

Accula™

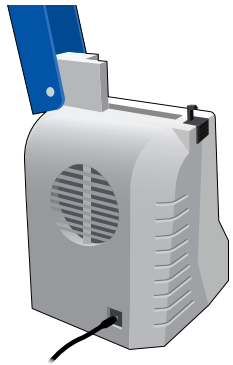
RSV

Quick Reference Guide
FOR NASAL SWAB SPECIMENS

CE Rx_{only} IVD REF RSV1300

IMPORTANT: Read the Accula Operators Guide and the Accula RSV Test Package Insert before running samples. The Package Insert with complete instructions is available via: <http://www.mesabiotech.com/products/>

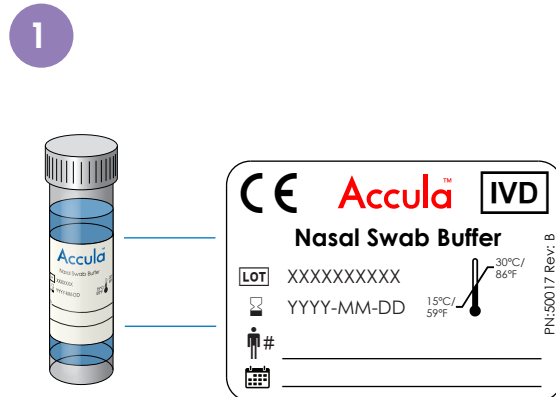
A. PREPARE DOCK



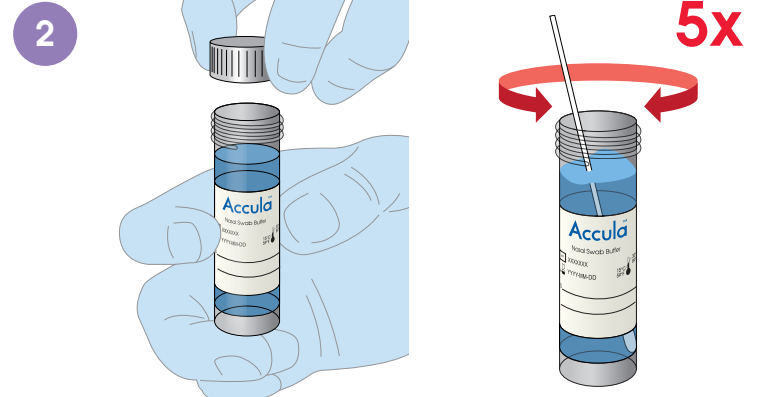
- Place Dock on flat surface.
 - Connect AC adapter to Power Cord.
 - Insert round connector of AC adapter into Dock. Plug power cord into electrical outlet.
- NOTE:** Dock will turn on.

B. PREPARE SAMPLE

For best results, test sample immediately. If not possible, store swab in its original package at room temperature for up to 2 hours. Swab can also be stored at 2-8° C for up to 24 hours from the time of collection. Allow sample to come to room temperature before testing.



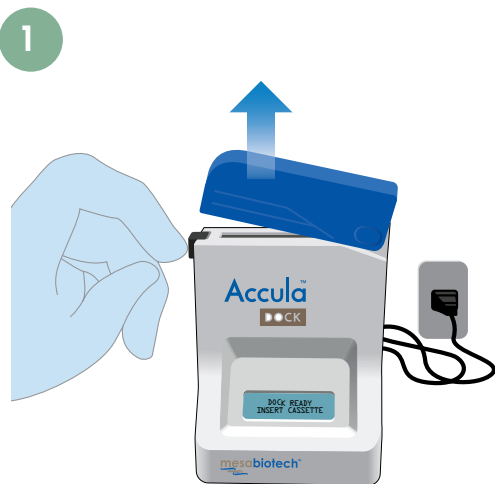
- Label Nasal Swab Buffer Vial with patient ID and date.



- Remove cap on Nasal Swab Buffer vial.
 - Insert swab specimen into Nasal Swab Buffer vial.
 - Rotate swab 5 times against wall of vial.
 - Dispose swab into biohazard container.
 - Replace cap on vial.
- NOTE:** Extracted sample in Nasal Swab Buffer can be stored at room temperature for 1 hour.

