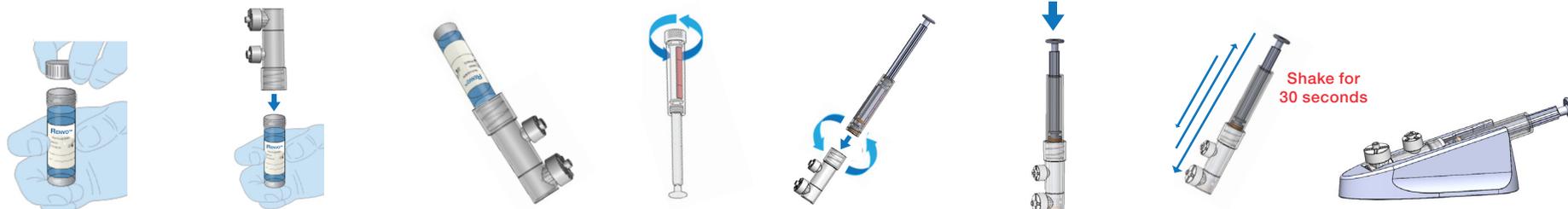


Renvo sample prep procedure

FOR USE WITH THE RENVO DOCK, AEROSOLSENSE SAMPLER AND AEROSOLSENSE SAMPLE CARTRIDGE.

IMPORTANT: The Renvo Rapid PCR Test is for environmental surveillance use only and not for diagnostic purposes. Read the Renvo Dock Operators Guide and the Renvo SARS-CoV-2 Test Instructions for Use for complete information.

PREPARE SAMPLE



- Put on the necessary PPE for conducting the Renvo SARS-CoV-2 Test.
- **Remove** the cartridge adapter from the bag. **Unscrew** the cap from the buffer vial.
- **Transfer** the buffer solution from the buffer vial to the cartridge adapter by placing the cartridge adapter over the buffer vial and inverting.
- Discard the empty buffer vial and place the cartridge adapter filled with buffer solution into the stand.

- Remove the cap from the AerosolSense Sample Cartridge.
- Remove the cartridge adapter from the stand, hold in a vertical position, and attach the AerosolSense Sample Cartridge by twisting clockwise.
- Ensure that the sample cartridge is fully tightened when screwing it to the adapter. The two are completely attached when a full stop is reached upon screwing together and the orange o-ring of the sample cartridge is completely past the frosted portion of the cartridge adapter.

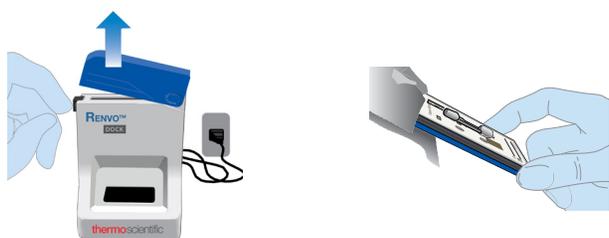
Note: Failure to fully connect the cartridge adapter to the cartridge will result in leakage of the buffer solution in the subsequent steps.

- Slowly press the sample cartridge plunger fully in the cartridge adapter which enables contact of the substrate with the buffer solution. The o-ring of the cartridge will be visually past the bottom frosted section of the cartridge adapter when fully inserted.

Once the plunger is depressed DO NOT pull the plunger back.

- Shake sample cartridge and cartridge adapter assembly by hand vigorously for 30 seconds. Place in stand.

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.
- **Open** dock by depressing the black button on the top left and verify Dock screen displays **"DOCK READY INSERT CASSETTE"**.

- **Remove** a test cassette and transfer pipette from the foil package (these items are packaged together).
- **Do not open the foil pouch until the sample is ready for testing. Initiate the test within 30 minutes of opening.**
- **Write** the identification (ID) information and testing date on the test cassette label in the area provided.



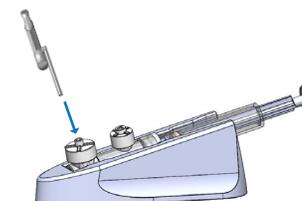
- **Insert** the test cassette into the dock, leaving the lid open. Press the test cassette down firmly to seat it in the dock.
 - **Verify** the dock screen displays: **"SARS-COV-2 CASS. INSERTED"**.
 - The dock screen will then display: **"ADD SAMPLE THEN CLOSE LID"**.
- Do not close dock lid until sample has been added to the test cassette.**

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



- **Completely remove** the foil tab covering the sample port on the test cassette. Discard the foil tab.
- **NOTE:** Do **NOT** remove the foil tab covering the sample port until immediately before testing.
- Once the test cassette is placed into the dock, you have 5 minutes to add the sample into the test cassette.

