

# RENVO™

## TEST

### SARS-CoV-2

## Renvo™ SARS-CoV-2 Control Kit Instruction for Use

Part Number 121972-00  
02Dec2021



# RENVO™

## TEST

### SARS-CoV-2



RENCOV4100-1

**For Environmental Surveillance Use Only. Not for diagnostic purposes**

**For Environmental Surveillance use with Thermo Scientific™ Renvo™ Dock and Thermo Scientific™ AerosolSense™ Sample Cartridges**

Instructions for Use

#### **INTENDED USE**

The Renvo™ SARS-CoV-2 Control Kit is intended for environmental surveillance use and not for diagnostic purposes.

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.

#### **SUMMARY AND EXPLANATION**

The Renvo SARS-CoV-2 Control Kit provides positive and negative control swabs for use with the Thermo Scientific™ Renvo™ SARS-CoV-2 Test. Positive swabs are coated with DNA Based Synthetic Oligo. When used for quality control in the Renvo SARS-CoV-2 Test, these controls are useful as an aid in verifying test and operator performance.

#### **MATERIALS PROVIDED**



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

## **MATERIALS PROVIDED:**

- SARS-CoV-2 High Positive Control Swab (3): DNA Based Synthetic Oligo dried onto a swab well-above the limit of detection of the test.
- SARS-CoV-2 Low Positive Control Swab (3): DNA Based Synthetic Oligo dried onto a swab near the limit of detection of the test.
- SARS-CoV-2 Negative Control swab (3): buffer solution dried onto a swab.
- Electronic Instructions for Use (eIFU) Card (1)
- Instructions for Use is provided on the Thermo Fisher Scientific website, <https://www.thermofisher.com/renvo>

## **MATERIALS PROVIDED SEPARATELY**

- Renvo Dock (Catalog # REND2000)
- Renvo SARS-CoV-2 Test Kit (Catalog #RENCOV4100-1)
- AerosolSense Sampler (Catalog # 2900-AA, 2900-BA, or 2900-CA)
- AerosolSense Sample Cartridge (Catalog # 121480-01)

## **STORAGE AND HANDLING**

- The Renvo SARS-CoV-2 Control Kit must be stored at room temperature (15°C to 30°C, 59°F to 86°F). Do not refrigerate or freeze.
- 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.
- Eluted samples in SARS-CoV-2 buffer may be kept at room temperature (15°C to 30°C, 59°F to 86°F) for up to 2 hours or refrigerated at 2°C to 8°C and tested within 24 hours from the time of elution.
- Eluted samples in SARS-CoV-2 buffer may be stored for up to 1 week at -20°C; longer storage should be at -80°C or colder.

## **PRECAUTIONS**

- For environmental surveillance use only with AerosolSense Air Sampler and AerosolSense Sample Cartridges and not for diagnostic purposes.
- 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 surface that can be easily disinfected.
- Disposable gloves, face covering and safety goggles should be worn throughout the process.
- To be used in conjunction with the Renvo SARS-CoV-2 Test and the Renvo Dock.
- DO NOT use the Controls past their expiration date.
- DNA Base Synthetic Oligo is used to make the control swabs. However, control swabs and used cassettes should be handled as though they could transmit disease.
- Observe established precautions against viral hazards during use and disposal.
- Do not use any damaged kit contents.
- Do not touch the heads of the Control swabs. Cross contamination may occur due to the high sensitivity of the test.
- Follow proper infection control guidelines for handling all specimens, control swabs and related items. Properly dispose of all contaminated waste according to federal, state, local and/or country requirements.
- Swabs stored in foil pouch at 15°C to 30°C (59°F to 86°F) are stable until the expiration date printed on the pouch.
- If the buffer solution contacts the skin, wash the area with soap and clean water and rinse thoroughly. Consult a physician if irritation develops.
- Use the Results Interpretation table in this Instructions for Use to interpret results accurately.

## **EXPECTED RESULTS**








- The SARS-CoV-2 Positive Controls should yield positive SARS-CoV-2 results
- The SARS-CoV-2 Negative Control should yield a negative result.


