qorvo BIOTECHNOLOGIES

INSTRUCTIONS FOR USE

SARS-CoV-2 ANTIGEN

INSTRUCTIONS FOR USE

Qorvo Biotechnologies Omnia™ SARS-CoV-2 Antigen Test

FOR PRESCRIPTION USE ONLY

FOR IN VITRO DIAGNOSTIC USE ONLY

FOR USE UNDER THE EMERGENCY USE AUTHORIZATION (EUA) ONLY

INTENDED USE

The Qorvo Biotechnologies Omnia SARS-CoV-2 Antigen Test is an integrated system of instrument and reagent cartridges using immunoassay principles for the qualitative detection of nucleocapsid viral antigens from SARS-CoV-2 in direct anterior nasal (NS) swab specimens without transport media from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests.

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

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is detectable in direct anterior nasal specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The Qorvo Omnia SARS-CoV-2 Antigen test is intended for use by trained clinical laboratory personnel specifically instructed and trained in in vitro diagnostic procedures and proper infection control procedures. In the United States, the Qorvo Omnia SARS-CoV-2 Antigen test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

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

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

PRINCIPLES OF THE PROCEDURE

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

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

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

MATERIALS PROVIDED

Catalogue # QPR8302 contains four boxes and each box consists of 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 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.

INSTRUCTIONS FOR USE

MATERIALS REQUIRED BUT NOT PROVIDED

- Qorvo Biotechnologies Omnia System (Catalog number # QPR9002)
- Qorvo Biotechnologies Omnia SARS-CoV-2 External Control (Catalog # QPR8302.QC). The control kit contains vials with sufficient volume for a total of 60 tests.
- 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
  - o Conjugate: Biotinylated anti-nucleocapsid protein (rabbit monoclonal) in HEPES based buffer with surfactant. Sodium azide and Proclin™-300 at ≤ 0.05% is used as a preservative.
  - o Enzyme Enhancer: Streptavidin conjugated to alkaline phosphatase in HEPES based buffer with surfactant. Sodium azide and Proclin™-300 at ≤ 0.05% is used as a preservative.
  - o Wash Buffers: HEPES buffer based with detergent and 0.05% sodium azide and/or 0.05% Proclin™-300 as a preservative.
  - o Substrate: AMP buffer based with a precipitating substrate and detergent. Proclin™-950 at 0.05% is used as a preservative.

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

Cartridge Handling and Storage

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

CHEMICAL HAZARD AND SAFETY INFORMATION

- The reagents in the cartridge carousel and lysis buffer tubes contain less than 0.1% sodium azide.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit please refer to the Safety Data Sheets (SDS) located at www.qorvobiotech.com.

INSTRUMENT

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

WARNINGS AND PRECAUTIONS

Warnings

- For use under Emergency Use Authorization Only.
- For prescription use only.
- For in vitro diagnostic use only.
- Read all instructions completely and carefully and follow all instructions. Failure to follow all instructions may result in inaccurate test results.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by laboratories certified under CLIA that meet requirements to perform moderate or high complexity tests.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §360bbb3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.
- Use appropriate precautions in the collection, handling and storage of patient samples. Refer to CDC Interim Guidelines for Collection, Handling and Transportation of clinical specimens from persons with Coronavirus Disease 2019 (COVID-19) at https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html, and to WHO's Interim guidance for Laboratory testing for coronavirus disease (COVID-19) in suspected human cases at http://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117, as amended and supplemented. Refer to the WHO website for additional publications.
- Used swabs must be treated as infectious waste.
- All samples, even after the extraction procedure, and reagents containing biological materials used for the assay must be considered as potentially able to transmit infectious agents; accordingly samples, reagents and the waste must be handled with utmost care and disposed of in compliance with the laboratory guidelines and the statutory provisions in force in each country.
- Do not use the kit contents beyond the expiration date.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
- Strict adherence to the Qorvo Omnia SARS-CoV-2 assay instructions is necessary to obtain accurate results.
- Lysis buffer supplied with the kit should not be separated from the cartridges as testing (including extraction) is expected to be performed by trained laboratory personnel.

INSTRUCTIONS FOR USE

Safety Precautions

- Specimens may be infectious. Use Universal Precautions when performing this assay.
- Use routine laboratory precautions. Do not eat, drink, or smoke in the area where samples are being handled and testing is being conducted. Avoid any contact between hands, eyes or mouth during sample collection and testing.
- Wear personal protective equipment (PPE) in accordance with laboratory and institutional policies, such as laboratory coats, disposable gloves, and eye protection when handling patient samples.
- Wash hands thoroughly after handling specimens and used cartridge.
- Dispose of used cartridge in a biohazard waste container. Proper handling and disposal methods should be established according to local regulations.
- Avoid splashing or aerosolization of samples or reagents as droplets are a means of transmission of SARS-CoV-2 virus. All drops and spills must be wiped up with an appropriate disinfectant such as a sodium hypochlorite solution with 0.5% active chlorine, and all soiled materials must be disposed of as infectious waste.

SPECIMEN COLLECTION AND PREPARATION

Patient Preparation

No special patient preparation is necessary.

Specimens Recommended

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

Specimen Collection

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

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.

