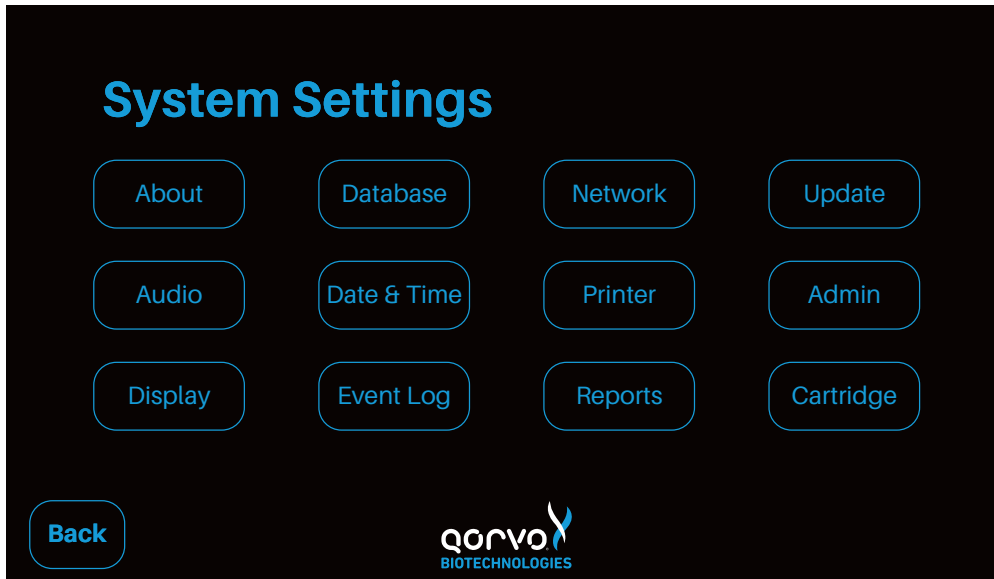


Figure 6a

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

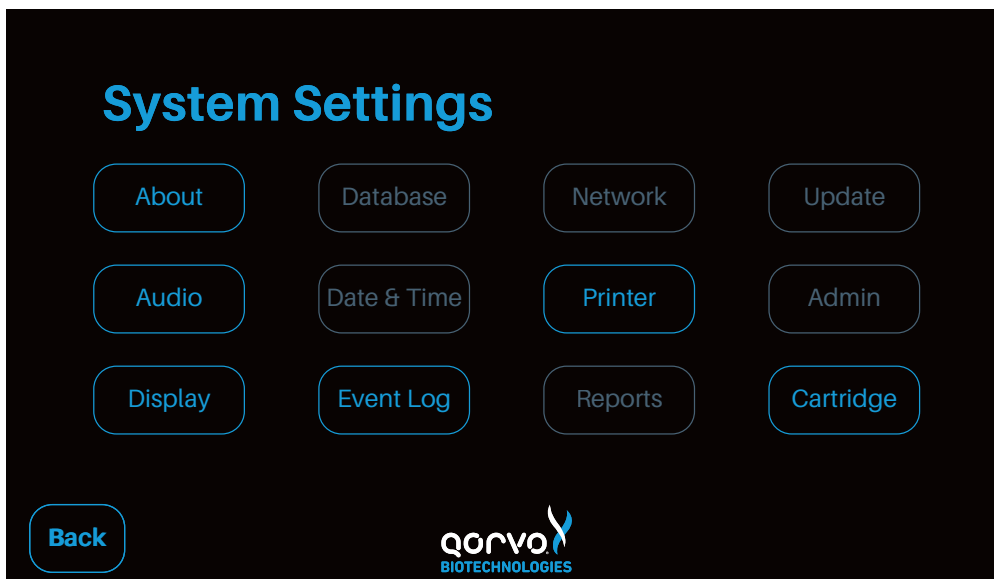


Figure 6b

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).

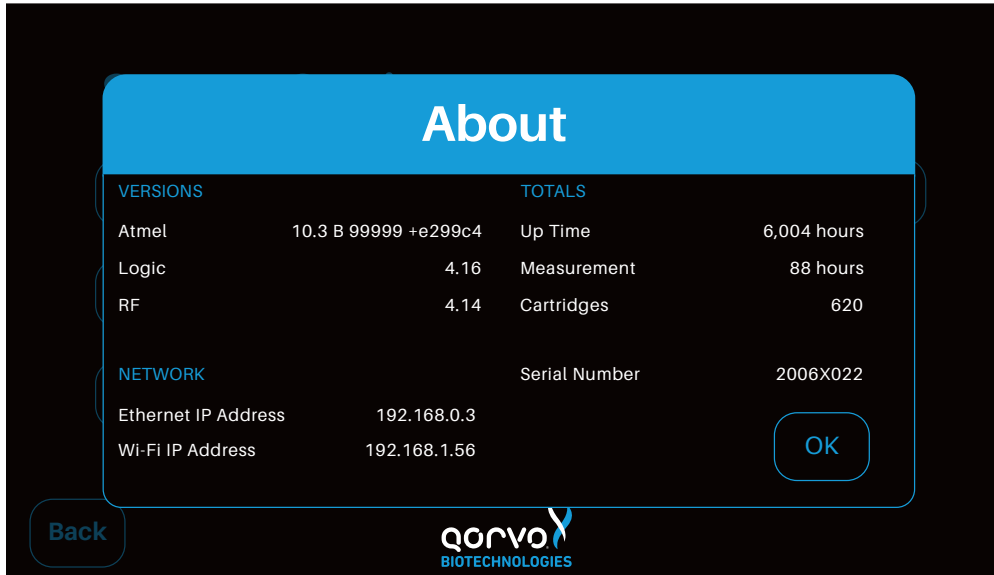


Figure 7

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

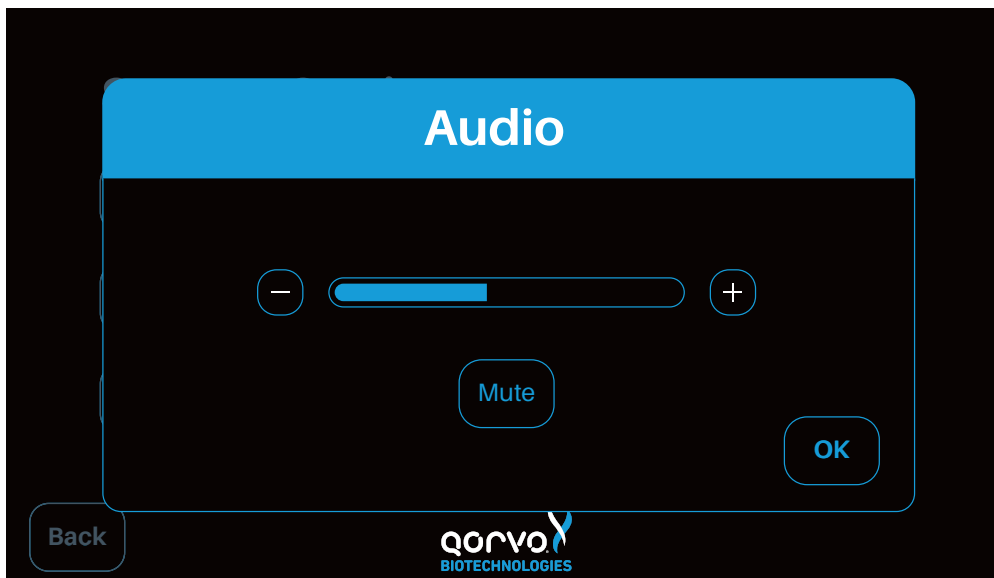


Figure 8

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

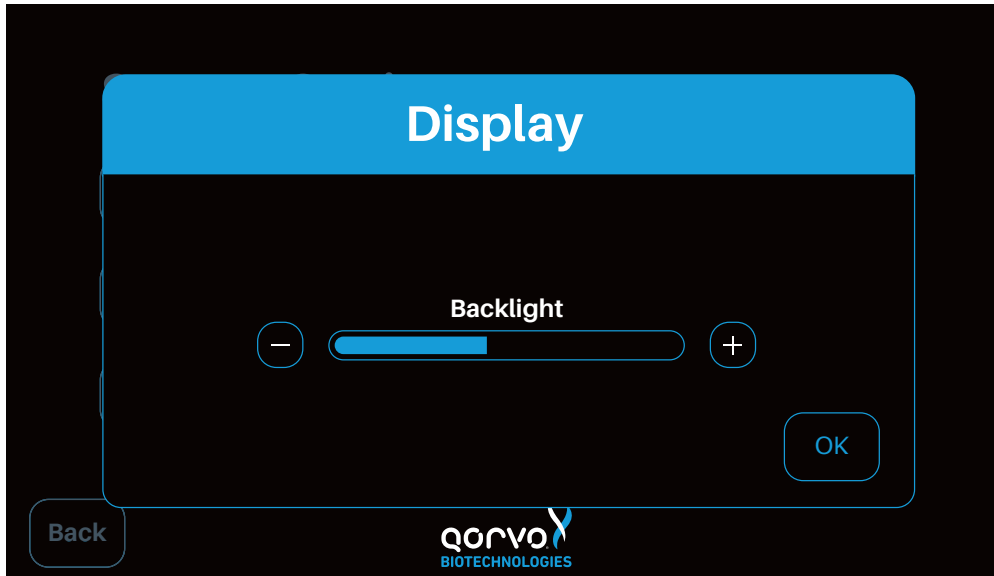


Figure 9

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.

