

AcculaTM

TEST



SARS-CoV-2 Test

Accula™

TEST



SARS-CoV-2

IVD

R_x only

REF

COV4100

For use under the Emergency Use Authorization (EUA) only

For in vitro diagnostic use

For use with Nasal and Nasal Mid-Turbinate Swabs

For use with the Accula™ Dock and Silaris™ Dock

Instructions For Use (60061 Rev. 4)

INTENDED USE

The Accula™ SARS-Cov-2 Test performed on the Accula™ Dock or the Silaris™ Dock is a molecular in vitro diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of the coronavirus SARS-CoV-2 viral RNA. The Accula SARS-CoV-2 Test uses nasal or nasal mid-turbinate swab specimens, collected from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The Accula SARS-CoV-2 Test is also 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..

Accula SARS-CoV-2 Test results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; 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. Testing facilities within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Accula SARS-CoV-2 Test is intended for use by trained operators who are proficient in performing tests on the Accula Dock and Silaris Dock. The Accula SARS-CoV-2 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

The Accula™ SARS-Cov-2 Test performed on the Accula™ Dock or the Silaris™ Dock is a molecular in vitro diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of the coronavirus SARS-CoV-2 viral RNA. The Accula SARS-CoV-2 Test uses a nasal or nasal mid-turbinate swab specimen collected from patients who meet CDC SARS-CoV-2 clinical criteria and in conjunction with epidemiological criteria to aid in the diagnosis of SARS-CoV-2 infection.

PRINCIPLE OF THE TEST

The Accula SARS-CoV-2 Test is a Nucleic Acid Amplification Test (NAAT) for detection of SARS-CoV-2 viral RNA in approximately 30 minutes. To perform the test, nasal or nasal mid-turbinate specimens are added to the SARS-CoV-2 Buffer to solubilize the sample. An aliquot of the SARS-CoV-2 Buffer is then dispensed into an Accula SARS-CoV-2 Test Cassette. The Test Cassette contains internal process positive and negative controls, enzymes, OscAR™ reagents, and a detection strip necessary for the 4

steps in the assay. These 4 steps are lysis of the virus, reverse transcription of viral RNA to cDNA, nucleic acid amplification, and detection. The Accula Dock controls reaction temperatures, timing, and fluid movements within the Test Cassette resulting in a fast and automated SARS-CoV-2 assay. After approximately 30 minutes, the test results are interpreted by the visualization of Blue Test Lines on the detection strip in the Test Cassette. A blue process control line at the control (C) area is used to ensure proper reagent and Accula Dock function and to confirm a valid negative test result.

REAGENTS AND MATERIALS

MATERIALS PROVIDED



SARS-CoV-2 Test Cassette



SARS-CoV-2 Buffer



Transfer Pipette



Sterile Swabs



SARS-CoV-2 High Positive Control Swab
SARS-CoV-2 Low Positive Control Swab
SARS-CoV-2 Negative Control Swab

ACCULA SARS-COV-2 TEST CONTENTS:

- Collection Swabs (25): Sterile swabs for nasal sample collection
- SARS-CoV-2 Buffer (25): Single-use vial of solution containing 5 mL of buffer with dimethyl sulfoxide and < 0.01% sodium azide.
- Transfer Pipette (25): Single-use, fixed volume Pipette used to transfer sample from the SARS-CoV-2 Buffer vial into the Test Cassette. NOTE: Supplied within the Test Cassette Pouch. Extra pipettes provided for your convenience.
- Accula SARS-CoV-2 Test Cassette (25): Single-use, foil-pouched with desiccant and Test Cassette containing lyophilized reagents for the targeted amplification and detection of bacterial nucleic acid.
- SARS-CoV-2 High Positive Control swab (1): DNA Based Synthetic Oligo dried onto a swab well-above the limit of detection of the test.
- SARS-CoV-2 Low Positive Control swab (1): DNA Based Synthetic Oligo dried onto a swab near the limit of detection of the test.
- SARS-CoV-2 Negative Control swab (1): buffer solution dried onto a swab
- Instructions For Use (IFU) (1)
- Quick Reference Guide (QRG) (1)

MATERIALS PROVIDED SEPARATELY

Accula Dock (Catalog # D2000) or Silaris Dock (Catalog #1026)

Accula SARS-CoV-2 Control Kit (Catalog #COV4100-1)

STORAGE AND HANDLING

- Store reagents at room temperature (15°C - 30°C, 59°F - 86°F). Do not refrigerate or freeze.
- Do not reuse kit contents: Collection Swabs, Test Cassettes, Transfer Pipettes, Control Swabs, or SARS-CoV-2 Buffer.
- Do not remove the Test Cassette from the foil pouch until immediately before use (within 30 minutes).
- Do not use kit or reagents past the expiration date.
- Sample stability when using Accula SARS-CoV-2 Test has not been established for suggested temperatures and time, but is based on viability data from testing similar viruses in the Accula SARS-CoV-2 Test Buffer.
- For best results, nasal swabs should be tested immediately after collection. If immediate testing is not possible, a swabs can be stored in its original packaging at room temperature (15°C to 30°C, 59°F to 86°F) for up to 2 hours prior to testing or refrigerated at 2°C - 8°C and tested within 24 hours from the time of collection.
- Prepared samples may be kept at room temperature (15°C to 30°C, 59°F to 86°F) for up to 24 hours or refrigerated at 2°C - 8°C and tested within 72 hours from the time of preparation.
- Prepared samples may be stored for up to 1 week at -20°C; longer storage should be at -80°C or colder.

