**A. PREPARE DOCK**

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

**NOTE:** Dock will turn on.

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

**C. TEST PROCEDURE**

**1.** DOCK READY

**2.** ADD SAMPLE THEN CLOSE LID

**3.** DO NOT SQUEEZE

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

- Remove foil tab covering sample port on Test Cassette and discard.
- Insert pipette tip containing sample into bottom of sample port until resistance is met.
- Squeeze top bulb of pipette firmly to dispense sample into Test Cassette.

**NOTE:** A small amount of sample may remain in overflow chamber.

- 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.

- 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.** 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

<table>
<thead>
<tr>
<th>Window</th>
<th>Window</th>
<th>Window</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>NC—</td>
<td>C—</td>
<td>T—</td>
<td>Take time to look at test lines very carefully.</td>
</tr>
<tr>
<td>T—</td>
<td>NC—</td>
<td>C—</td>
<td>Positive test for SARS-CoV-2</td>
</tr>
<tr>
<td>C—</td>
<td>T—</td>
<td>NC—</td>
<td>Take time to look at test lines very carefully.</td>
</tr>
<tr>
<td>NC—</td>
<td>T—</td>
<td>C—</td>
<td>Take time to look at test lines very carefully.</td>
</tr>
<tr>
<td>T—</td>
<td>NC—</td>
<td>C—</td>
<td>Take time to look at test lines very carefully.</td>
</tr>
<tr>
<td>NC—</td>
<td>T—</td>
<td>C—</td>
<td>Invalid Result*</td>
</tr>
</tbody>
</table>

*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.

**NOTE:** This test has not been FDA cleared or approved but has been authorized for emergency use by FDA 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 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. § 360bb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.