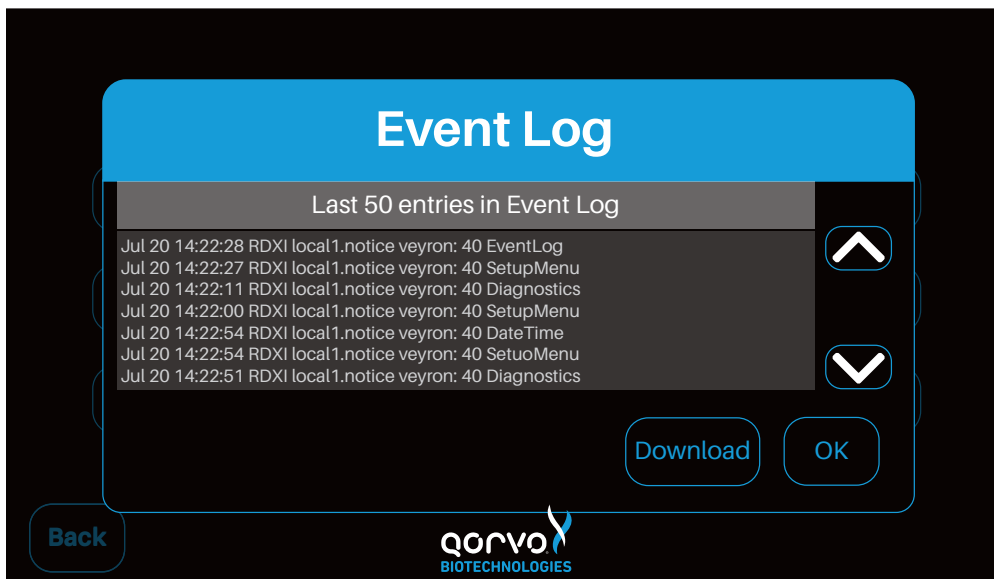


Figure 10

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.

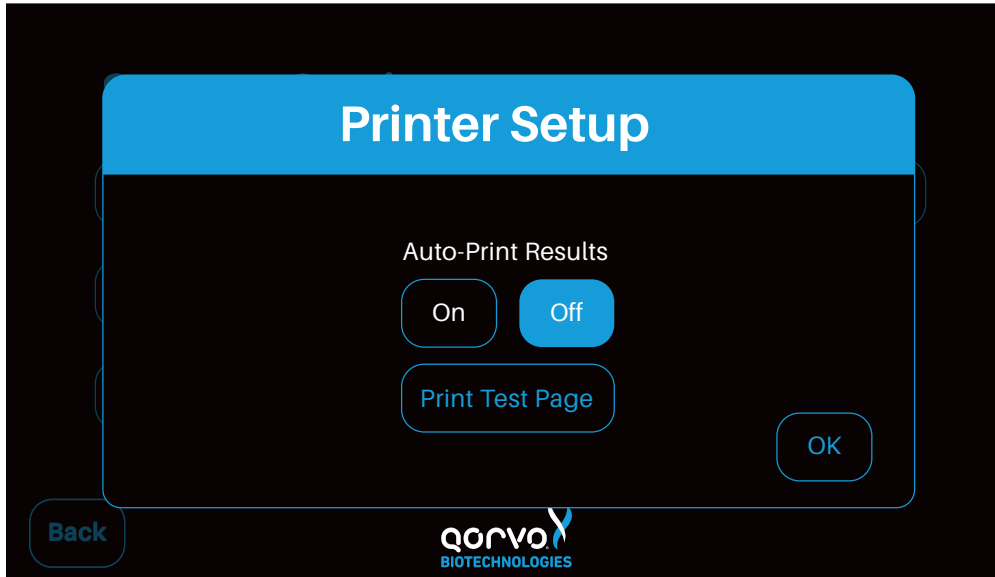


Figure 11

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

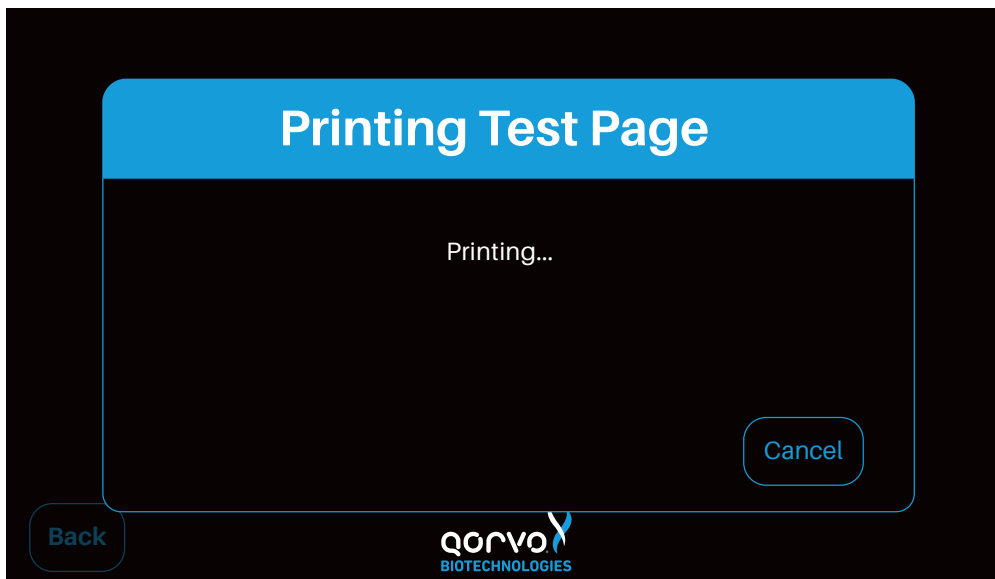


Figure 12

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.

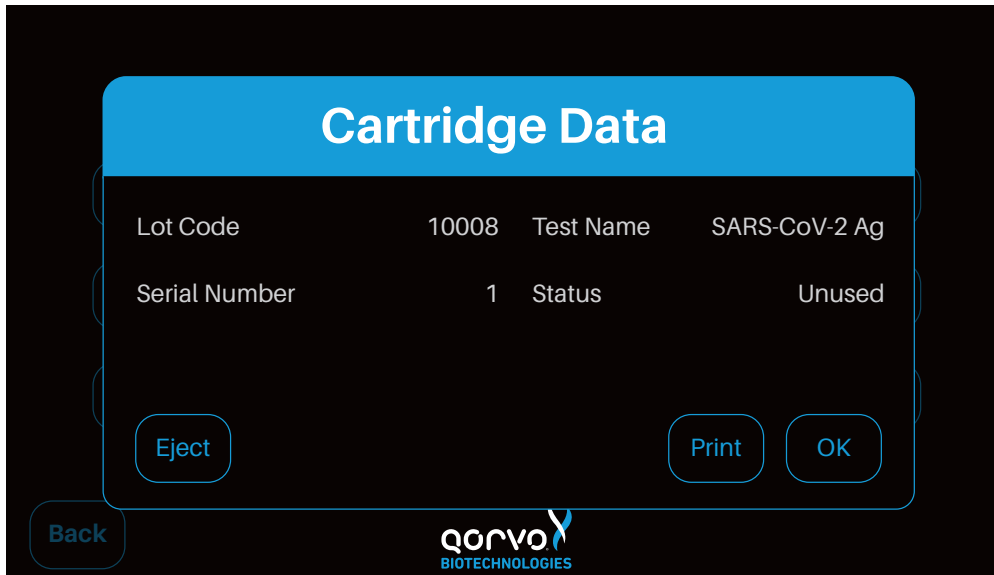


Figure 13

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 **Database** screen (Figure 14) enables test results to be automatically uploaded to the database immediately after the test finishes. Check the "Auto-Send After Measurement" to enable this feature.

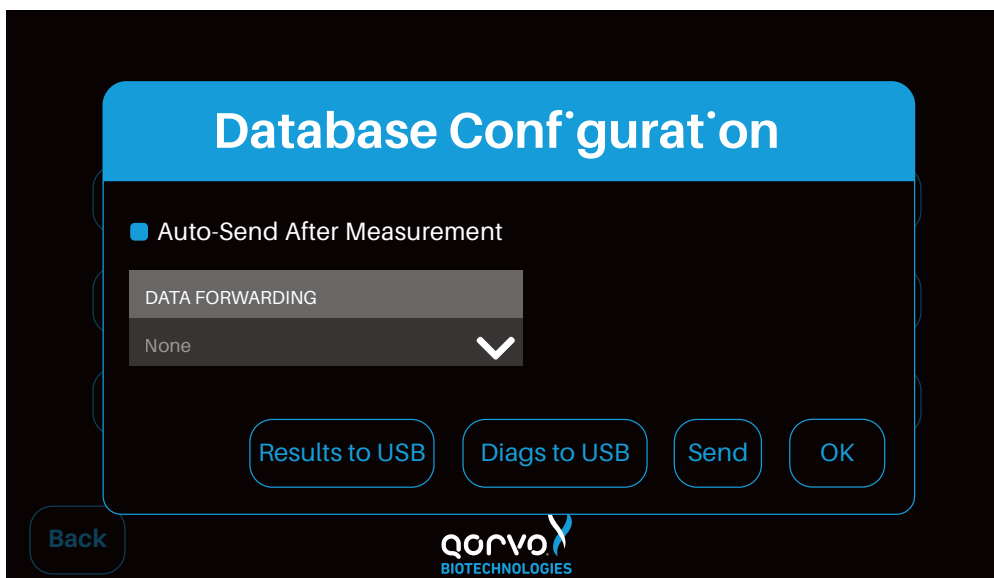


Figure 14

The **Date and Time** screen allows the user to set the current date and time (see Figure 15).