PRECAUTIONS

- For in vitro diagnostic use under Emergency Use Authorization only.
- This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. The Test is also 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 test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This test 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 authorization is terminated or revoked sooner.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- To be used in conjunction with the Accula Dock or Silaris Dock.
- Follow universal precautions when handling patient samples. All patient samples should be treated as if potentially infectious. Follow standard BSL-2 guidelines when working with patient samples. Put on the appropriate personal protective equipment.
- DNA Based Synthetic Oligo is used to make the positive control swabs. However, Control Swabs, patient samples and Test Cassettes should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- Dispose of kit reagents and patient samples according to all local, state and federal regulations.
- Do not use Swabs or SARS-CoV-2 Buffer other than those provided with the Accula SARS-CoV-2 Test Kit.
- Do not write on the Test Cassette except in the indicated area on the Test Cassette label for recording sample identification and test date.
- Do not remove the foil tab from the Test Cassette until immediately before use. Once the tab is removed, add sample immediately (within 5 minutes) and start testing.
- Once sample is added and the Dock lid is closed, the test has started. Do not move the Dock, open the lid, or unplug the Dock until the Dock indicates the test has completed.
- Do not use any damaged kit contents.
- Do not use kit components after their expiration date.
- Sample collection and handling procedures require specific training and guidance.
- All test kit components are single use items. Do not use with multiple specimens.
- To help obtain accurate results, follow all instructions and regard all precautions in this Instructions For Use.
- Inadequate or inappropriate sample collection, handling, processing, and/or storage can yield inaccurate results.
- Use only the fixed volume Transfer Pipette provided in the kit to transfer the patient sample from the Accula SARS-CoV-2 Buffer tube into the Test Cassette port. Do not pour the patient sample from the Accula SARS-CoV-2 Buffer vial into the Test Cassette sample port.
- Do not use visually bloody or overly viscous samples.
- When transferring the prepared patient sample, avoid drawing up large particulates, which may clog the Transfer Pipette.
- Due to the high sensitivity of the Accula SARS-CoV-2 Test, contamination of the work area with previous samples may cause false positive results. Clean the Accula Dock or Silaris Dock and surrounding surfaces as described in the procedure in the Accula Dock or Silaris Dock Operators Guide.
- Do not attempt to open a used Test Cassette or a Test Cassette with closed sample port.

- Do not touch the heads of the Control Swabs. Cross contamination may occur due to the high sensitivity of the test.
- Use the Results Interpretation table in this Instructions For Use to interpret results accurately.

QUALITYCONTROL

Process Controls

Each Accula SARS-CoV-2 Test Cassette contains two internal process controls: an internal positive control (labeled 'C' on the Test Cassette) and negative control (labeled 'NC' on the Test Cassette). The positive process control is a non-infectious RNA bacteriophage in the Test Cassette and is used as the positive process control to verify assay steps (RNA extraction, reverse transcription, amplification and detection) were executed properly. A non-SARS-CoV-2 nucleic acid probe is used as a negative control for false positive results due to nonspecific binding.

Refer to the Interpretation of Results section of this Instruction For Use for instructions on interpreting the results for the Process Control

External Positive and Negative Controls

External controls may be used to show that the Accula SARS-CoV-2 Test is working properly. The Accula SARS-CoV-2 Test kit contains three Control Swabs:

- 1 SARS-CoV-2 High Positive Control Swab
- 1 SARS-CoV-2 Low Positive Control Swab
- 1 SARS-CoV-2 Negative Control Swab

Mesa Biotech recommends that a SARS-CoV-2 negative and SARS-CoV-2 positive controls be run:

- Once for each new lot or shipment of kits received
- Once for each new operator
- As deemed additionally necessary to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

Additional Control Swabs may be purchased from Mesa Biotech (Catalog # COV4100-1). Run control swabs using the same procedure as for a patient specimen.

If External QC testing fails, repeat the test using a new Control swab, reagent and test cassette or contact Mesa Biotech Technical Support for assistance before testing patient samples.

SPECIMEN COLLECTION AND HANDLING

Each test should be completed with a nasal swab sample using one SARS-CoV-2 Buffer vial.

Proper sample collection is an important step for an accurate test result. Carefully follow the instructions below.

NOTE: Use only the Collection Swabs supplied with the kit or one of the approved swab types listed below:

- Puritan Sterile Rayon Swab w/ Polystyrene Handle (REF. 25-806-1PR)
- Puritan Sterile Standard Foam Swab w/Polystyrene Handle (REF. 25-1506 1PF)
- Copan FLOQSwabs™
 - (REF. 56380CS01) - Contoured Adult Size Nylon® Flocked Swab with Stopper with 80mm Breakpoint
 - (REF. 56780CS01) - Contoured Pediatric Size Nylon® Flocked Swab with Stopper with 80mm Breakpoint
 - (REF. 56750CS01) - Contoured Pediatric Size Nylon® Flocked Swab with Stopper with 50mm Breakpoint
- McKesson Cotton Tip Wood Shaft 6 Inch Sterile (REF. 24-106-2S or REF. 24-106-1S)
- Dynarex Cotton Tipped Applicators (REF. 4305)

Nasal Swab Sample

To collect a nasal swab sample, insert a new sterile swab approximately 1 inch into the patient's nostril. Firmly rotate the swab against the nasal wall for 10-15 seconds.

Using the same swab, repeat this sampling procedure in the other nostril.