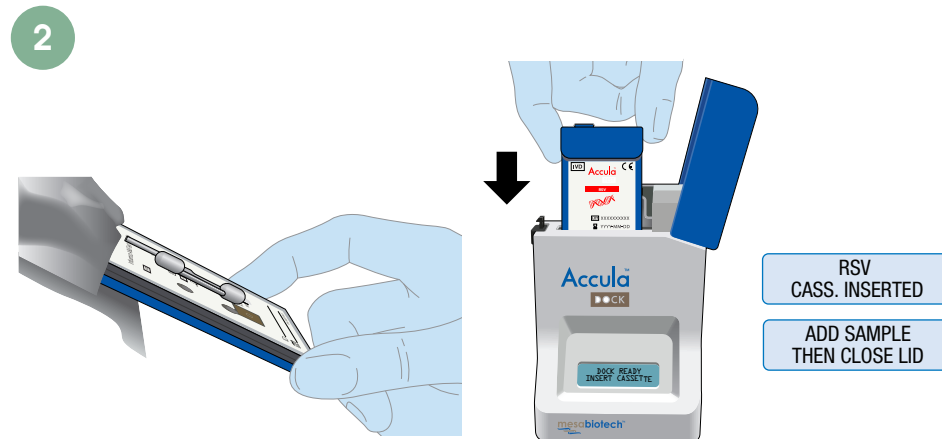
C. TEST PROCEDURE

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.

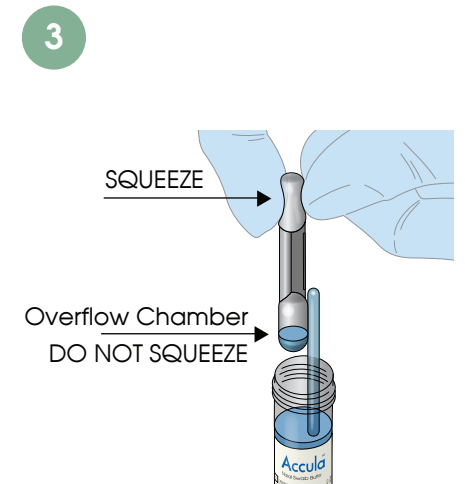


DOCK READY
INSERT CASSETTE

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

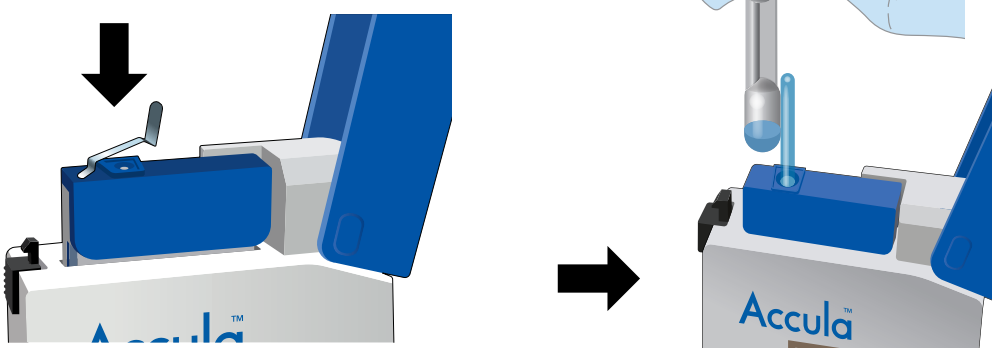


- Remove Test Cassette and pipette from foil pouch.
 - Label: Test Cassette with patient ID and date.
 - Insert Test Cassette into Dock and press firmly to seat.
 - Verify Dock screen displays: "RSV CASS. INSERTED" and "ADD SAMPLE THEN CLOSE LID".
- DO NOT REMOVE FOIL TAB COVERING SAMPLE PORT**