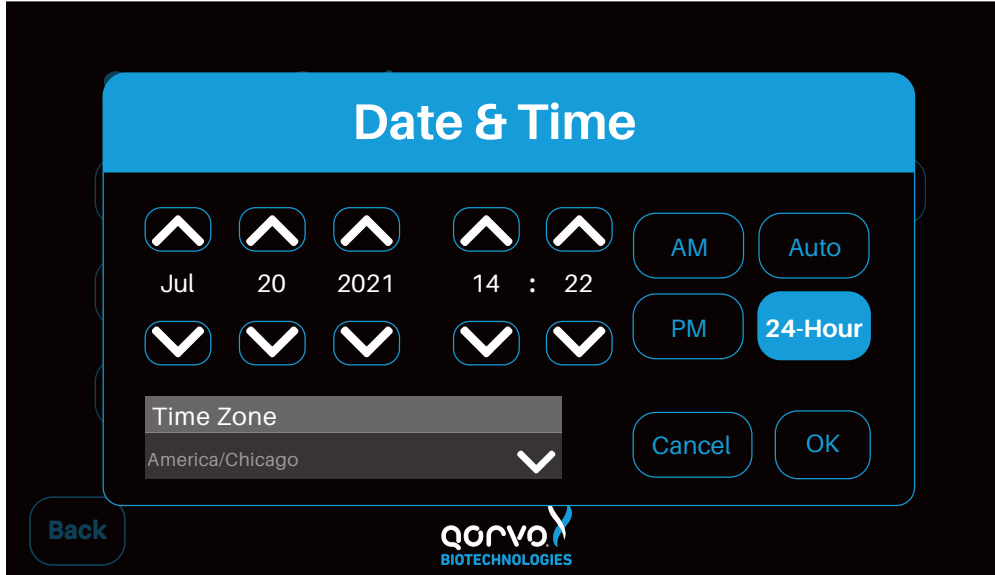


Figure 15

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 16).

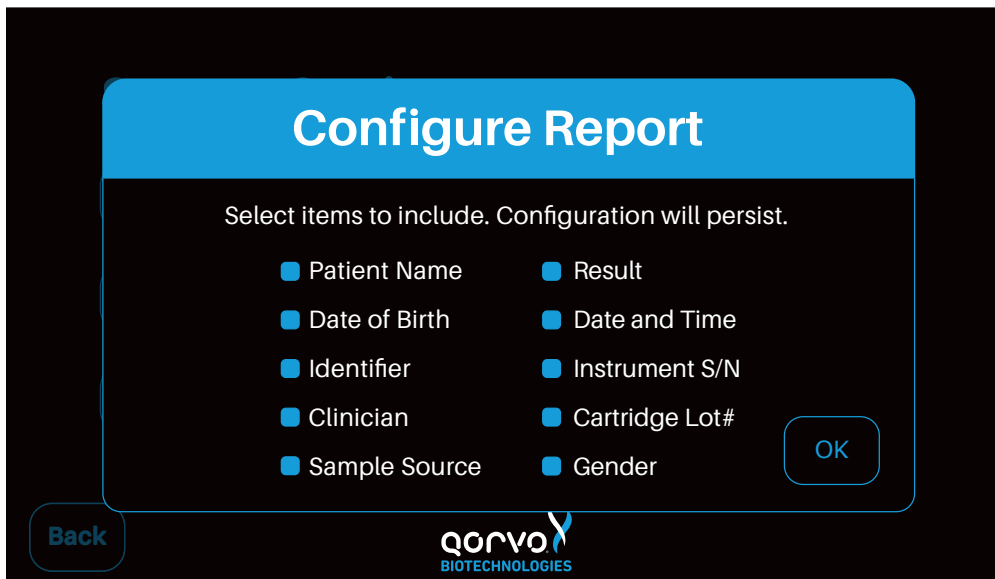


Figure 16

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 requires administrator credentials (see Figure 17).

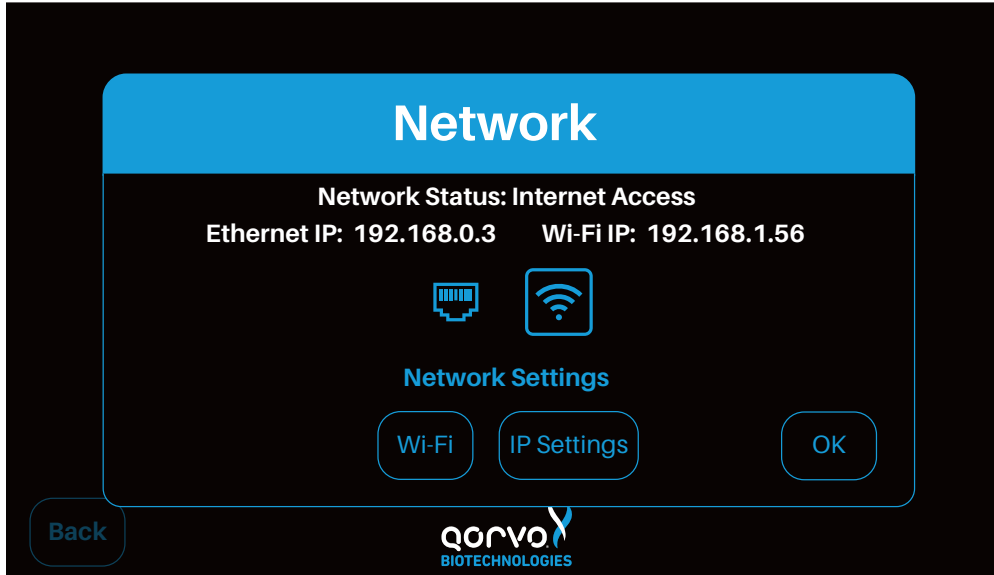


Figure 17

From the Settings/Network panel, you may press "Wi-Fi" to bring up the Wi-Fi configuration panel (Figure 17a). From this panel you may turn the Wi-Fi on or off. When the Wi-Fi is turned on, you will see a list of available networks and you may select a network for connection. Touch one of the displayed networks and enter the login password for that network (Figure 17b). The Omnia system permits connections only to WPA2-PSK (Personal) networks.

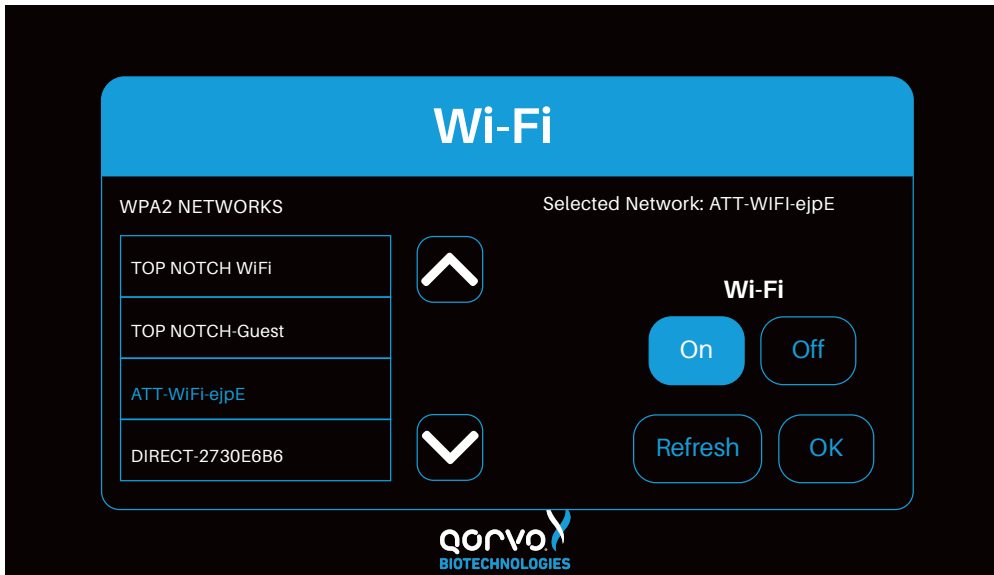


Figure 17a

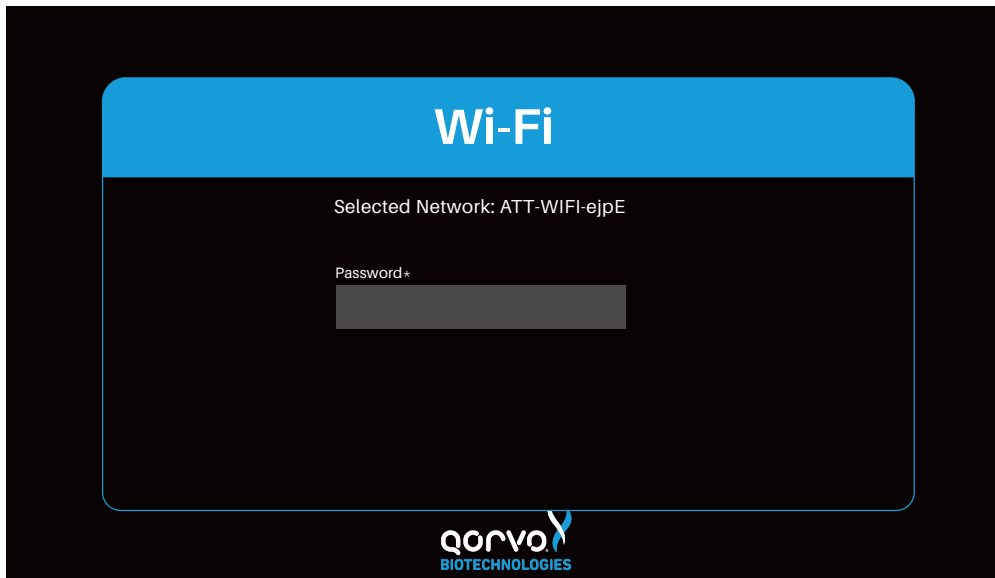


Figure 17b

Press IP Settings button to bring up the IP Settings pop-up panel (Figure 18). Here, you may configure the IP settings for either automatic or manual mode. Automatic mode is recommended and is set by default. You may change the mode to manual by pressing the "Off" button labeled "Automatic IP". Once in manual mode, you may enter the IP configuration settings in the "Static IP Configuration" control fields on the left side of the panel.