Nasal Mid-Turbinate Swab Sample

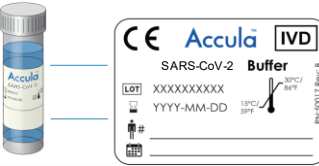
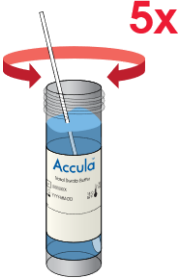


To collect a nasal mid-turbinate swab sample, first tilt the patient's head back 70 degrees. While gently rotating the mid-turbinate

swab, insert swab into the nostril until resistance is met at turbinates. Rotate the swab several times against nasal wall.

Using the same swab, repeat this sampling procedure in the other nostril.

SAMPLE STORAGE AND SAMPLE EXTRACTION

- For best results, swabs should be tested immediately after sample collection. If immediate testing is not possible, a direct nasal swab can be stored in its original packaging at room temperature (15°C to 30°C, 59°F to 86°F) for up to 2 hours prior to testing. If a direct nasal swab cannot be tested within 2 hours, it can be refrigerated at 2°C - 8°C and tested within 24 hours from the time of collection.
- **For best results, do not freeze the prepared sample prior to testing.**
- Patient nasal swabs previously stored in viral transport media are not recommended and may yield invalid results or false results.

<p>Write the patient identification (ID) information and testing date onto the SARS-CoV-2 Buffer vial label in the area provided.</p>	
<p>Insert the nasal swab specimen into the SARS-CoV-2 Buffer and rotate it 5 times rubbing it against the wall of the vial.</p> <p>Remove the patient nasal swab from the SARS-CoV-2 Buffer vial and discard it into a biohazardous waste container.</p>	
<p>Replace the cap on the SARS-CoV-2 Buffer vial.</p> <p> If immediate testing is not possible, the prepared sample may be stored at room temperature (15°C - 30°C, 59°F - 86°F) for up to 24 hours.</p> <p>The prepared sample may be refrigerated at 2°C - 8°C and tested within 72 hours from the time of collection. Sample may be stored for up to 1 week at -20°C.</p>	





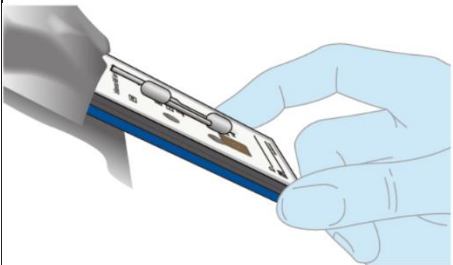


TEST PROCEDURE



All clinical samples must be at room temperature before beginning the assay.



Check expiration date on outer box before using. Do not use any Test after the expiration date on the box.

<p>Place Dock on a flat surface.</p> <p>Connect the AC Adapter to the Power Cord.</p> <p>Insert round end of the power cord into the Dock. Plug the AC end of the power cord into an electrical outlet.</p>	
<p>Open the Dock by depressing the black button located on the top left.</p>	
<p>Verify the Dock screen displays: "DOCK READY INSERT CASSETTE".</p>	
<p> <u>Do not open the foil pouch until the sample is ready for testing. Initiated the test within 30 minutes of opening.</u></p> <p>Remove a Test Cassette and Transfer Pipette from the foil package (these items are packaged together).</p> <p>Write the patient identification (ID) information and testing date on the Test Cassette label in the area provided.</p> <p>NOTE: The foil pouch contains a desiccant pack. This can be discarded after Test Cassette and Transfer Pipette are removed.</p>	
<p>Insert the Test Cassette into the Dock, leaving the lid open. Press the Test Cassette down firmly to seat it in the Dock.</p> <p>NOTE: Do NOT remove the foil tab covering the sample port until immediately before testing.</p> <p> <u>Once the test cassette is placed into the Dock, you have 5 minutes to add the sample into the Test Cassette.</u></p>	

Do not close Dock lid until sample has been added to the Test Cassette.

Verify the Dock screen displays: "SARS-COV-2 CASS. INSERTED"

The Dock screen will then display: "ADD SAMPLE THEN CLOSE LID"

SARS-COV-2
CASS. INSERTED

ADD SAMPLE
THEN CLOSE LID

Invert SARS-CoV-2 Buffer vial to mix.

Remove the cap from the prepared patient sample in the SARS-CoV-2 Buffer.



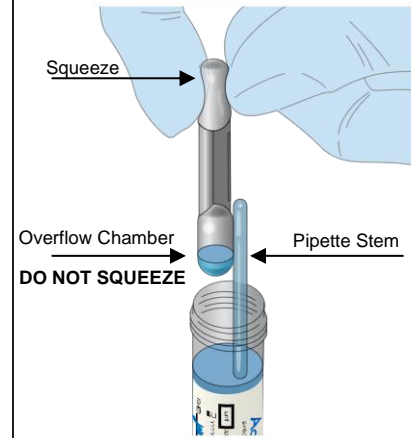
Firmly squeeze the **TOP** bulb of the pipette.

While continuing to squeeze the top bulb firmly, place the pipette tip well below the surface of the liquid in the SARS-CoV-2 Buffer vial.

Keep the pipette tip well below the surface of the liquid of the vial containing the prepared patient sample in SARS-CoV-2 Buffer vial.

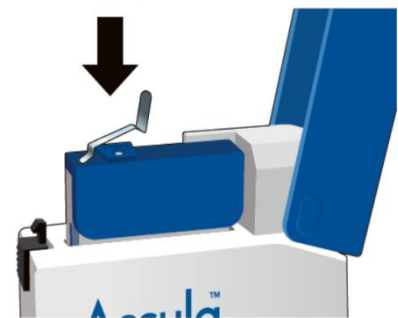
Slowly release the top bulb to completely fill the pipette stem with sample. Some liquid may also be in the overflow reservoir.

