Accula™ TEST

SARS-CoV-2

Quick Reference Guide

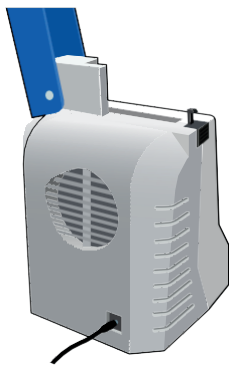
EUA Only COV4100

℞ only IVD REF

FOR USE WITH THE ACCULA OR SILARIS DOCK
FOR ANTERIOR NASAL OR MID-TURBINATE NASAL SWAB SPECIMENS

IMPORTANT: Read the Accula Operators Guide and the Accula SARS-CoV-2 Test Instructions for Use for complete information.

A. PREPARE DOCK



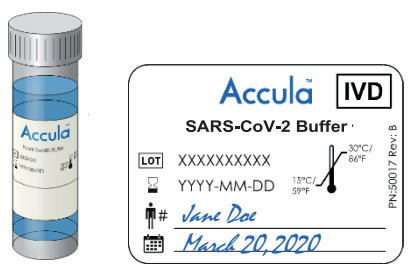
- **Place Dock on flat surface**
- **Connect** AC adapter to Power Cord.
- **Insert** round connector of AC adapter into Dock. Plug power cord into electrical outlet.

NOTE: Dock will turn on.

B. PREPARE SAMPLE

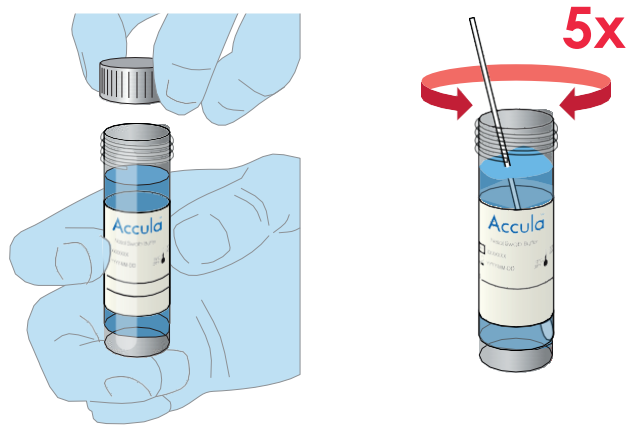
Specimen swabs must be eluted in Accula™ SARS-CoV-2 Buffer immediately after sample collection. Eluted samples in Accula™ Buffer may be kept at room temperature (15°C - 30°C, 59°F - 86°F) for up to 2 hours or refrigerated at 2°C - 8°C and tested within 24 hours from the time of elution. Eluted samples in Accula™ Buffer may be stored for up to 1 week at -20°C; longer storage should be at -80°C or colder.

1



- **Label** SARS-CoV-2 Buffer with patient ID and date.
- **Collect** Anterior Nasal or Mid-Turbinate Nasal swab according to the Instructions for Use.

2



- **Remove** cap on SARS-CoV-2 Buffer.
- **Insert** nasal swab specimen into Buffer.
- **Rotate swab 5 times** against wall of vial.
- **Dispose** swab into biohazard container.
- **Replace** Buffer Cap.

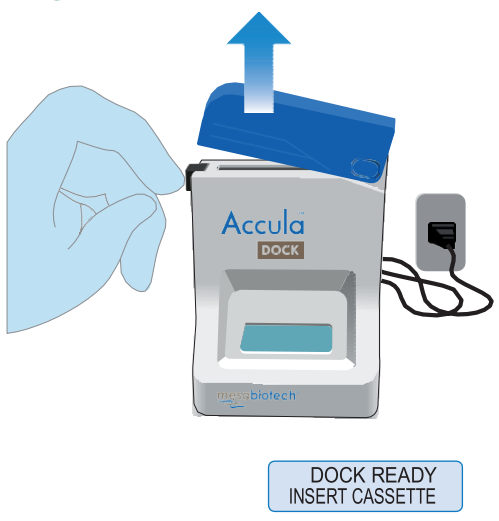
NOTE: If the Buffer solution contacts the skin, wash the area with soap and clean water and rinse thoroughly. Consult a physician if irritation develops.

NOTE: Eluted sample in Buffer can be stored at room temperature up to 2 hours. If sample cannot be tested within 2 hours, refrigerate at 2-8 C and test within 24 hours from when the sample was collected.