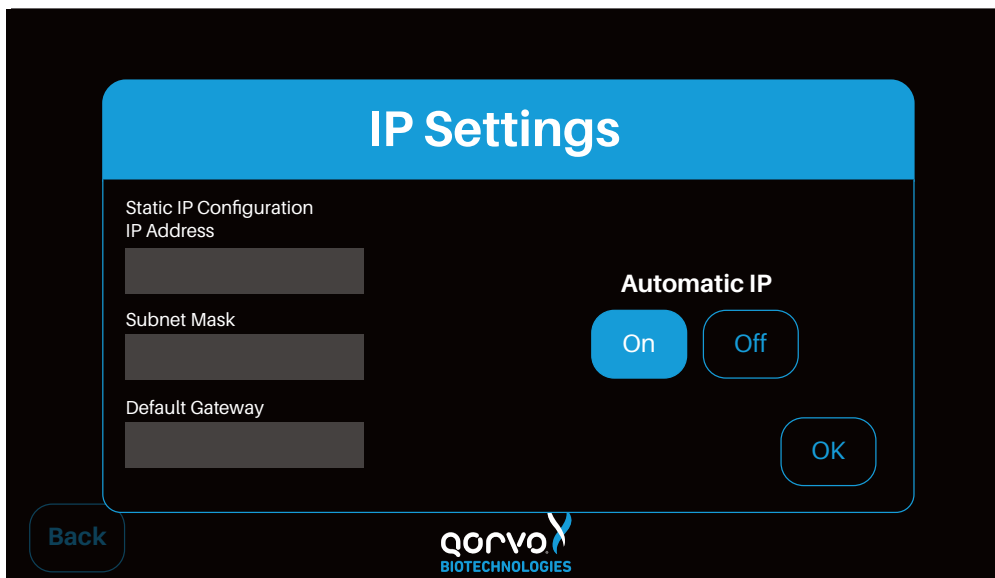


Figure 18

The **Update** button brings up the Software Update screen (Figure 19) that enables updates of the system software by those with administrator privileges.



Figure 19

The **Admin** button will bring up the Admin screen (Figure 20), permitting an operator with administrator credentials to add or remove users.

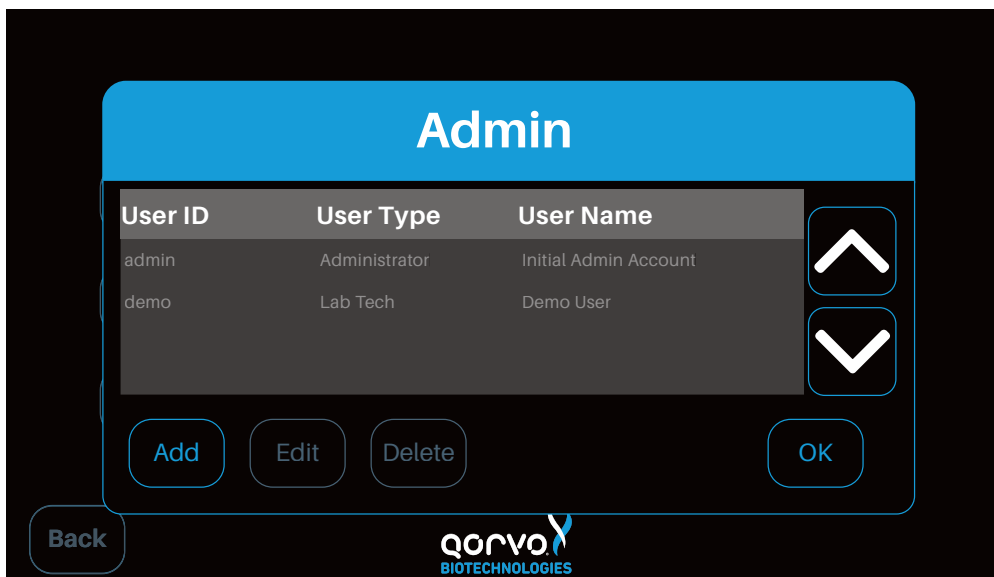
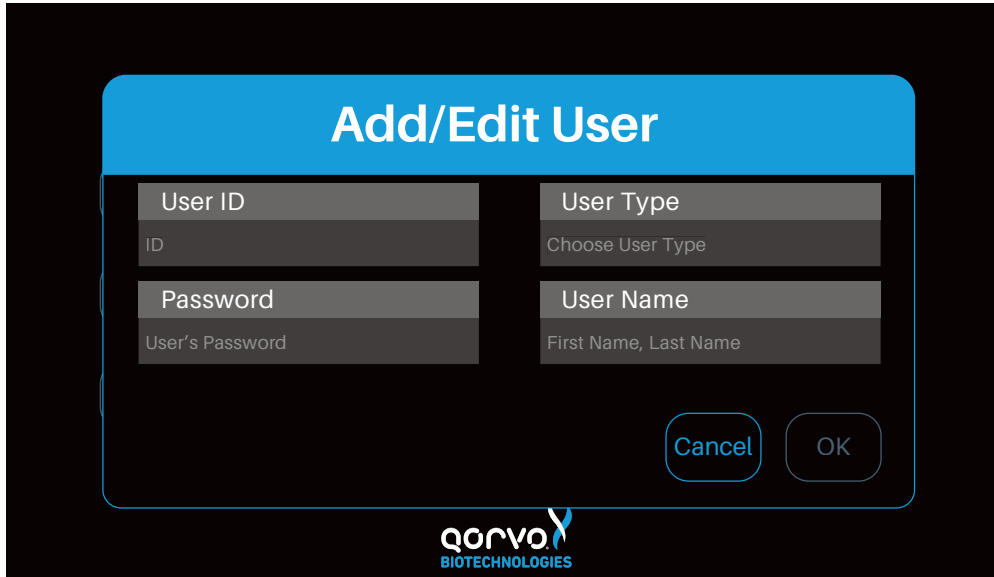


Figure 20

Pressing the "Add" button will bring up the Add/Edit User screen (Figure 21). 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.

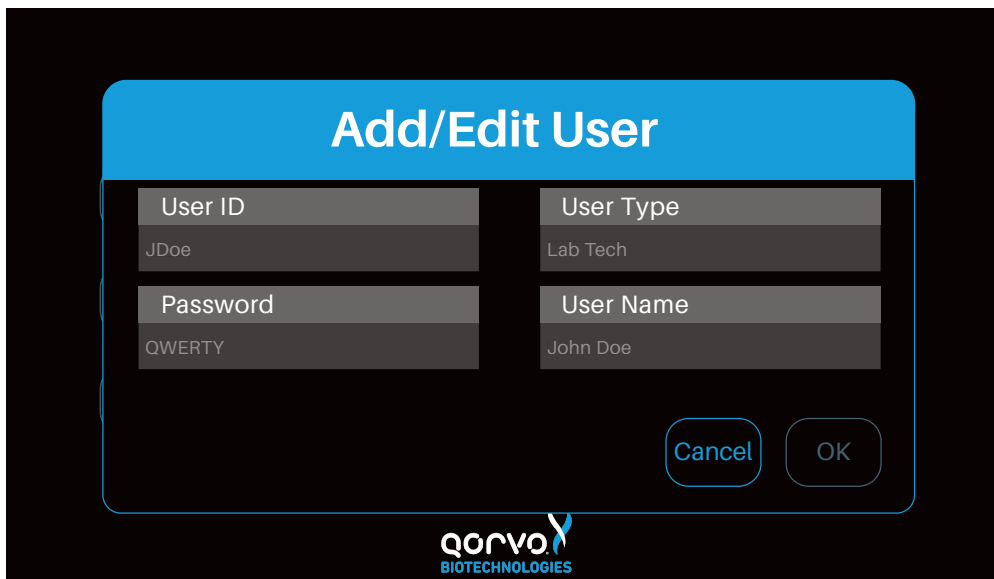
A screenshot of the "Add/Edit User" screen. The screen has a black background with a blue header bar containing the text "Add/Edit User" in white. Below the header, there are four input fields arranged in a 2x2 grid. The top-left field is labeled "User ID" and contains the text "ID". The top-right field is labeled "User Type" and contains the text "Choose User Type". The bottom-left field is labeled "Password" and contains the text "User's Password". The bottom-right field is labeled "User Name" and contains the text "First Name, Last Name". At the bottom right of the form area, there are two buttons: "Cancel" and "OK". The Qorvo Biotechnologies logo is visible at the bottom center of the screen.

User ID	User Type
ID	Choose User Type
Password	User Name
User's Password	First Name, Last Name

Cancel OK

Figure 21

The following image (Figure 22) shows an example after entering the user information.

A screenshot of the "Add/Edit User" screen, similar to Figure 21, but with user information entered. The "User ID" field now contains "JDoe", the "User Type" field contains "Lab Tech", the "Password" field contains "QWERTY", and the "User Name" field contains "John Doe". The "Cancel" and "OK" buttons are still present at the bottom right. The Qorvo Biotechnologies logo is visible at the bottom center of the screen.

User ID	User Type
JDoe	Lab Tech
Password	User Name
QWERTY	John Doe

Cancel OK

Figure 22

After the user information is entered, press the OK button. The interface will return to the Admin screen (Figure 23) and the new user and user type will appear.