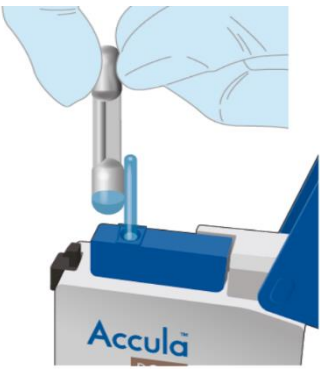
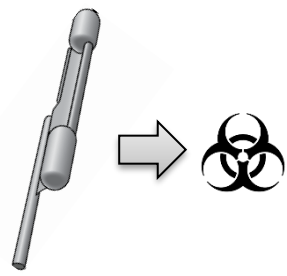
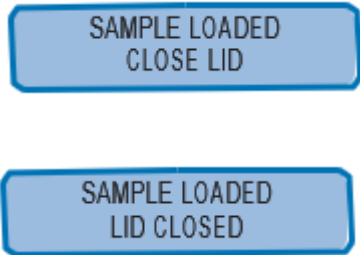


NOTE: Although excess liquid will enter the pipette's overflow chamber, only the liquid in the pipette stem will be dispensed.


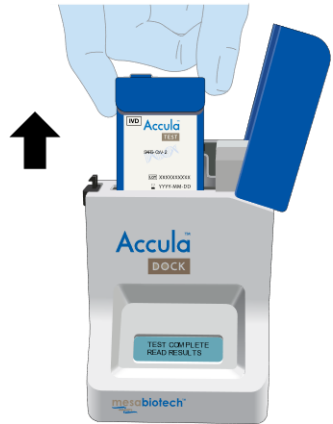
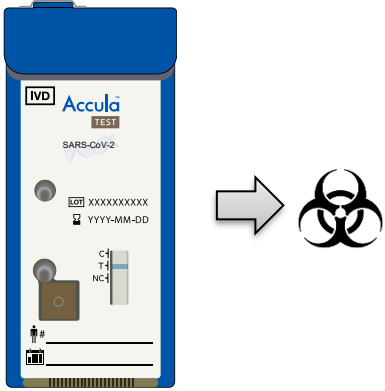


Completely remove the foil tab covering the sample port on the Test Cassette. Discard the foil tab.

NOTE: Once the tab is removed from the sample port, sample must be added immediately (within 5 minutes).



<p>Insert the tip of the pipette all the way into the sample port of the Test Cassette until resistance is met.</p> <p>Squeeze the TOP bulb of the pipette firmly to dispense all of the sample from pipette stem into the Test Cassette.</p> <p>NOTE: A small amount of sample may remain in the overflow chamber (lower bulb). This is normal.</p>	
<p>Dispose of the Pipette in a biohazardous waste container.</p>	
<p>The Dock screen will then read: “SAMPLE LOADED CLOSE LID”.</p> <p>Close the lid of the Dock immediately to automatically begin the test program.</p> <p>Verify the Dock screen displays: “SAMPLE LOADED LID CLOSED”.</p>	
<p>Verify the Dock screen displays: “CASSETTE SEALED TEST STARTED”.</p>	
<p>Verify the Dock screen displays: “TEST RUNNING REMAINING XX:XX”.</p> <p>Note: The test takes approximately 30 minutes to complete. The screen will continue to display “TEST RUNNING” until complete. The Dock will beep at the end of test processing.</p> <p>⚠ Do not re-open the Dock lid until the display indicates the test is complete. Do not move or unplug the Dock while the test is processing.</p>	

<p>Verify the Dock screen displays: “TEST COMPLETE READ RESULTS”.</p>	
<p>Open the lid of the Dock.</p> <p>Remove the Test Cassette and interpret the results according to the Interpretation of Results section below.</p> <p>Note: Results should be interpreted within 1 hour of test completion</p>	
<p>Dispose of the Test Cassette in the biohazardous waste container.</p>	

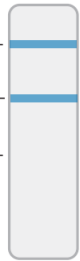
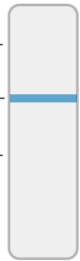

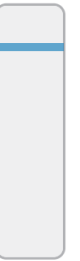




INTERPRETATION OF RESULT

NOTE: LOOK CLOSELY WHEN INTERPRETING RESULTS! The appearance of any shade of Blue Test Line at the “T” position is a valid result that is interpreted as positive for SARS-CoV-2. A negative result will only contain a Blue Test Line at the “C” position.

C = Internal Positive Process Control

T = SARS-CoV-2

NC = Internal Negative Process Control

Window	Window	Window	Interpretation	
			Positive test for SAR-CoV-2	<p>Take time to look at test lines very carefully.</p> <p>The appearance of ANY shade of a Blue Test Line at the T position indicates a positive result for the presence of SARS-CoV-2.</p> <ul style="list-style-type: none"> • WITH OR WITHOUT the appearance of a blue process control line at the C position • AND the absence of a negative process control line NC position
			Negative test for SAR-CoV-2	<p>Take time to look at test lines very carefully.</p> <p>The absence of ANY shade of a Blue Test Line at the T position indicates a negative result for the presence of SARS-CoV-2.</p> <ul style="list-style-type: none"> • AND the presence of a blue process control line at the C position • AND the absence of a negative process control line NC position
			Invalid Result*	<p>Take time to look at test lines very carefully.</p> <p>The appearance of ANY shade of a negative process control line at the NC position indicates an invalid test.</p> <p>The appearance of ALL or NO lines at the C, T and NC position indicates an invalid test.</p>

***If an invalid result is obtained, the sample may be rerun with a fresh Test Cassette only if the prepared sample has been stored for less than 24 hours at room temperature. (15°C - 30°C or 59°F -86°F). Alternatively, a new sample should be collected and run with a new Buffer and Test Cassette.**

NOTE: The absence of a Blue Test Line at the “C” position in conjunction with a Blue Test Line at the “T” position means that the SARS-CoV-2 target was amplified and detected as a valid result. This can occur due to the overabundance of SARS-CoV-2 target that competes with the Control target.