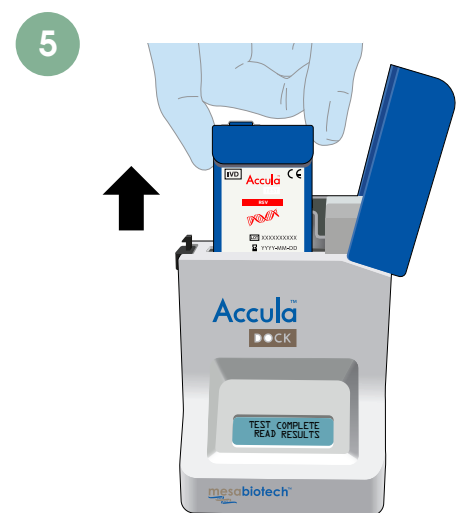
- Invert tube, then remove cap.
- Fill pipette by firmly squeezing top bulb and placing pipette tip into sample. Slowly release bulb while tip is still in sample. This will pull liquid into pipette. Make sure there are no air bubbles in lower part of pipette.

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.
- Dispose of pipette into biohazard container.
- Verify Dock screen displays: "SAMPLE LOADED CLOSE LID."
- Immediately close lid of Dock to automatically begin test.
- Dock screen will briefly display "CASSETTE SEALED TEST STARTED" then "TEST RUNNING REMAINING: XX:XX"

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

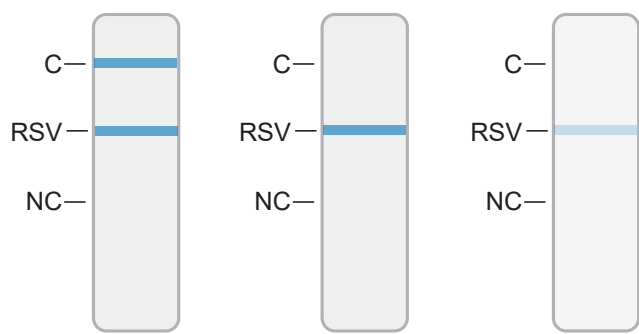


- When test is done Dock screen will read: "TEST COMPLETE READ RESULTS"
- Open Dock lid and remove Test Cassette.
- Interpret and Record results.
- NOTE: Results should be interpreted within 1 hour of test completion.

Discard Test Cassette in biohazard container

NOTE: LOOK CLOSELY WHEN INTERPRETING THE RESULTS! The appearance of any shade of a Blue Test Line at the Accula RSV test positions is a valid result that is interpreted as a positive for RSV. A negative result will only contain a Blue Test Line at the C position.

RSV Positive Test Result

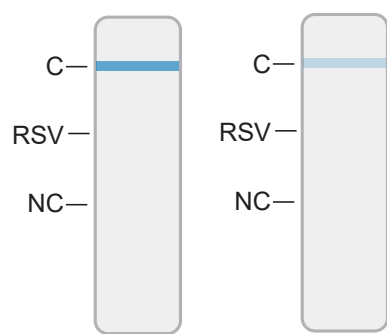


Take time to look at test lines very carefully.

Interpretation: The appearance of **ANY** shade of a Blue Test Line at the RSV position indicates a positive result for the presence of RSV.

- **WITH OR WITHOUT** the appearance of a blue process control line at the C position
- **AND** the absence of a negative process control line at the NC position

RSV Negative Test Result

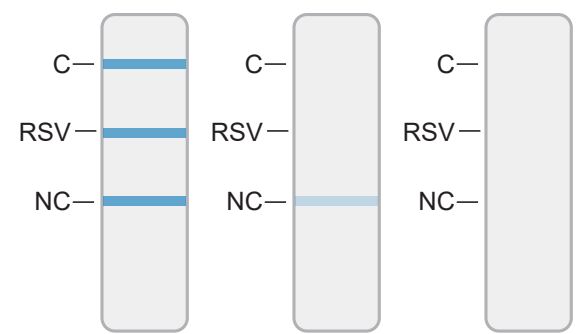


Take time to look at test lines very carefully.

Interpretation: The absence of **ANY** shade of a Blue Test Line at the RSV position indicates a negative result for the presence of RSV.

- **AND** the appearance of a blue process control line at the C position
- **AND** the absence of a negative process control line at the NC position

Invalid Test Result



Interpretation: 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 C, RSV, and NC position indicates an invalid test.