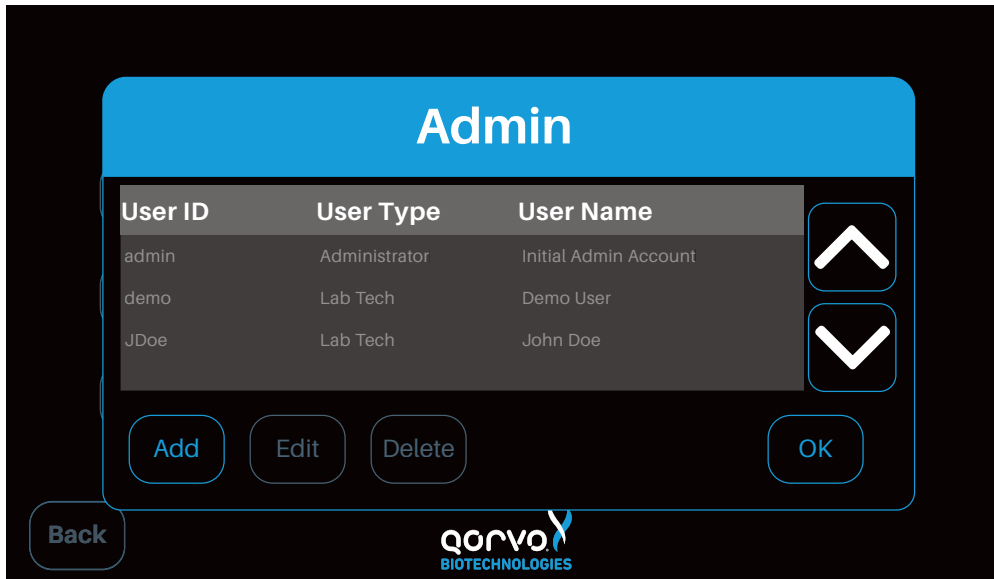


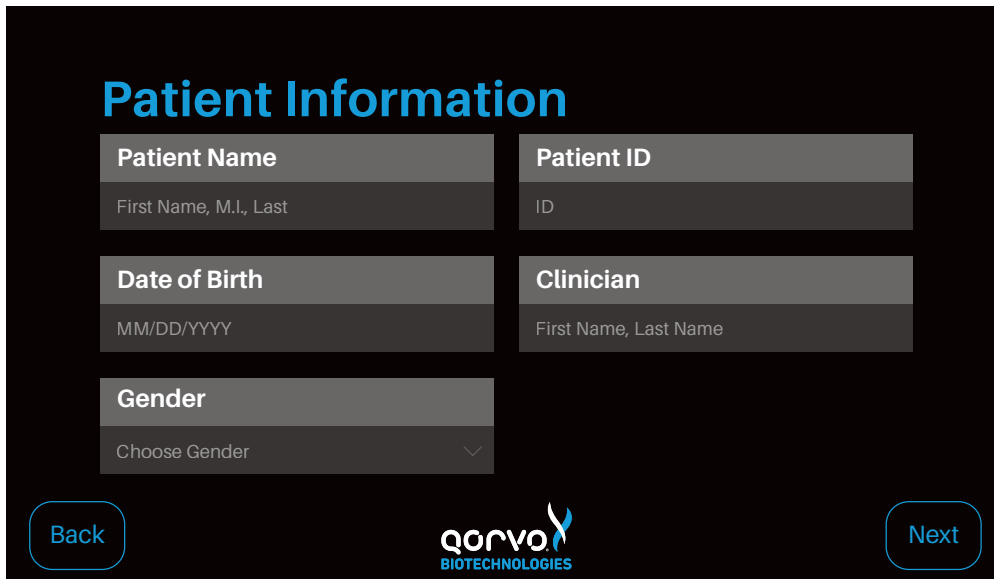
Figure 23

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

STARTING A NEW TEST

From the Main Menu press "Start New Test". The Patient Information screen appears, and the following patient information associated with the sample must be entered (Figure 24a):

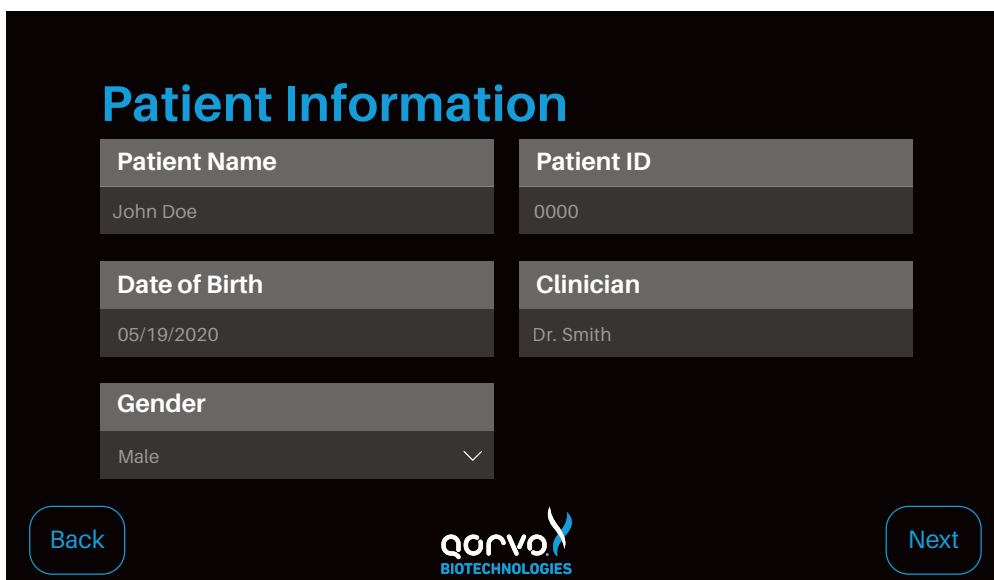
1. Patient Name
2. Patient ID
3. Date of Birth
4. Clinician
5. Gender

The screenshot shows the "Patient Information" screen with five input fields: Patient Name (placeholder: First Name, M.I., Last), Patient ID (placeholder: ID), Date of Birth (placeholder: MM/DD/YYYY), Clinician (placeholder: First Name, Last Name), and Gender (placeholder: Choose Gender). The screen includes "Back" and "Next" buttons and the Qorvo Biotechnologies logo at the bottom center.

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

Figure 24a

Figure 24b shows the Patient Information screen after the fields have been filled in with example patient information.

The screenshot shows the "Patient Information" screen with the same five input fields as Figure 24a, but now filled with example data: Patient Name (John Doe), Patient ID (0000), Date of Birth (05/19/2020), Clinician (Dr. Smith), and Gender (Male). The screen includes "Back" and "Next" buttons and the Qorvo Biotechnologies logo at the bottom center.

Patient Name	Patient ID
John Doe	0000
Date of Birth	Clinician
05/19/2020	Dr. Smith
Gender	
Male	

Figure 24b

RUNNING A TEST

Note: The workflow between Qorvo Biotechnologies Omnia test 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 25).

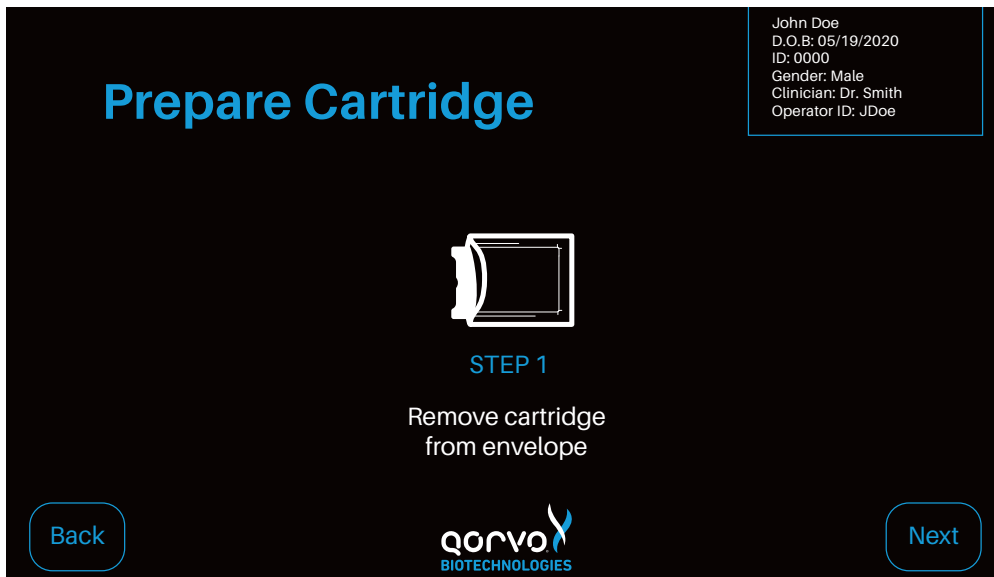


Figure 25

3. Remove cartridge from pouch (pouch also contains a desiccant and humidity indicator 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 26 will appear.

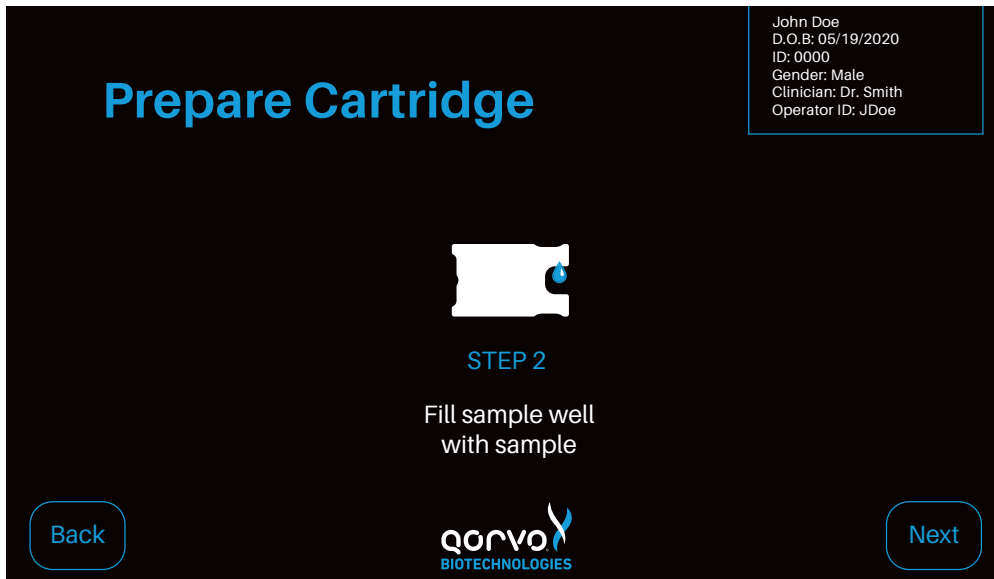


Figure 26

6. Refer to the test cartridge Instructions For Use to dispense sample into the 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 “minimum sample fill” line. After the cartridge has been prepared, press “Next” (Figure 27).