DOCK CLEANING

Mesa Biotech recommends cleaning the Dock each day it is used.

Procedure:

Clean the Accula or Silaris Dock and surrounding area according to the instructions provided in the cleaning section of the Accula Dock or Silaris Dock Operator's Guide.

LIMITATIONS

- The performance of the Accula™ SARS-Cov-2 Test was determined using the procedures provided in this Instructions For Use. Failure to follow these procedures may alter test performance.
- The Accula™ SARS-Cov-2 Test is for use with nasal or nasal mid-turbinate swab specimens.
- Improper collection, storage or transport of specimens may lead to false negative or invalid results.
- Test results should be interpreted in conjunction with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests performed.
- As with other tests, negative results do not rule out SARS-CoV-2 infections and should not be used as the sole basis for patient management decisions.
- Detection of SARS-CoV-2 RNA may be affected by sample collection methods, patient factors (e.g., presence of symptoms), and/or stage of infection.
- False negative or invalid results may occur due to interference or the presence of inhibitors. The Internal Control is included Accula SARS-CoV-2 Test to help identify the specimens containing interfering substances or inhibitors.
- This is a qualitative test. Test line intensity is not indicative of the quantity of virus in the sample.
- False negative results may occur if viruses are present at levels below the test's limit of detection.
- False negative results may occur if mutations are present in the regions targeted by the test.
- Cross-reactivity with respiratory tract organisms other than those listed in the Analytical Specificity Study may lead to erroneous results.
- This test cannot rule out diseases caused by other viral or bacterial agents.
- Analyte targets (viral nucleic acid) may persist in vivo, independent of virus viability. Detection of analyte targets does not imply that the corresponding viruses are infectious, or are the causative agents for clinical symptoms.

Conditions of Authorization for Laboratories and Patient Care Settings

The Accula SARS-CoV-2 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/vitro-diagnostics-euas>

To assist clinical laboratories using the Accula SARS-CoV-2 Test, the relevant Conditions of Authorization are listed below, and are required to be met by laboratories and/or patient care settings performing the test.

- A. Authorized laboratories¹ and patient care settings using the Accula SARS-CoV-2 test will include with result reports of the Accula SARS-CoV-2 Test 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 and patient care settings using the Accula SARS-CoV-2 Test will perform the Accula SARS-CoV-2 Test as outlined in the Accula SARS-CoV-2 Test Instructions for Use. Deviations from the authorized procedures, including authorized clinical specimen types and authorized control materials required to perform the Accula SARS-CoV-2 Test, are not permitted.
- C. Authorized laboratories and patient care settings that receive the Accula SARS-CoV-2 Test must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- D. Authorized laboratories and patient care settings using the Accula SARS-CoV-2 Test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories and patient care settings will collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Mesa Biotech, Inc. Technical Support (via email: info@mesabiotech.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they have become aware.
- F. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- G. Mesa Biotech, its authorized distributors and authorized laboratories and patient care settings using the Accula SARS-CoV-2 Test will 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.

¹ The Letter of Authorization refers to "laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to high, moderate or waived complexity tests. The Test is also 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

Limit of Detection

Limit of Detection (LoD) testing was performed with RNA: SARS-CoV-2 RNA/strain USA_WA1/2020. For each replicate, a contrived sample was prepared by pipetting 5 µL of the RNA dilution into 55 µL of three diluents: 1) Accula SARS-CoV-2 Buffer, 2) Pooled negative Throat Swab human clinical matrix, and 3) Pooled negative Throat and Nasal Swab human clinical matrix. Twenty replicate samples were prepared for each dilution. The dilution that reproducibly produced at least 19/20 (95%) positive results was confirmed as the LoD.

The LoD was determined to be 200 copies/reaction when tested in either of the two human clinical matrices. This LoD was used when preparing samples for other performance testing. In Accula SARS-CoV-2 buffer, the LoD was determined to be 100 copies/reaction. The data are summarized in the table below.

Accula SARS CoV-2 Test Limit of Detection (LoD)	
RNA Diluted in Accula SARS-CoV-2 Buffer	
Final Concentration	Test Result
100 copies per reaction	20/20
50 copies per reaction	15/20
RNA Diluted in Pooled Throat Swab Human Clinical Matrix	
Final Concentration	Test Result
200 copies per reaction	20/20
100 copies per reaction	18/20
RNA Diluted in Pooled Throat and Nasal Swab Human Clinical Matrix	
Final Concentration	Test Result
200 copies per reaction	19/20
100 copies per reaction	17/20

Analytical Reactivity/Inclusivity

Due to the limited availability of SARS-CoV-2 isolates for inclusivity testing, *in silico* analysis was employed to evaluate the extent of homology between Accula SAR-CoV-2 primer and probes and all sequenced SARS-CoV-2 isolates available in the public databases (NCBI and GISAID). 404 sequences were examined using BLAST to identify the extent of predicted assay inclusivity. The table below summarizes the homology between 404 SARS-CoV-2 sequences and the proposed Accula SARS-CoV-2 Test primers and probes. Where homology is less than 100%, sequence changes are listed. The forward primer shares 100% homology with 351 of the 404 available sequences. 7 isolates carry a single polymorphism (96.8% homology) in the forward primer binding region near the primer 5' end. 46 isolates, reported predominantly from the Netherlands and Switzerland, carry 3 mismatches (90.3% homology) in the 5' half of the primer. 403 of the 404 available SARS-CoV-2 isolates are 100% homologous to the reverse primer sequence with one reported sequence carrying an N in the sequence data in the reverse primer binding region. Both capture and detection probes share 100% homology with all 404 sequences. Primers and probes are predicted to detect all 404 sequences currently available for analysis.