C. TEST PROCEDURE

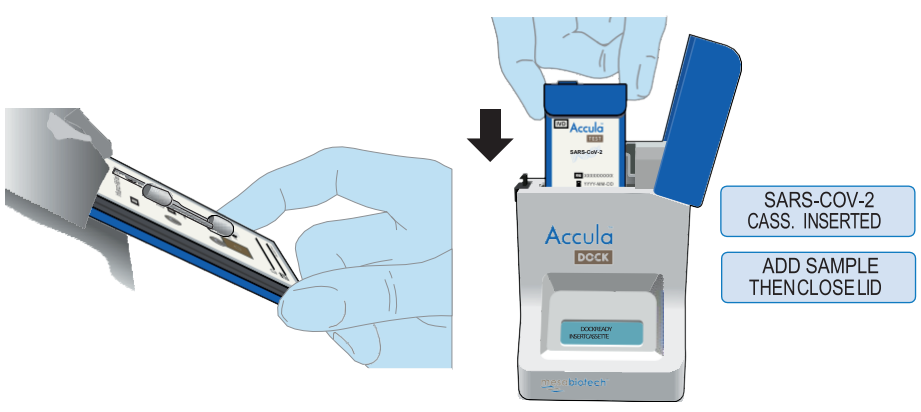
NOTE: Do not open the Test Cassette foil pouch until the sample is ready for testing. The test must be started within 30 minutes of opening the foil pouch.

1



- **Open** Dock by **pressing** black button located on left.
- **Verify** Dock screen displays: **"**DOCK READY INSERT CASSETTE**"**.

2

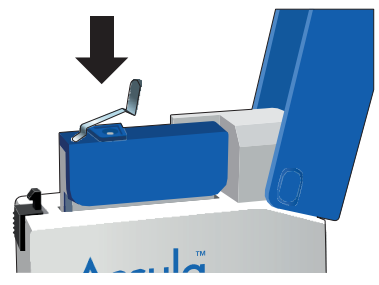


- **Remove** Test Cassette and pipette from foil pouch.
- **Label:** Test Cassette with patient ID and date.
- **Insert** Test Cassette into Dock and press firmly to seat.
  DO NOT CLOSE DOCK LID
- **Verify** Dock screen displays: **"**SARS-COV-2 CASS. INSERTED**"** and **"**ADD SAMPLE THEN CLOSE LID**"**.

DO NOT REMOVE FOIL TAB COVERING SAMPLE PORT UNTIL JUST BEFORE TESTING.

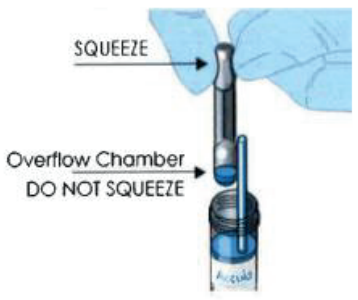
3

ONCE FOIL TAB IS REMOVED, SAMPLE MUST BE ADDED IMMEDIATELY. (WITHIN 5 MINUTES)



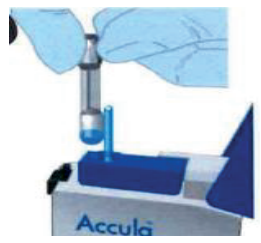
- **Once the sample is ready to be inserted, Remove** foil tab covering sample port on Test Cassette and discard

4



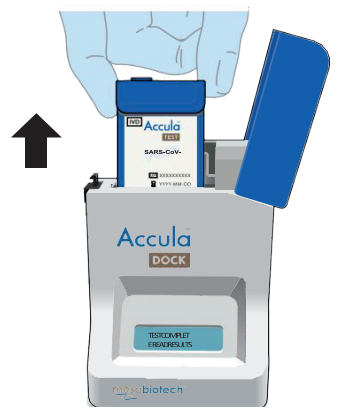
- Invert tube, then remove cap.
- Fill pipette by firmly squeezing top bulb and placing pipette tip into sample. Slowly release bulb while tip is still in sample. This will pull liquid into pipette. Make sure there are no air bubbles in lower part of pipette.

5



- Insert pipette tip containing sample into bottom of sample port **until resistance is met.**
- **Squeeze and hold** top bulb of pipette **firmly** to dispense sample into Test Cassette. Keeping the top bulb squeezed, withdraw the pipette from the Test Cassette. Once you dispense the sample, continue squeezing the bulb as you remove it from the inlet port.
- **NOTE:** A small amount of sample will remain in overflow chamber.
- **Verify** Dock screen displays: SAMPLE LOADED CLOSE LID
- **Immediately** close lid of Dock to automatically begin test.
- **Dispose** of pipette into biohazard container. Dock screen will briefly display CASSETTE SEALED TEST STARTED then TEST RUNNING REMAINING: XX:XX
- **NOTE:** The test takes approximately 30 minutes to complete.

6



DO NOT MOVE, UNPLUG DOCK, OR OPEN LID WHILE TEST IS RUNNING.

- When test is done Dock screen will read: "TEST COMPLETE READ RESULTS"
- **Open** Dock lid and remove Test Cassette.
- **Interpret and Record** results.