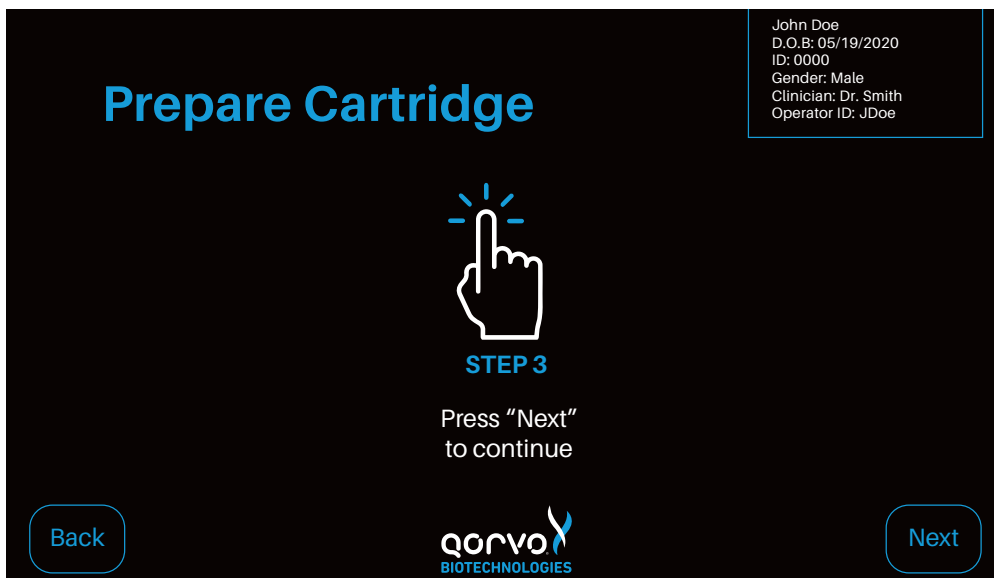


Figure 27

8. Place the cartridge into the 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 28). Gently push the cartridge into the Cartridge Receiver until the instrument accepts and draws in the cartridge.

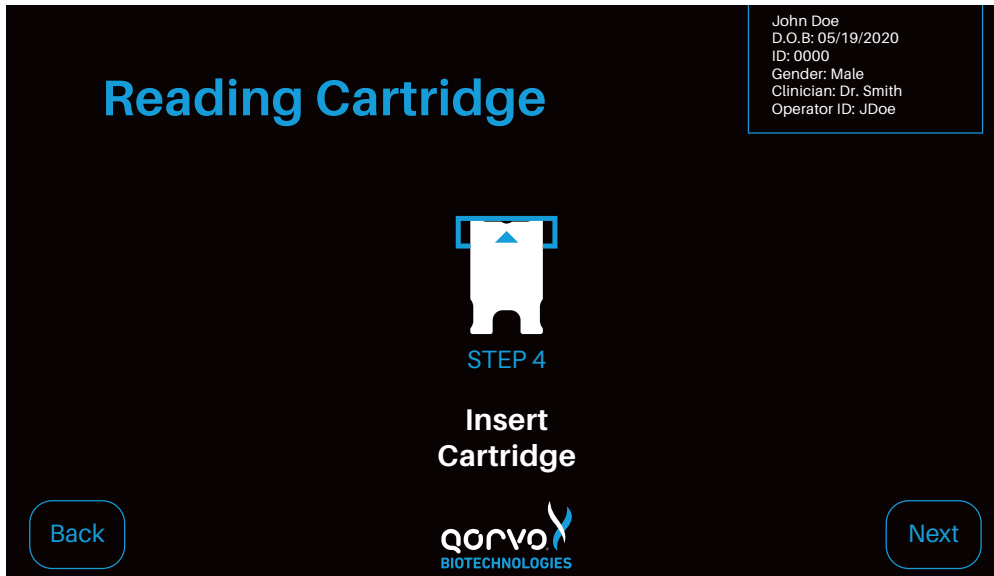


Figure 28

- 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 29).

Note: The assay information in Figure 29 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.

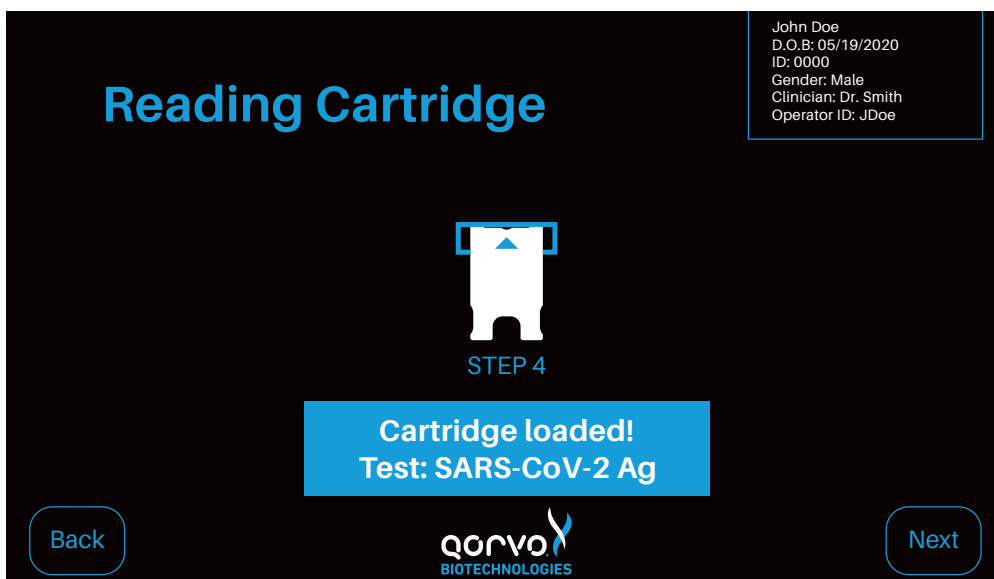


Figure 29

- Once the cartridge is read and identified, the user may be required to select the sample type as shown in Figure 30. Press "Select Source" or the down arrow to select the sample type from the pull-down display for the assay. Only sample types appropriate for the currently-configured test will be displayed.

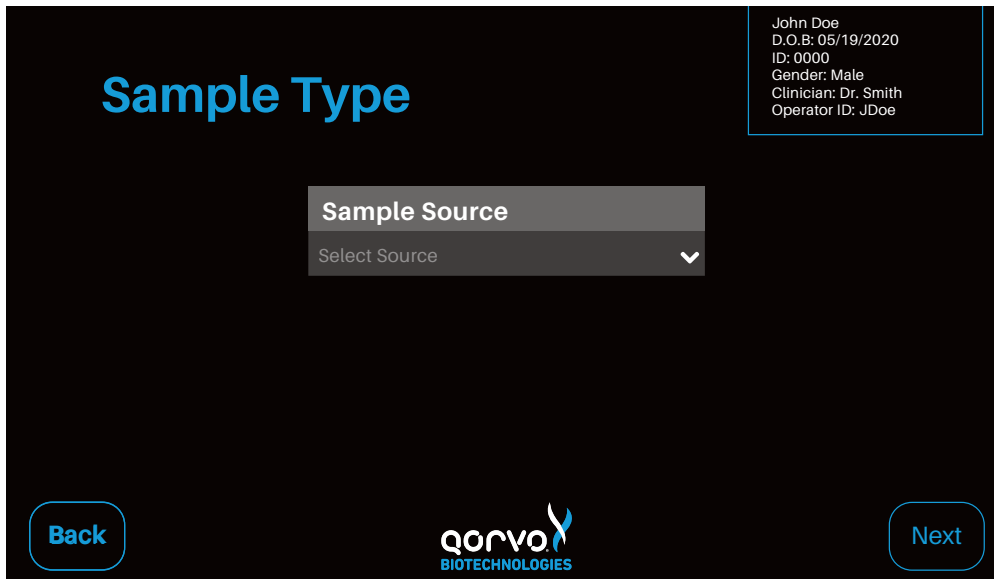


Figure 30

- Once the sample type is selected, press "Next".
- After the cartridge has been read, a confirmation panel will appear where you can press "Run Test" to proceed with the test or "Cancel" to cancel the test (Figure 31a). If "Cancel" is pressed, the system will eject the cartridge and return to the Main Menu (Figure 31b). If "Run Test" is pressed, the test will proceed.