In Silico Analysis of Inclusivity for the Accula SARS-CoV-2 Test

Oligonucleotide	100% Homology	< 100% Homology
N gene Forward Primer	351/404	96.8% homology G->A in 7 sequenced isolates 90.3% homology GGG->AAC in 46 sequenced isolates
N gene Reverse Primer	403/404	N at 5' end in one isolate
Detection Probe	404/404	NA
Capture Probe	404/404	NA

Analytical Specificity –Exclusivity (Cross Reactivity)

The table below summarizes the findings of *in silico* exclusivity analysis examining the homology between the indicated organisms and the Accula SARS-CoV-2 Test primers and probes. Potential interactions are noted where primer homology exceeds 75%. SARS-CoV is the only organism identified as potentially cross-reactive by *in silico* analysis. While the primer binding sites are well conserved between sequenced isolates of SARS-CoV and SARS-CoV-2, the capture and detection probe binding regions share only 70% and 65% homology respectively. Probe homology with the consensus of a 226 sequence SARS-CoV alignment is listed in Table 3. Based only on sequence analysis, we cannot rule out the possibility that the Accula SARS-CoV-2 Test may cross-react with SARS-CoV. However, the low prevalence of SARS-CoV renders the observation of cross-reactivity unlikely. Indeed, SARS-CoV has not been detected in the human population since 2004.

In addition to *in silico* analysis, the Accula SARS-CoV-2 Test will be challenged with nucleic acids isolated from human coronaviruses OC43, NL63, HKU1 and 229E to confirm the test does not cross-react with these human coronaviruses.

In Silico Analysis of exclusivity for the Accula SARS-CoV-2 Test

Organism	Homology
SARS-CoV	Forward primer 93.5% homology with SARS-CoV Consensus Reverse primer 90.3% homology SARS-CoV Consensus Detection probe 65% homology with SARS-CoV Consensus Capture probe 70% homology with SARS-CoV Consensus
MERS-CoV	No alignment found
Human coronavirus 229E	No alignment found
Human coronavirus OC43	No alignment found
Human coronavirus HKU1	No alignment found
Human coronavirus NL63	No alignment found
Adenovirus	No alignment found
Human Metapneumovirus	No alignment found
Parainfluenza virus 1-4	No alignment found
Influenza A & B	No alignment found
Enterovirus	No alignment found
Respiratory Syncytial virus	No alignment found
Rhinovirus	No alignment found
<i>Chlamydia pneumoniae</i>	No alignment found
<i>Haemophilus influenza</i>	No alignment found
<i>Legionella pneumophila</i>	No alignment found
<i>Mycobacterium tuberculosis</i>	No alignment found
<i>Streptococcus pneumoniae</i>	No alignment found
<i>Streptococcus pyogenes</i>	No alignment found
<i>Bordetella pertussis</i>	No alignment found
<i>Mycoplasma pneumoniae</i>	No alignment found
<i>Pneumocystis jirovecii</i>	No alignment found
<i>Candida albicans</i>	No alignment found
<i>Pseudomonas aeruginosa</i>	No alignment found
<i>Staphylococcus epidermis</i>	No alignment found
<i>Staphylococcus salivarius</i>	No alignment found

Exclusivity (Cross-Reactivity) Testing

The exclusivity study was performed by testing 32 potentially cross-reacting organisms with the Accula SARS-CoV-2 Test. Each organism was diluted in a pooled negative human throat swab and nasal swab matrix and tested in triplicate. The organisms and concentrations are shown in the table below. None of the 32 organisms cross-reacted in the Accula SARS-CoV-2 Test at the concentrations tested.

Cross-Reactivity Testing for the Accula SARS-CoV-2 Test

Target Organisms	Organism Reference Number or strain available	Unit	Concentration Tested	% Agreement with Expected Result
Adenovirus (e.g. C1 Ad. 71)	Type 1	TCID50/mL	5.10E+06	100% (3/3)
Human Metapneumovirus (hMPV)	IA14-2003	TCID50/mL	1.00E+05	100% (3/3)
Parainfluenza Type 1	Type1	TCID50/mL	1.00E+05	100% (3/3)
Parainfluenza Type 2	Type2	TCID50/mL	1.00E+05	100% (3/3)
Parainfluenza Type 3	Type3	TCID50/mL	1.00E+05	100% (3/3)
Influenza A	Texas	TCID50/mL	5.00E+06	100% (3/3)
Influenza B	Nevada	CEID50/mL	8.00E+06	100% (3/3)
Enterovirus (e.g. EV68)	Type 71	TCID50/mL	1.00E+05	100% (3/3)
Respiratory syncytial virus	CH93(18)-18	TCID50/mL	1.00E+05	100% (3/3)