*If an invalid result is obtained, the sample may be rerun with a fresh Test Cassette if the prepared sample in the Nasal Swab Buffer has been stored for less than 1 hour at room temperature.

C = Internal Positive Process Control
RSV = Respiratory Syncytial Virus
NC = Internal Negative Process Control

E. QUALITY CONTROL

Process Controls: Each Accula RSV Test Cassette contains two internal process controls: a positive control (labeled 'C' on the Test Cassette) and negative control (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 RSV Test is working properly. Run control swabs using the same procedure as for a patient sample.

The Accula RSV Test kit contains two Control Swabs:

- 1 Positive RSV swab (green shaft)
- 1 Negative RSV swab (pink shaft)

Mesa Biotech recommends that an RSV positive and a negative control be run once for each new lot or shipment of kits received, once for each new operator, and as required to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

If External QC testing fails, repeat the test using the prepared Nasal Swab Buffer (if within one hour of preparation) and a new test cassette. Contact your local distributor or Mesa Biotech for technical support before testing patient samples.

F. INTENDED USE, PRECAUTIONS AND SYMBOL INDEX

INTENDED USE

A molecular in vitro diagnostic test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of respiratory syncytial virus (RSV) viral RNA.

PRECAUTIONS

- For in vitro diagnostic use.
- The sale of this device is to or on the order of a licensed practitioner only.
- Use Accula RSV Tests only with the Accula Dock.
- Follow universal precautions when handling patient samples. Treat all patient samples as if potentially infectious. Follow standard BSL2 guidelines when working with patient samples. Wear the appropriate personal protective equipment.
- Consider control swabs, patient samples and used cassettes as potentially infectious and handle using standard biosafety procedures during use and for disposal.
- Dispose of kit reagents and patient samples according to local regulations.
- The Nasal Swab Buffer in the Accula RSV and Flu A/Flu B Test Kit is the same. You may use the buffer from either kit.
- Only use Swabs or Nasal Swab Buffer provided with the Accula RSV or Flu A/Flu B Test Kit.
- Test the sample immediately after collection. If needed, the extracted sample in Nasal Swab buffer can be stored at room temperature (15°C to 30°C) for up to 1 hour.
- Only write on the Test Cassette in the indicated area for recording patient ID and test date.
- Do not remove the foil tab from the Test Cassette until immediately before use. Once the tab is removed, add sample promptly and start testing (within 5 minutes).

- Once sample is added and the Dock lid is closed, the test has started. Do not move, open, or unplug the Dock until the Dock indicates the test is complete.
- Do not use any damaged or expired contents from the kit.
- All test kit components are single use items.
- For accurate results, follow all instructions and heed all precautions in this Quick Reference Guide.
- Inadequate or inappropriate sample collection, handling, processing, and/or storage can yield inaccurate results.
- Sample collection and handling procedures require specific training and guidance.
- Use the Pipette provided in the kit to transfer the patient sample from the Nasal Swab Buffer tube into the Test Cassette port. Do not pour the patient sample from the Nasal Swab Buffer tube into the Test Cassette sample port.
- Do not use visually bloody or overly viscous samples.
- When transferring the prepared patient sample, avoid large particulates, which may clog the Pipette.
- Clean the Accula Dock and surrounding surfaces as described in the Dock Cleaning section in the Package Insert. Contamination of the work area with previous samples may cause false positive results.
- Do not attempt to open a used Test Cassette or a Test Cassette with a closed sample port.
- Do not touch the heads of the Control Swabs. Contamination may occur.
- Use the Interpretation of Results table in this Quick Reference Guide to interpret results.

Prescription Use Only	CE mark
Single-Use Only	Positive control
Consult Instructions for Use	Negative Control
Warnings and Cautions	Quantity per kit
Temperature Limitation	Catalog Number
The Use-by Date (Expiration Date)	Date
Product Batch Code	For In Vitro Diagnostic Use
Not for Self-Testing	Near Patient Testing
Manufacturer	Authorized Representative in the European Community

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Accula™
RSV

For questions, assistance, or if the Accula Dock or Accula RSV Test is not performing as expected, contact us at +1-858-800-4929 or info@mesabiotech.com

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