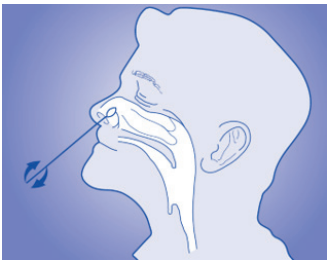

Figure 1: Nasal specimen collection

- 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 Omnia SARS-CoV-2 Antigen test.

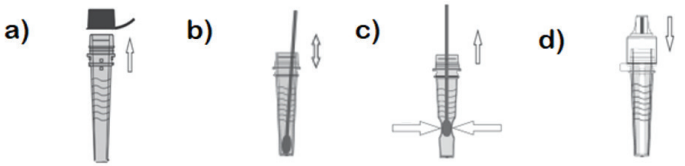

Figure 2: Specimen processing

Specimen Handling and Storage Conditions

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

TEST PROCEDURE

Operating Instructions

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

9. Enter "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 the arrow on the cartridge.
11. If prompted, select the sample type. Press "Next".
12. Press "Confirm" and the test will run automatically.

Figure 3: Specimen loading

13. After the test is complete, the cartridge will be ejected from the instrument and results (AU/mL and positive/negative) will be displayed on the screen.
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. 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

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

Interpretation of Results

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

LIMITATIONS OF THE PROCEDURE

Limitations

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

- The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. This is especially important if the patient has had recent exposure to COVID-19, or clinical presentation indicates that COVID-19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. In this case, direct testing for the SARS-CoV-2 virus (e.g. PCR testing) should be considered.
- Positive results do not rule out co-infections with other pathogens.
- Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.

Conditions of Authorizations for the Laboratories
The Qorvo Omnia SARS-CoV-2 Antigen test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2. 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 your 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 your product prior to initiating testing.
D. Authorized laboratories using the Qorvo Omnia SARS-CoV-2 Antigen test must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
E. Authorized laboratories must collect information on the performance of the Qorvo Omnia SARS-CoV-2 Antigen test and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Qorvo Biotechnologies 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 your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

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

PERFORMANCE CHARACTERISTICS

Clinical Performance

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

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

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

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

Statistic	Estimate
Sensitivity (Positive Percent Agreement)	51/57 (89.47%) (95% CI 78.88%-95.09%)
Specificity (Negative Percent Agreement)	32/32 (100%) (95% CI 89.28%-100%)
Positive Predictive Value (PPV)	51/51 (100%) (95% CI 93.00%-100%)
Negative Predictive Value (NPV)	32/38 (84.21%) (95% CI 68.58%-92.56%)

PPV: proportion of positive device results that are true positive
NPV: proportion of negative device results that are true negative

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

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 $2.8x10^6$ $TCID_{50}$/mL ($1.75x10^9$ genome equivalents/mL) and diluted to respective concentrations with negative pooled nasal wash matrix. For each test, 50 µL of sample was absorbed onto a flocked swab and the swab was tested per the above specimen processing instructions.

Limit of Detection – Initial Assessment
An initial LoD study was performed using a 5-fold serial dilution of the characterized inactivated SARS-CoV-2 virus into pooled negative human nasal matrix. A total of 4 dilutions were tested in triplicate with the starting concentration being 15,625 $TCID_{50}$/mL. The lowest concentration at which all replicates (3 of 3 replicates) were positive, 625 $TCID_{50}$/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 $TCID_{50}$/mL (125,000 genome equivalents/mL).

SARS-CoV-2 Refined LoD Assessment and Confirmation

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

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

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

Organism	Concentration
Human coronavirus 229E	1.51×10^6 $TCID_{50}$/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 U/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 U/mL
Influenza B	4.17×10^5 $TCID_{50}$/mL
Legionella pneumonphila	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
Pooled human nasal wash	100%
Respiratory syncytial virus type A	3.16×10^6 U/mL
Respiratory syncytial virus type B	1.26×10^6 $TCID_{50}$/mL
Rhinovirus	4.17×10^5 U/mL
Staphylococcus aureus	5.5×10^9 CFU/mL
Staphylococcus epidermidis	9.27×10^9 CFU/mL
Streptococcus pneumoniae	2.26×10^9 CFU/mL
Streptococcus pyogenes	1.64×10^9 CFU/mL

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

- SARS-CoV-1: BLAST results showed high homology between the nucleocapsid of SARS-CoV-1 reference isolates TW11 and BJ01 and SARS-CoV-2. Alignment results for isolate TW11 Sequence ID AAR87518.1 (Query Cover: 100%, Percent Identity: 90.76) and isolate BJ01 Sequence ID AAP30037.1 (Query Cover: 100%, Percent Identity: 90.52%) means cross-reactivity cannot be ruled out.

- Human Coronavirus HKU1: BLAST results showed 36 sequence IDs, all nucleocapsid protein, showing homology. The top two alignment scores were Sequence ID AXT92485.1 (Query Cover: 82%, Percent Identity: 36.74%) and Sequence ID AGW27840.1 (Query Cover: 76%, Percent Identity: 39.10%). Homology is relatively low, but cross-reactivity cannot be ruled out.

Endogenous Interference Substances
The following substances, either naturally present in respiratory specimens or artificially introduced into the nasal passage, were evaluated with the Qorvo Omnia SARS-CoV-2 Antigen test at the concentrations listed below. Each material was prepared individually in the absence and presence of 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 $2.8x10^6$ $TCID_{50}$/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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DOCUMENT VERSION

Part Number: QPR8302-PK075
Revision: E
Date: June 2021
SAP #: QPR8302IFU.01