Rhinovirus	A16	TCID50/mL	1.00E+05	100% (3/3)
Chlamydia pneumoniae	VR-1310	cfu/ml	6.25E+05	100% (3/3)
Haemophilus influenzae	Type b; Eagan	cfu/ml	1.20E+07	100% (3/3)
Legionella longbeachae	Long Beach 4	cfu/ml	9.65E+07	100% (3/3)
Mycobacterium tuberculosis	H37Ra-1	cfu/ml	3.62E+07	100% (3/3)
Streptococcus pneumoniae	19F; Z022	cfu/ml	2.09E+07	100% (3/3)
Streptococcus pyogenes	BAA946	cfu/ml	7.15E+07	100% (3/3)
Bordetella pertussis	A639	cfu/ml	4.22E+07	100% (3/3)
Mycoplasma pneumoniae	M129	CCU/ml	2.81E+06	100% (3/3)
Pneumocystis jirovecii (PJP)	W303-Pji	cfu/ml	7.80E+06	100% (3/3)
Candida albicans	Z006	cfu/ml	9.80E+06	100% (3/3)
Pseudomonas aeruginosa	Z139; VIM-1	cfu/ml	6.05E+06	100% (3/3)
Staphylococcus epidermis	MRSE; RP62A	cfu/ml	3.24E+08	100% (3/3)
Staphylococcus saprophyticus	Z170	cfu/ml	9.50E+06	100% (3/3)
Human coronavirus 229E	ATCC® VR-740DQ	genome copies/μL	1.30E+04	100% (3/3)
Human coronavirus OC43	ATCC® VR-1558D	ng/ul	2.50E-03	100% (3/3)
Human coronavirus HKU1	ATCC® VR-3262SD	genome copies/μL	2.85E+04	100% (3/3)
Human coronavirus NL63	ATCC® VR-3263SD	genome copies/μL	3.40E+04	100% (3/3)
SARS-coronavirus	2003-00592	cfu/ml	NA*	100% (3/3)
MERS-coronavirus	EMC/2012	genome copies/μL	NA*	100% (3/3)
Escherichia coli	Clinical Isolate	cfu/ml	1.92E+08	100% (3/3)
Burkholderia cepacia	Z066	cfu/ml	2.07E+08	100% (3/3)
Klebsiella pneumoniae	Z148, OXA-48, CTX-M	cfu/ml	4.15E+08	100% (3/3)

*Information currently not available from supplier

Analytical Specificity - Interfering Substances

To assess substances with the potential to interfere with the performance of the Accula SARS-CoV-2 Test, contrived samples with SARS-CoV-2 RNA (SARS-CoV-2 RNA/strain USA_WA1/2020) were tested in replicates of three (3) with each interfering substance at the “worst case” concentration, and negative samples without RNA were tested in replicates of two (2) with each interfering substance at the “worst case” concentration. The SARS-CoV-2 RNA was tested at 3X the LoD confirmed in the Limit of Detection Study described above. For each positive sample, RNA was diluted into a pooled negative nasal and throat mix swab matrix to achieve a 3X LoD concentration.

The SARS-CoV-2 RNA was tested with an interferent concentration representing the highest concentration likely to be found in a respiratory or throat sample. Potentially interfering substances that were sourced in their solid phase were re-suspended and diluted to a concentration deemed to be likely worst case. Liquid phase potential interferents were not diluted before testing. Additionally, the SARS-CoV-2 RNA was tested without the interfering substance as a control. Potential interferents and their concentrations, samples tested, and test results are summarized in the table below. No interference was observed with any of the substances tested.

Accula SARS-CoV-2 Interfering Substances Evaluation

Potential Interferent	Active Ingredient	Final Concentration	Target	% Agreement with Expected Results
Blood (Human)	NA	25%	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Chloroseptic Max	Phenol 1.5%, Glycerin 33%	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Cold&Flu Relief Cough Syrup	Acetaminophen 21.7 mg/mL, Dextromethorphan 0.67 mg/mL, Guaifenesin 13.3 mg/mL, Phenylephrine 0.33 mg/mL	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Listerine Cool Mint Antiseptic Mouth Wash	Eucalyptol 0.092%, Menthol 0.042%, Methyl Salicylate 0.060%, Thymol 0.064%	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Cepacol (throat lozenge)	Benzocaine, Menthol	1 Lozenge/5 mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Sucrets	Dyclonine Hydrochloride, Menthol	1 Lozenge/5 mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Crest Pro Health Fluoride Toothpaste	Stannous Fluoride 0.454% (0.14% W/V Fluoride Ion)	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Eucalyptus Oil ⁴	Eucalyptus Oil	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Advil Liqui-Gels	Ibuprofen	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Miralax	Polyethylene Glycol	0.304 g/mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Tums Extra Strength	Calcium Carbonate	1 tum/2.5 mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Food Dye	N/A	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Whole Milk (Dairy) ¹	N/A	1.60%	Positive SARS-COV-2(3X LoD)	100% (3/3)
		12.50%	Negative	100% (2/2)
Orange Juice	N/A	50%	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Penicillin G	Penicillin G Sodium Salt	100 mg/mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Cephalexin	Cephalexin	25 mg/mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Mucin, Type II (from porcine stomach) ²	Purified mucin protein	50 mg/mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
		100 mg/mL	Negative	100% (2/2)
Tobramycin	Tobramycin	75 mg/mL	Positive SARS-COV-2(3X LoD)	100% (3/3)