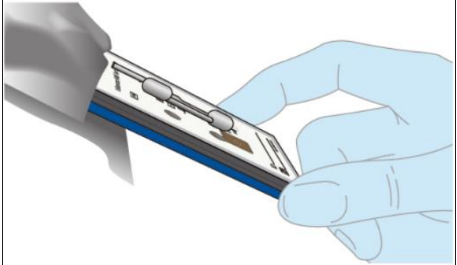

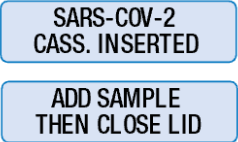

## TECHNICAL ASSISTANCE

- If External QC testing fails, repeat the test using a new Control Swab, reagent and Test Cassette or contact Thermo Fisher Scientific Technical Support at support.adp@thermofisher.com or +1 (800) 209-8763 for assistance before testing environmental samples.

## TEST PROCEDURE

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

<p><b>Unscrew</b> the cap from the SARS-CoV-2 Buffer.</p> <p><b>Insert</b> the control swab specimen into the SARS-CoV-2 Buffer and rotate it <b>5</b> times rubbing it against the wall of the vial.</p> <p><b>Remove</b> the control swab from the SARS-CoV-2 Buffer vial and discard it into a biohazardous waste container.</p> <p><b>NOTE:</b> If the buffer solution contacts the skin, wash the area with soap and clean water and rinse thoroughly. Consult a physician if irritation develops.</p>	
<p> <b>Replace</b> the cap on the SARS-CoV-2 Buffer vial.</p> <p> If immediate testing is not possible, the eluted sample in SARS-CoV-2 buffer may be stored at room temperature (15°C - 30°C, 59°F - 86°F) for up to 2 hours.</p> <p> The eluted sample in SARS-CoV-2 buffer may be refrigerated at 2°C - 8°C and tested within 24 hours from the time of collection, or may be stored for up to 1 week at -20°C.</p>	
<p><b>Place Dock on a flat surface.</b></p> <p><b>Connect</b> the AC Adapter to the Power Cord.</p> <p><b>Insert</b> round end of the power cord into the Dock. Plug the AC end of the power cord into an electrical outlet.</p>	
<p><b>Open</b> the Dock by depressing the black button located on the top left.</p>	

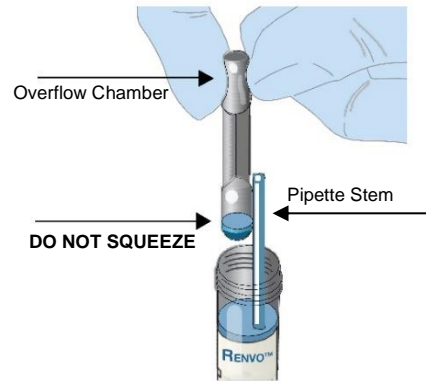
<p><b>Verify</b> the Dock screen displays: “DOCK READY INSERT CASSETTE”.</p>	
<p><b>⚠ Do not open the foil pouch until the sample is ready for testing. Initiate the test within 30 minutes of opening.</b></p> <p><b>Remove</b> a Test Cassette and Transfer Pipette from the foil package (these items are packaged together).</p> <p><b>Write</b> the 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><b>Insert</b> the Test Cassette into the Dock, leaving the lid open. Press the Test Cassette down firmly to seat it in the Dock.</p> <p><b>NOTE:</b> Do <b>NOT</b> remove the foil tab covering the sample port until immediately before testing.</p> <p><b>⚠ Once the test cassette is placed into the Dock, you have 5 minutes to add the sample into the Test Cassette.</b></p>	
<p><b><u>Do not close Dock lid until sample has been added to the Test Cassette.</u></b></p> <p><b>Verify</b> the Dock screen displays: “SARS-COV-2 CASS. INSERTED” The Dock screen will then display: “ADD SAMPLE THEN CLOSE LID”</p>	
<p><b>Invert</b> SARS-CoV-2 Buffer vial to mix.</p> <p><b>Remove</b> the cap from the eluted sample in the SARS-CoV-2 Buffer.</p>	

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

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

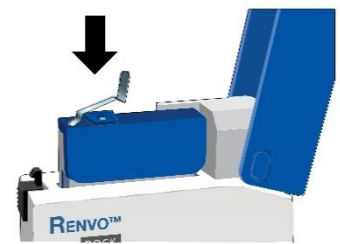
**Slowly** release the top bulb to completely fill the pipette stem with sample. Some liquid may also be in the overflow reservoir.

**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).



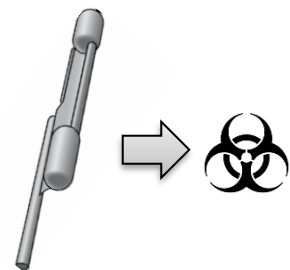
**Insert** the tip of the pipette all the way into the sample port of the Test Cassette until resistance is met.