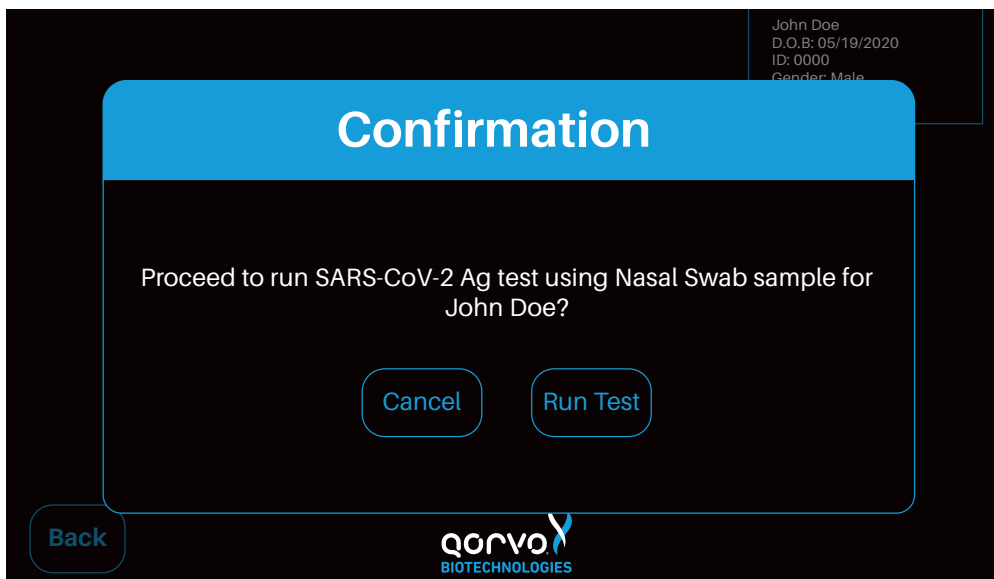


Figure 31a

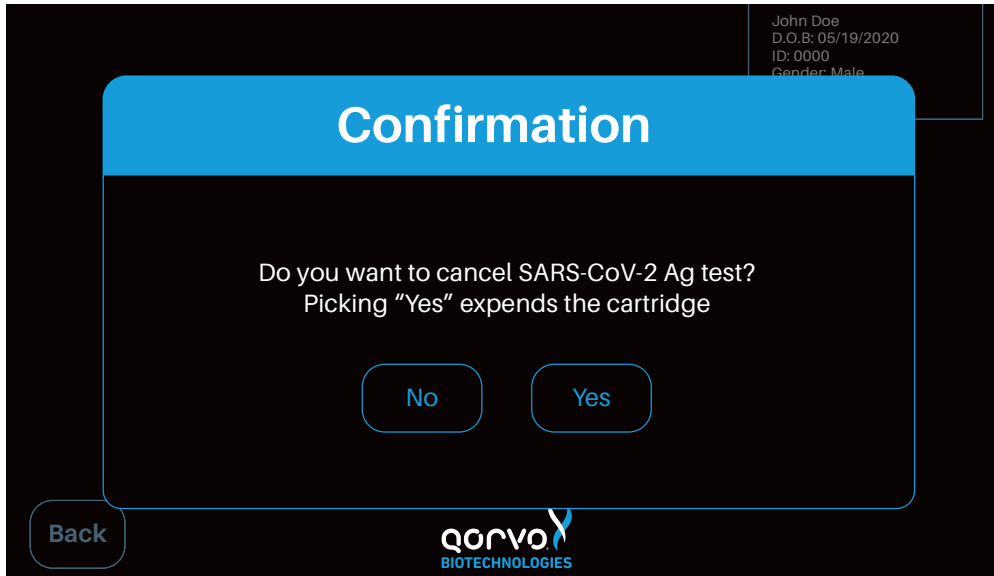


Figure 31b

The screen will show the progress of the testing (Figure 32). After the test is complete, the cartridge will be ejected from the instrument. Dispose of the used cartridge as biological waste.

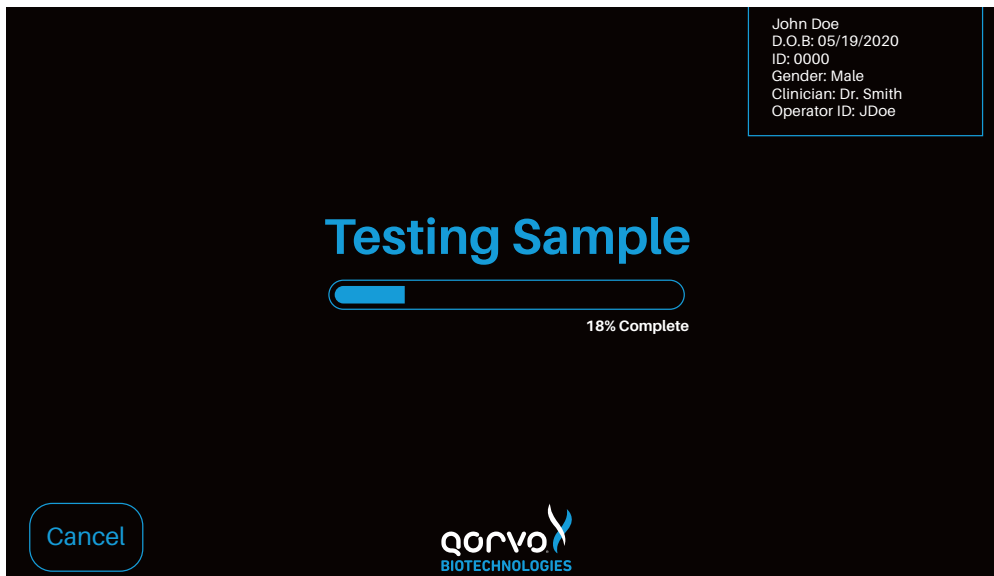


Figure 32

Test results will be displayed immediately after cartridge is ejected. Figure 33 is an example only. See the Qorvo Omnia test cartridge instructions for Use for information on interpretation of results.

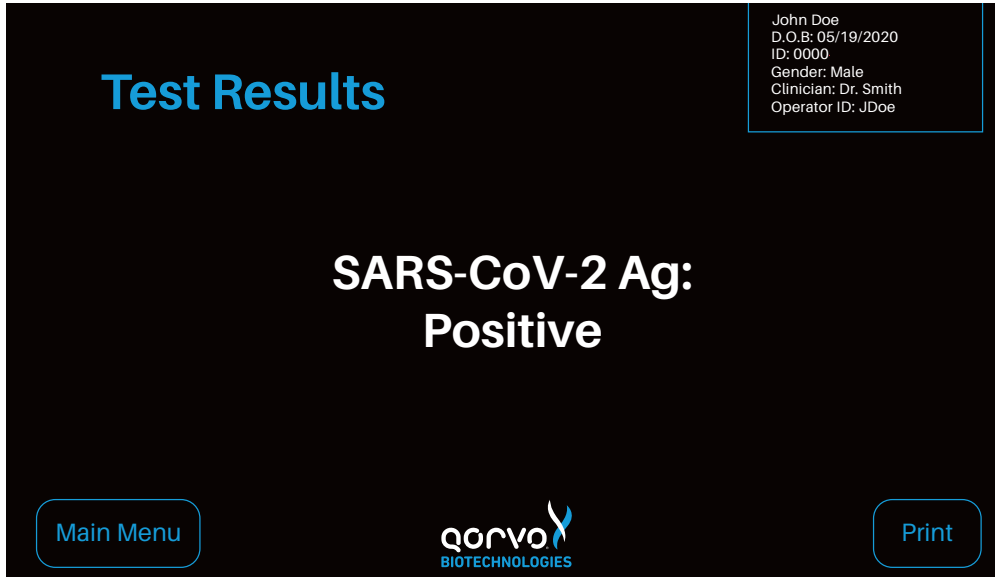


Figure 33

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 34).

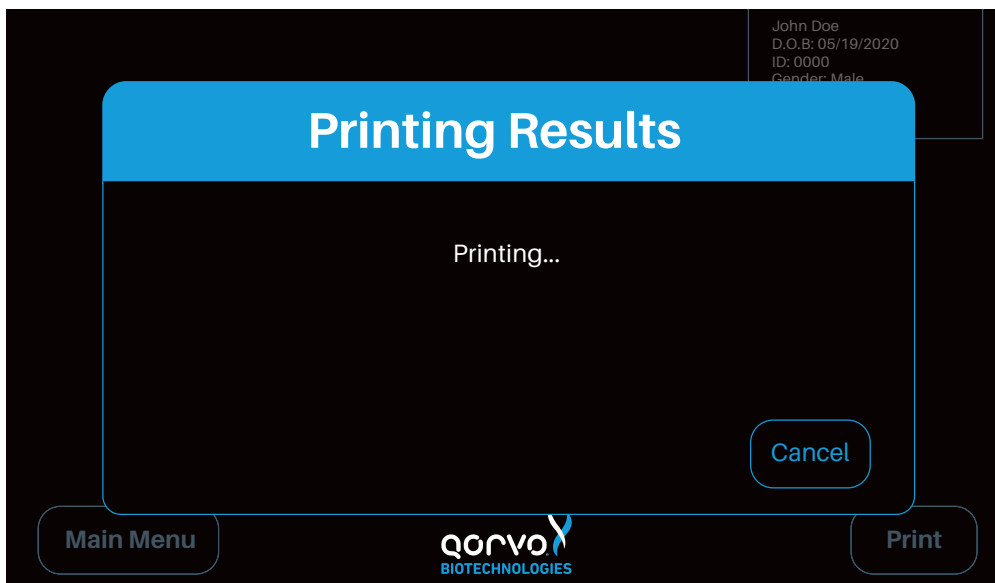


Figure 34

When a test has completed, test results are automatically uploaded to the data portal if “Auto-Send After Measurement” is selected in the Settings/Database menu. During the upload, you may see the “Uploading Results” panel (Figure 35) briefly appear. Please wait until this panel closes before proceeding.

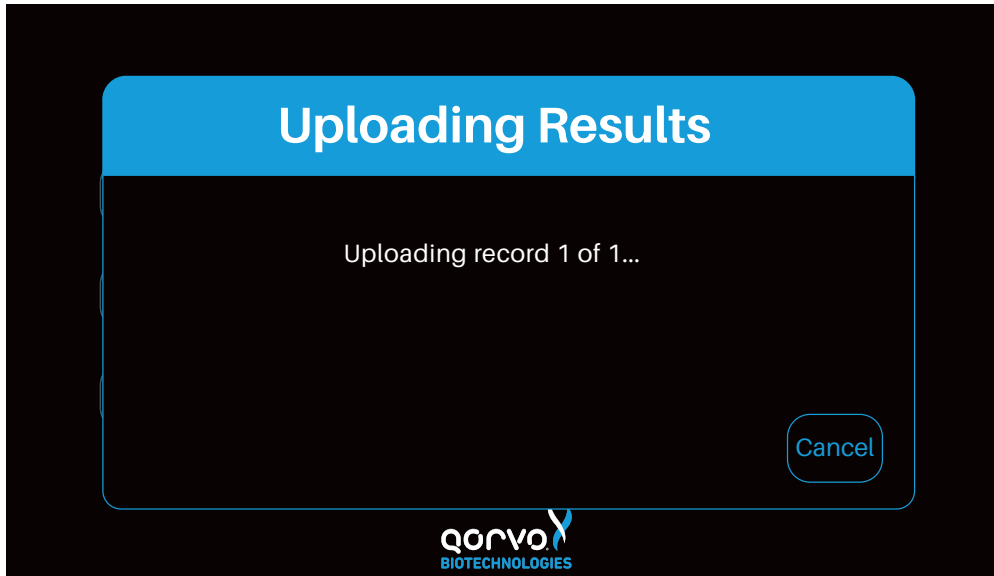


Figure 35

To Power Off, press and hold the Power button for 5 seconds (Figure 36)