Potential Interferent	Active Ingredient	Final Concentration	Target	% Agreement with Expected Results
(antibacterial) ³			Negative	100% (2/2)
Amoxicillin ³	Amoxicillin	100 mg/mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Anti-viral drug	Zanamivir	10 mg/mL	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Nasal spray	Phenylephrine	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Nasal spray	Oxymetazoline	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Nasal spray	Sodium Chloride	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Nasal Corticosteroid	Triamcinolone	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
Zicam (Nasal Gel, homeopathic allergy relief)	Oxymetazoline hydrochloride 0.05%	Neat	Positive SARS-COV-2(3X LoD)	100% (3/3)
			Negative	100% (2/2)
<p>1 – Milk inhibited target RNA at 12.5%. Milk was diluted to 6.25%, and still inhibited 3 of 3 reactions, and was subsequently diluted to 1.6%, which showed 100% positive target lines. Internal positive control was active and visible at 12.5% milk.</p> <p>2 – Mucin inhibited target RNA at 100 mg/mL. Mucin was diluted to 50 mg/mL and showed 3 positives out of 3 attempts (100%). Internal positive control was active and visible at 100 mg/mL of Mucin.</p> <p>3 – Tobramycin and Amoxicillin positive samples were initially tested without RNA by mistake. These were repeated and yielded 100% expected results.</p> <p>4 – Eucalyptus Oil was used as a substitute for Halls Triple Soothing Cough Drops.</p>				

Clinical Evaluation

Testing of Contrived Samples

Thirty (30) negative samples and 30 positive contrived samples were tested with the Accula SARS-CoV-2 Test. Negative samples were collected from consented healthy volunteers under IRB approval. A throat swab and a nasal swab was collected from a donor and eluted together in a vial of Accula SARS-CoV-2 Buffer. Positive samples were prepared from these thirty negative samples. Positive samples were spiked with SARS-CoV-2 RNA (SARS-CoV-2 RNA/strain USA_WA1/2020) at the concentrations shown in the table below.

Samples were randomized, de-identified and blinded to the testing operator. Sample concentration and test results are summarized in the table below. 100% agreement was observed with expected results.

Accula SARS-CoV-2 Evaluation with Throat/Nasal Swab Samples

Sample Concentration	N	Percent (%) Agreement with Expected Results (Observed/Expected)
2x LoD	20	100 (20/20)
5x LoD	7	100 (7/7)
10x LoD	2	100 (2/2)
50x LoD	1	100 (1/1)
Negative	30	100 (30/30)

Testing of Clinical Samples

Retrospective Specimen Study

Fifty (50) retrospective clinical specimens, which had already been tested with a EUA authorized SARS-CoV-2 Real-Time RT-PCR Assay were tested with the Accula SARS-CoV-2 Test. Each specimen was diluted in the minimum amount of Accula SARS-CoV-2 Buffer required to obtain a valid (presence of a control line), as VTM can inhibit the assay. Accula test result. Required dilutions ranged from 1:6 to 1:40. Test results are summarized in the table below. One test result was discordant (negative Accula/positive by the comparator). This specimen was re-tested with the Comparator assay and also tested with a second EUA RT-PCR test. The specimen gave negative results in both tests.

Accula SARS-CoV-2 Test	Comparator Assay		
	Positive	Negative	Total
Positive	23	0	23
Negative	1*	26	27
Total	24	26	50
Positive Percent Agreement (PPA)	95.8% (95% CI: 78.88% – 99.89%)		
Negative Percent Agreement (NPA)	100% (95% CI: 86.77% - 100%)		
Overall Percent Agreement (OPA)	98.0% (95% CI: 89.35% - 99.95%)		

*1 negative discordant sample was not detected with a secondary comparator test or in re-test with the primary comparator.

Prospective Clinical Study
















A prospective study was performed with 52 nasal swabs collected from pediatric patients at a drive-through collection site. Testing was performed with the Accula SARS-CoV-2 test and the comparator method, a EUA authorized RT-PCR SARS-CoV-2 test. Test results are summarized in the table below.

Accula SARS-CoV-2 Test	Comparator Assay		
	Positive	Negative	Total
Positive	4	0	4
Negative	0	48	48
Total	4	48	52
Positive Percent Agreement (PPA)	100% (95% CI: 39.76% - 100%)		
Negative Percent Agreement (NPA)	100% (95% CI: 92.60% - 100%)		
Overall Percent Agreement (OPA)	100% (95% CI: 93.15% - 100%)		

ASSISTANCE AND CONTACT INFORMATION

For technical questions or assistance, or if the Accula Dock and/or Accula SARS-CoV-2 Test is not performing as expected, please contact Mesa Biotech at info@mesabiotech.com or (858) 800-4929.

SYMBOLS

	This symbol indicates that the product is for single-use only. It is not to be re-used
	This symbol indicates that you should consult the instructions for use.
	This symbol is used for both warnings and cautions. A warning indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed. A caution indicates the possibility of loss of data or damage to, or destruction of, equipment if operating procedures and practices are not strictly observed.
	This symbol indicates that the product has a temperature limitation
	This symbol indicates the use-by date
	This symbol indicates the product batch code.
	This symbol indicates the name and location of the product manufacturer.
	This symbol indicates the product's catalog number.
	This symbol indicates a positive control.
	This symbol indicates a negative control.
	Contents sufficient for <n> tests
	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
	Date
	For In Vitro Diagnostic Use
	Biohazard: Follow proper infection control guidelines for handling all samples, Test Cassettes, SARS-CoV-2 Buffer, and swabs. Properly dispose of all contaminated waste according to federal, state, and local requirements.

This product may be covered by one or more U.S. and/or foreign patents or pending patent applications. See www.mesabiotech.com/patents for details.



Mesa Biotech, Inc.
6190 Cornerstone Court East, Suite 220
San Diego, CA 92121 USA
858-800-4929
info@mesabiotech.com

Accula™ SARS-CoV-2 Instructions for Use
The Mesa Biotech logo and Accula™ name are trademarks of Mesa Biotech