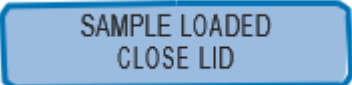
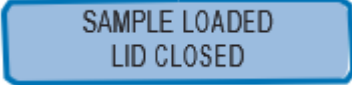





**Squeeze** the **TOP** bulb of the pipette firmly to dispense all of the sample from pipette stem into the Test Cassette.

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



**Dispose** of the pipette in a biohazardous waste container.



<p>The Dock screen will then read: “SAMPLE LOADED CLOSE LID”.</p> <p><b>Close the lid of the Dock immediately to automatically begin the test program.</b></p> <p><b>Verify</b> the Dock screen displays: “SAMPLE LOADED LID CLOSED”.</p>	  
<p><b>Verify</b> the Dock screen displays: “CASSETTE SEALED TEST STARTED”.</p>	
<p><b>Verify</b> the Dock screen displays: “TEST RUNNING REMAINING XX:XX”.</p> <p><b>Note:</b> 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> <b><u>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.</u></b></p>	
<p><b>Verify</b> the Dock screen displays: “TEST COMPLETE READ RESULTS”.</p>	
<p><b>Open</b> the lid of the Dock.</p> <p><b>Remove</b> the Test Cassette and interpret the results according to the Interpretation of Results section below.</p> <p><b>Note:</b> Results should be interpreted within 1 hour of test completion.</p>	



**Dispose** of the Test Cassette in the biohazardous waste container.



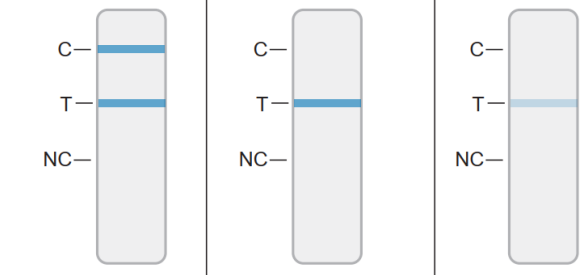
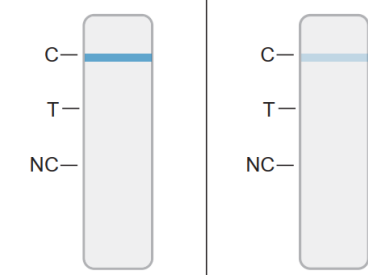
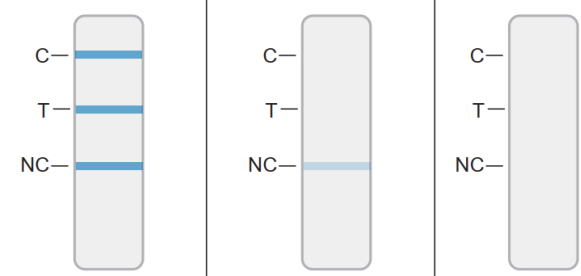
**INTERPRETATION OF RESULT**

**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	
 <p>Three test cassette windows showing positive results. Each window has a blue line at the C position, a blue line at the T position, and no line at the NC position.</p>			Positive test for SAR-CoV-2	<p><b>Take time to look at test lines very carefully.</b></p> <p>The appearance of <b>ANY</b> 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"> <li>• <b>WITH OR WITHOUT</b> the appearance of a blue process control line at the C position</li> <li>• <b>AND</b> the absence of a negative process control line NC position</li> </ul>
 <p>Two test cassette windows showing negative results. Each window has a blue line at the C position, no line at the T position, and no line at the NC position.</p>			Negative test for SAR-CoV-2	<p><b>Take time to look at test lines very carefully.</b></p> <p>The absence of <b>ANY</b> 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"> <li>• <b>AND</b> the presence of a blue process control line at the C position</li> <li>• <b>AND</b> the absence of a negative process control line NC position</li> </ul>
 <p>Three test cassette windows showing invalid results. Each window has a blue line at the C position, a blue line at the T position, and a blue line at the NC position.</p>			Invalid Result*	<p><b>Take time to look at test lines very carefully.</b></p> <p>The appearance of <b>ANY</b> shade of a negative process control line at the NC position indicates an invalid test.</p> <p>The appearance of <b>ALL</b> or <b>NO</b> 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 eluted sample in Renvo 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 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.

## 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
	Date
	<b>Biohazard:</b> 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.

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Find out more at [thermofisher.com/renvo](https://thermofisher.com/renvo)

**ThermoFisher**  
S C I E N T I F I C