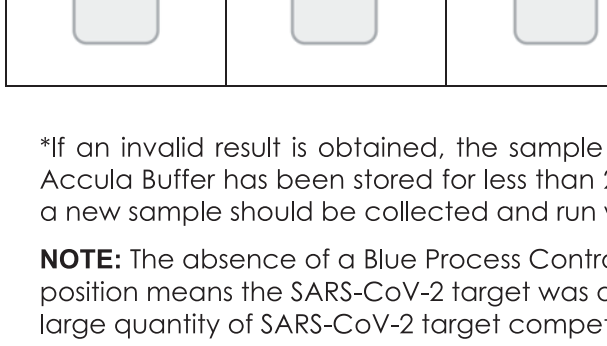
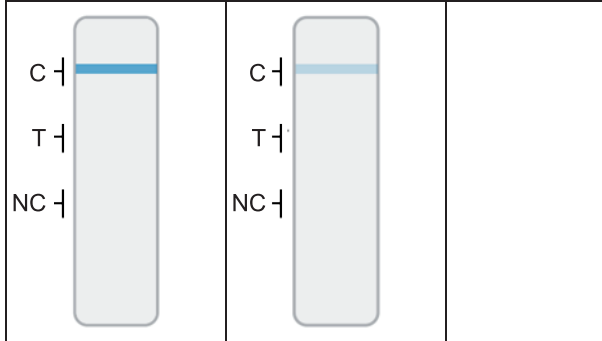
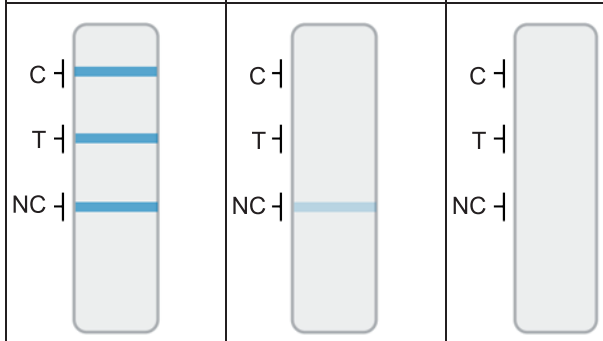
NOTE: Results should be interpreted within 1 hour of test completion.

DISCARD TEST CASSETTE IN BIOHAZARD CONTAINER ONCE RESULTS ARE RECORDED

D. INTERPRETATION OF RESULTS

NOTE: LOOK CLOSELY WHEN INTERPRETING THE RESULTS! The appearance of **any** shade of a Blue Test Line at the T position is a valid result that is interpreted as a positive for SARS-CoV-2 viral RNA. 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 SARS-CoV-2	**Take time to look at test lines very carefully.** 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. • **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 SARS-CoV-2	**Take time to look at test lines very carefully.** 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. • **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*	**Take time to look at test lines very carefully.** The appearance of **ANY** shade of a negative process control line at the NC position indicates an invalid test. The appearance of **ALL** or **NO** lines at the C, T and NC position indicates an invalid test.

*If an invalid result is obtained, the sample may be rerun with a fresh Test Cassette only if the eluted sample in Accula Buffer has been stored for less than 2 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 Process Control Line at the C position and the presence of a Blue Test Line at the T position means the SARS-CoV-2 target was amplified and detected. This is a valid result. This can occur when a large quantity of SARS-CoV-2 target competes with the Control target.

QUALITY CONTROL
Process Controls

Each Accula SARS-CoV-2 Test Cassette contains two internal process controls. The positive control is labeled **"C"** on the Test Cassette. The negative control is labeled **"NC"** on the Test Cassette. The positive process control is used to verify all test steps were performed properly. A negative control tests for false positive results due to nonspecific binding.

Refer to the instructions on interpreting the results for the Process Controls.

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 High Positive SARS-CoV-2 swab
- 1 Low Positive SARS-CoV-2 swab
- 1 Negative SARS-CoV-2 swab

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

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

Additional Accula SARS-CoV-2 Control Swabs may be purchased from Mesa Biotech. Run control swabs using the same procedure as for a patient sample.

If External QC testing fails, repeat the test using the prepared SARS-CoV-2 Buffer (if within 24 hours of preparation) and a new test cassette or contact Mesa Biotech Technical Support at info@mesabiotech.com for assistance before testing patient samples.

NOTE: This test has not been FDA cleared or approved but has been authorized for emergency use by FDA for use by authorized laboratories; 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 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. The emergency use of 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 declaration is terminated or authorization is revoked sooner.

Accula™ TEST

SARS-CoV-2

For questions, assistance, or if the Dock or Accula SARS-CoV-2 Test is not performing as expected, contact us at info@mesabiotech.com

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