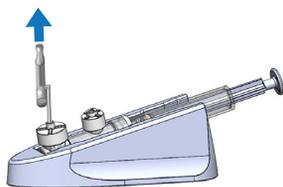
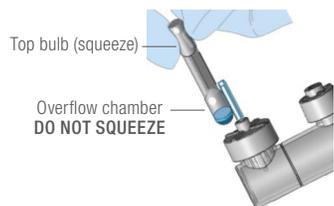
PREPARE SAMPLE



- **Firmly hold** the transfer pipette stem near the tip and insert the transfer pipette stem fully into the lower port on the cartridge adapter while the cartridge and adapter assembly is in the stand.
- **NOTE:** There is a strong force needed to pierce through the port seal.

Renvo sample prep procedure

PREPARE SAMPLE



THE TEST TAKES APPROXIMATELY 30 MINUTES TO COMPLETE

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

- Once the transfer pipette is fully inserted, **firmly** squeeze the **TOP** bulb of the transfer pipette once. Do not squeeze until the stem is fully engaged in the cartridge adapter port.
- If solution has spilled, use a disinfectant that is efficacious against SARS-CoV-2 (e.g. disinfectants listed on US EPA's List N in the United States). If the sample gets in contact with skin, immediately wash the area with abundant water and soap.
- Slowly** release the top bulb to completely fill the transfer pipette stem with sample. Some liquid may also be carried over to the

overflow chamber. Verify that the sample was drawn into the transfer pipette stem.

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

- Hold** the transfer pipette between the pipette bulb and the overflow chamber and remove the transfer pipette from the cartridge adapter port.
- DO NOT** squeeze the pipette bulb or overflow chamber when removing the pipette from the adapter. A spill will result.

NOTE: Leave the sample cartridge and cartridge adapter assembly in the stand in case further testing is needed.

- Insert the tip of the pipette all the way into the sample port of the test cassette until resistance is met.
- Squeeze the TOP bulb of the transfer pipette firmly to dispense all of the sample from the transfer pipette stem into the test cassette.

NOTE: A small amount of sample may remain in the overflow chamber (lower bulb). This is normal.

- Dispose of the used transfer pipette as Biohazard waste according to Federal, State and local regulatory requirements.
- The dock screen will then read: **"SAMPLE LOADED CLOSE LID"**.
- Close the lid of the dock immediately to automatically begin the test program.**
- Verify** the dock screen displays: **"SAMPLE LOADED LID CLOSED"**.
- Verify** the dock screen displays: **"CASSETTE SEALED TEST STARTED"**.

- Verify** the dock screen displays: **"TEST RUNNING REMAINING XX:XX"**.
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.
- Do not re-open the dock lid until the display indicates the test is complete.

AFTER TEST

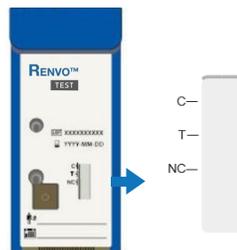


- Verify** the dock screen displays: **"TEST COMPLETE READ RESULTS"**.
- Open** the lid of the dock.
- Remove** the test cassette and interpret the results according to the Interpretation of Result section.

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

- Dispose of the used test cassette, sample cartridge, and cartridge adapter as biohazard waste according to Federal, State and local regulatory requirements.

INTERPRETATION OF RESULTS



- See next page for full interpretation of test results.

INTERPRETATION OF RESULTS

Window	Window	Window	Interpretation
			<p>Positive test for SARS-CoV-2</p> <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
			<p>Negative test for SARS-CoV-2</p> <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
			<p>Invalid Result*</p> <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>

• **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

*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 Renvo SAR-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 Renvo SARS-CoV-2 Test is working properly. The Renvo 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

Thermo Fisher Scientific 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 deemed additionally necessary to conform with your internal quality control procedures.

Additional control swabs may be purchased from Thermo Fisher Scientific. Follow the workflow in the Renvo SARS-CoV-2 Control Kit Instruction for Use to elute and test control swabs.

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 Thermo Scientific Technical Support at support.apd@thermofisher.com for assistance before testing air samples.

NOTE: The Renvo™ SARS-CoV-2 Test performed on the Renvo™ Dock is a molecular test utilizing polymerase chain reaction (PCR) and lateral flow technologies for the qualitative, visual detection of nucleic acid from SARS-CoV-2. Renvo™ SARS-CoV-2 Test is performed on environmental air samples from the AerosolSense™ Sampler and AerosolSense™ Sample Cartridge and is intended for environmental surveillance use only and not for diagnostic purposes. This test has been intended only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

Testing should be conducted by a trained operator (1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the product used under his or her supervision, (2) who is responsible for using the product appropriately according to the methods to reduce such risks, and (3) who is able to adhere to all safety procedures related to the product's storage, use, and disposal.

Testing should be conducted on a flat surface that can be easily disinfected. Disposable gloves, face covering, and safety goggles should be worn throughout the process.

Find out more at thermofisher.com/renvo