

#### Environmental surveillance rapid PCR test

### Frequently asked questions

### Renvo Rapid PCR Test

Used with the AerosolSense Sampler. For environmental surveillance use only and not for diagnostic purposes.

#### **Test preparation**

## Can the Thermo Scientific<sup>™</sup> Renvo<sup>™</sup> rapid PCR test be used for individual testing?

No, the Renvo rapid PCR test is an environmental surveillance solution only. It cannot be used for individual testing purposes.

#### What PPE should be used when performing the test?

We recommend operators to wear a mask, gloves and safety goggles to minimize the risk of exposure.

### Once the cassette is opened from the pouch, how much time do you have to start a test?

After the cassette is removed from its protective pouch, the user has 30 minutes to start a test.

### How much time do you have to start a test after the cassette is inserted into the dock?

The user has five minutes to load a sample after the cassette has been inserted into the dock. If the test cassette has been sitting in the dock for more than five minutes, the test will abort and the test cassette must be discarded.

### Can I use the cassette with other rapid PCR test devices?

The Renvo cassette can only be used with the Renvo dock.

#### Can a different pipette be used to aspirate the sample?

Users must use the provided transfer pipette to load the sample into the cassette.

### How do you know that the sample was properly aspirated with the transfer pipette?

Users need to squeeze the top bulb of the pipette, but never the bottom overflow chamber. Once the sample is aspirated with the transfer pipette, the overflow chamber should not be filled more than half with liquid. Also, ensure that air bubbles are absent from the pipette stem. If the overflow chamber is filled more than half and/or bubbles are present in the pipette stem, discard the

transfer pipette and aspirate the sample again with a new pipette.

#### Can the eluted sample be stored?

It is recommended that users keep the eluted sample (elution is the process of extracting one material from another by washing with a solvent) in case the test needs to be repeated (e.g., when invalid results are obtained). The eluted sample can be kept up to two hours at room temperature. If the eluted sample needs to be kept for longer, it can be refrigerated (2° C - 8° C) for up to 24 hours. If the sample was refrigerated, it is recommended to bring the sample to room temperature 30 minutes before starting a test. If needed, the eluted sample can also be frozen up to 1 week at -20° C.

### How do you know if the right sample volume is being loaded into the cassette?

Users need to insert the pipette into the cassette until they meet resistance and then squeeze only the top bulb in one firm and quick motion. The top bulb of the transfer pipette needs to be pressed only once to release the proper volume (60 uL). If the sample is slowly dripped into the cassette, the sample may not be detected. If this is performed correctly, the dock will display the message "Sample Added" for verification. Do not squeeze the bulb to release the remaining volume or squeeze the overflow chamber in the transfer pipette as this will cause an overflow and the cassette will have to be discarded.

## What should you do if the eluted sample fluid is spilled or gets in contact with skin?

Tests should be conducted on a surface that can be easily disinfected (e.g. a non-porous surface such as metal, glass, plastic and varnished wood surfaces). Surfaces should be decontaminated at the end of testing and if any material has spilled, use a disinfectant that is efficacious against SARS-CoV-2 (e.g. disinfectants listed on <u>US EPA's List N</u> in the United States).If the sample gets in contact with skin, immediately wash the area with abundant water and soap.



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#### Can a label be placed on the test cassette?

It is not recommended to place adhesives on the cassette because they could interfere with the dock function. If labels are needed, place them in the upper region or lower region of the front cassette or blue areas of the back of the cassette. Do not cover the results window, chambers or lips of the cassette.

#### Dock operation and troubleshooting

### How long should you wait to close the dock lid after loading the sample into the cassette?

User should wait until the dock prompts them to close the lid. It can take up to 30 seconds for the dock to recognize the test cassette.

### What should be done when an error displays on the dock?

Please refer to the error description and solution page in the manual.

### What should be done if the dock lid is opened before test completes?

Opening the dock lid prior to test completion will cancel the test. At that point, the assay will be electronically marked as "used" and the user will need to repeat the test.

#### What should you do if the dock is not working?

Ensure power cord is properly plugged to both power source and the dock. If you still have issues, please contact our technical support team at 800-209-8763 or support.apd@thermofisher.com.

#### Does the dock need calibration and maintenance?

The Thermo Scientific™ Renvo™ dock comes calibrated from the factory and does not need any additional calibration or quality control. When not in use, store dock with the lid closed.

#### How many tests can be run with the Renvo dock?

Users can run up to 3,000 tests. When the dock has completed 3,000 runs, the error "Dock expired ,replace dock" will be displayed. Contact your sales representative or distributor to purchase a replacement dock.

#### How can the dock be cleaned?

It is recommended to wipe the external surfaces of the dock and surrounding area daily with 70% ethanol wipes, CaviWipes<sup>TM</sup> germicidal disposable wipes or 10% bleach solution on a damp lint free cloth.

#### What is the maximum time for a test to be completed?

Tests are usually completed in approximately 30 minutes. If the test takes more than 40 minutes to complete, then it is likely that something went wrong with the test and it may need to be repeated.

#### Can an extension cord be used to power the dock?

Yes, an extension cord can be used to connect the dock to a power source.

#### How should the waste be disposed?

Dispose waste in according to all local, state, and federal regulations.

#### Reading the results

### How much time do you have to read the results after the test is completed?

Users have up to one hour to remove the cassete from the dock after the test has been completed. If more time elapses, the results will not be valid. After removing the cassette from the dock, results need to be read immediately.

### What should be done if there is condensation in the cassette window?

This is a normal event. In the case that condensation is interfering with reading the results, users can gently tap the cassette to move the condensation outside the cassette window.

### What does the blue shading/streaking on the cassette window mean?

This is a result of the extra dye that has not conjugated to the sample. This does not interfere with result reading.

#### What should you do when you get an invalid result?

The most common cause of invalid results is an error in the user's procedure that causes issues wih the fluidics of the cassette, too little sample being added, or too much sample being added. It is recommended to repeat the test using the stored eluted sample and a new test cassette. If the result is still invalid, results should be reported as such.

#### Why did the positive control not generate a blue line?

In some cases, when the amount of SARS-CoV-2 RNA is high, it can outcompete the RNA of the positive control for PCR reagents. However, if any shade of blue line is present at the "T" position, the result is still considered a positive.

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### Is a test result valid if only a half blue line is generated?

An incomplete blue line in the "T" position is a positive result.

### What should be done if a blue line appears on the cassette minutes after being removed from the dock?

If a test completes and the cassette is initially blank when removed from the dock, but develops any shade of blue line after being on the benchtop for minutes, the cassette is counted as an invalid.

#### Technology and performance

#### How does the rapid test work?

The Renvo Rapid PCR Test technology relies on RT-PCR and lateral flow to detect the SARS-CoV-2 RNA from samples.

#### What SARS-CoV-2 gene does the assay detect?

The assay targets the N gene of SARS-CoV-2.

### Can the assay detect other pathogens besides SARS-CoV-2?

This test is only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

#### How has the technology been validated?

Our collaborators at University of Oregon have validated the use of the Renvo technology in controlled laboratory conditions and realworld field setting sampling to verify its specificity and sensitivity.

#### Does the assay provide a Ct value?

No, Renvo assay only generates qualitative information.

### When should the external SARS-CoV-2 positive and negative controls be run?

It is recommend to run the external controls in the following situations:

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