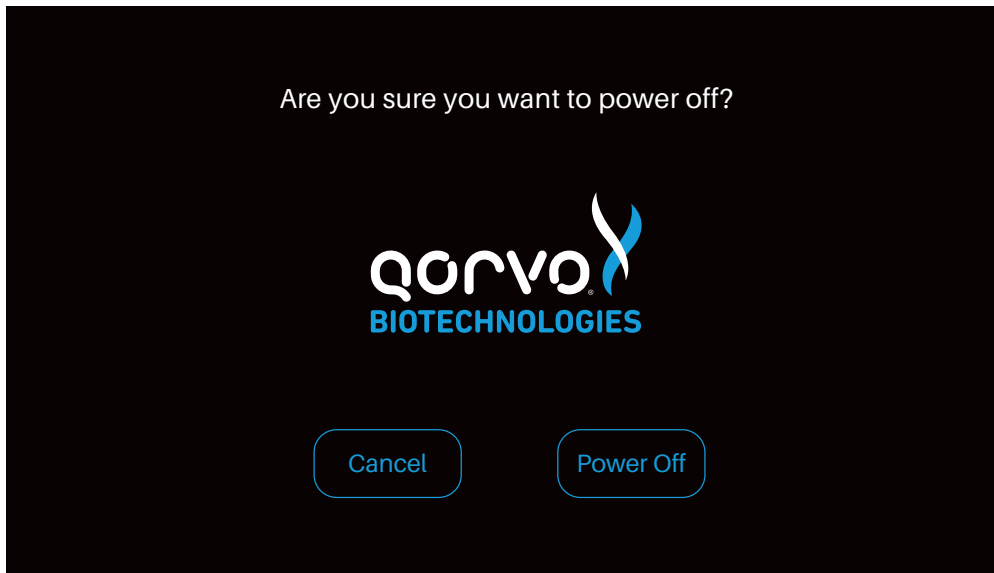


Figure 36

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 70% 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 37), the back of the instrument contains a fan filter (part number 151215) and retainer (part number 150615).

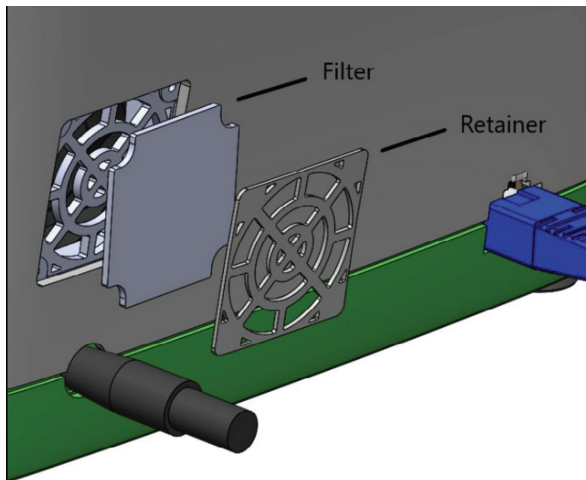


Figure 37

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 technical support questions or if the instrument needs to be returned for service, please contact Qorvo Biotechnologies Technical Support:

Toll-Free: 1.833.384.1522

Email: OmniaCOVID19Test@qorvo.com

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, 1 \emptyset
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)

CONNECTIVITY

Network connectivity for the Qorvo Omnia instrument may be established in two ways: (1) Ethernet and (2) Wi-Fi. Regardless of the method chosen, it is not necessary to log in to an enterprise network to establish connectivity. See DATA TRANSFER section below for more details.

Ethernet

To establish connectivity using Ethernet, the operator will connect the instrument to an active Ethernet socket using a standard RJ-45 non-crossover cable. The cable may be connected prior to engaging instrument power or afterward.

When Wi-Fi is **disabled**, Ethernet is enabled automatically, and the instrument will attempt to connect to Ethernet. Ethernet connectivity is verified by pressing Settings from the Main Menu, then Network. The Ethernet icon will appear highlighted if there is a physical cable connected and Wi-Fi is disabled. (See the next section for instructions on how to disable Wi-Fi.)

It is recommended that the instrument be configured for automatic IP address assignment. This configuration may be accessed by pressing Settings from the Main Menu, then Network, then IP Settings, and then setting Automatic IP to "On". If the instrument has been assigned an IP address, it will appear on the second line of the Network menu. The IP address can also be seen by pressing Settings from the Main Menu, then About. If the instrument has been assigned an IP address, it will appear in the lower, left-hand corner of the About panel. It may take up to 15 seconds for the instrument to get an IP address after Automatic IP is On and Ethernet is enabled.

Wi-Fi

The Omnia instrument supports WPA2-PSK (Personal) Wi-Fi network protocol. Enterprise networking via Wi-Fi is not supported at present. To connect to Wi-Fi, make sure that there is a WPA2-PSK network in the area where you wish to connect. If there is no existing Wi-Fi network, you may establish a network using a smart phone and the hot-spot feature of the phone.

To enable Wi-Fi connectivity, press Settings from the Main Menu, then Network, then Wi-Fi, then Wi-Fi "On". The instrument will automatically identify nearby WPA2-PSK (personal) networks. Select the network you wish to connect to by touching the network name. The password entry field will appear. Type in the password and press "OK". (If the selected network was the last one connected to, you will not need to enter the password. If you have established a network using a smart phone, be sure to enter the password provided when you set up the hot spot.) Press "OK" to return to the Network panel. The Wi-Fi icon will be highlighted, indicating connectivity to the selected network. Press "OK" to return to the Settings menu.

It is recommended that the instrument be configured for automatic IP address assignment. This configuration may be accessed by pressing Settings from the Main Menu, then Network, then IP Settings, and then setting Automatic IP to "On". If the instrument has been assigned an IP address, it will appear on the second line of the Network menu. The IP address can also be seen by pressing Settings from the Main Menu, then About. If the instrument has been assigned an IP address, it will appear in the lower, left-hand corner of the About panel.

To disable Wi-Fi connectivity, press Settings from the Main Menu, then Network, then W-Fi, then "Off". Press "OK" to return to the Network panel. Wi-Fi will be disabled, Ethernet will automatically enable, and connectivity will be indicated by a highlighted Ethernet icon.

Data Transfer

When the instrument has concluded each test, the system will, by way of the network connection (Ethernet or Wi-Fi) send the test results to a secure database portal. This action does not require the instrument to be logged into an enterprise network. It requires only one of the connectivity options listed above. Test results are encoded into HL7 FHIR v4 format and transmitted using secure TCP/IP protocol. The secure database is configured in accordance with medical device regulations.

Data Retrieval

Data from a test session may be retrieved by using the credentials of the instrument operator at the time the tests were completed. A user logging into the database may only view results keyed to that user's credentials and the instrument serial number. Test results may also be viewed or downloaded in PDF or HL7 v2.5.1/IHE PaLM format. A login link to the database can be provided by Qorvo Biotechnologies.

Troubleshooting

If the user experiences difficulty in connecting to a Wi-Fi network, please review the Problem Solving section below.

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 PC 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 Qorvo 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 Technical 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.

5. Recovery from lost login credentials

- a. If you have forgotten one or more login credentials, try logging in with a known user name that has administrative rights.
- b. If you have lost or forgotten all login credentials, please contact Customer Technical Support for assistance in recovering your login information.

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 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 Customer 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 Customer Support if the error persists.
0222 & 0223	Hardware PID Error	Could not load PID file. Power cycle the instrument. If the problem persists, contact Qorvo Customer Technical Support.
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.
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. A new cartridge needs to be used. Confirm sample is added to the "minimum sample fill" line. If the error persists, contact Qorvo Technical Support.
0081	Liquid Dispense Error	Conductivity was out of range during liquid dispense. Repeat the test with a new cartridge.
0130	Conductivity Error	Bad Solution Conductivity. Try repeating the test with a new cartridge. Contact Qorvo Technical Support if the error persists.
0240	Test Error on Internal Control or Reference	The response of the internal control or reference test is outside the dynamic range of the instrument. Repeat the test with a new cartridge. If the error persists, contact Qorvo Technical Support.
0270	Cartridge Error	The cartridge has an internal component failure. Try repeating the test with a new cartridge. Contact Qorvo Technical Support 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.

TECHNICAL SUPPORT

Toll-Free: 1.833.384.1522

Email: OmniaCOVID19Test@qorvo.com

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WWW.QORVOBIOTECH.COM

Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Positive Control

FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY

FOR IN VITRO DIAGNOSTIC USE ONLY

FOR PRESCRIPTION USE ONLY

FOR PROFESSIONAL USE 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.

WARNINGS AND PRECAUTIONS

- For prescription use only
- For use under an Emergency Use Authorization Only
- For in vitro diagnostic use.
- Read all instructions completely and carefully and follow all instructions. Failure to follow all instructions may result in inaccurate test results.

INSTRUCTIONS FOR USE

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories certified under CLIA 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, 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 and Proclin-300.
- 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.qorvobiotech.com>

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 with dropper caps
- 1 package insert

Materials Required but Not Provided

Qorvo Omnia SARS-CoV-2 Antigen test kit, part number QPR8302

Qorvo Omnia Instrument, part number QPR9002

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
6. Press "Next"
7. Prepare the cartridge following the on-screen instructions
 - Select cartridge labeled Qorvo Omnia SARS-CoV-2 Antigen
 - Remove cartridge from pouch
 - Place cartridge on flat surface
8. Mix the control vial gently by rocking or inversion.

INSTRUCTIONS FOR USE

9. Using the dropper cap, dispense 5 drops (~100 µL) of Qorvo Omnia SARS-CoV-2 Antigen Positive Control into the sample port until the liquid is visible in the "minimum sample fill" area on the test cartridge. NOTE: ADD THE CONTROL DIRECTLY TO THE CARTRIDGE. DO NOT PROCESS THE CONTROL IN THE LYSIS BUFFER VIAL PRIOR TO DISPENSING ONTO THE TEST CARTRIDGE.
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. Record the results or print the results if connected to an external printer

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

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MANUFACTURER INFORMATION:

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