

- Easy to perform
- Fast results in 15 minutes
- Visual interpretation
- For In Vitro Diagnostic use

- No special equipment needed
- Technical cooperation with Taiwan's Academia Sinica
REF: <https://iptt.sinica.edu.tw/posts/139911>

Performance and Features

Test Principle	Lateral Flow Chromatographic Immunoassay
Target Antigen	SARS-CoV-2 Nucleocapsid Protein
Sample Type	Fresh Nasopharyngeal Swab Specimen or Fresh Nasal Swab Specimen
Limit of Detection (LoD)	1.26 x10 ² TCID ₅₀ per mL
Cross-Reactivity & Interferences	Viruses, Bacteria and Interferences tested do not cross-react or interfere
Reaction time	15 minutes

Test content:

1. Individually Foil Packaged Test Cassette
2. Extraction Buffer Tube (0.5mL per bottle)
3. User Manual
4. Quick Reference Instruction
5. Sterile Swab

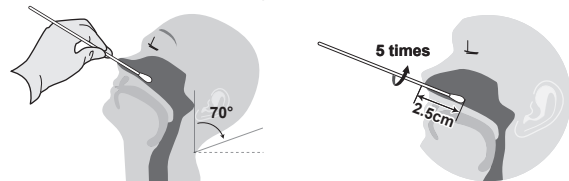
Instruction for Use

SAMPLE COLLECTION AND HANDLING

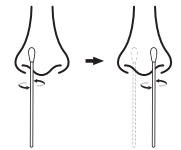
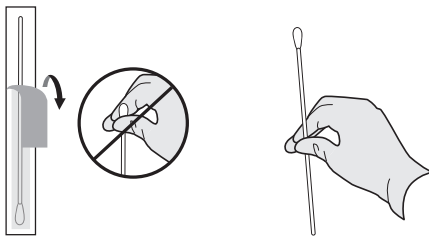
Mid-turbinate or Anterior nasal Sample

1. Take the test strip out from the sealed packaging and place it on a flat and clean surface. Once opened, start the test within 20 minutes.
2. **Gently blow your nose into a tissue and throw the tissue away in a closed bin. If you are testing a child help them to blow their nose.** This is so that you get rid of excess mucus.
3. Wash your hands thoroughly, using soap and water, or hand sanitiser. Dry your hands before performing the test.
4. Take the swab out.
Never touch the soft, fabric tip of the swab with your hands.

5. Tilt the head back about 70 degrees.

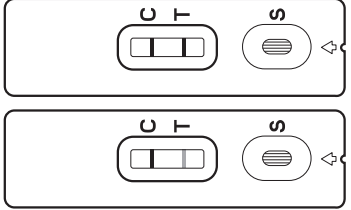
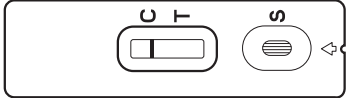
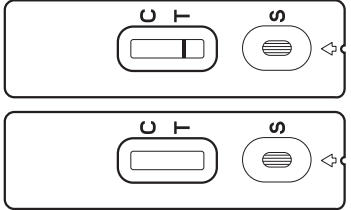
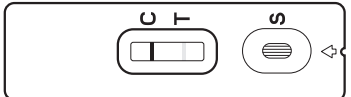


6. Gently insert the entire absorbent tip of the swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 5 times. Make sure the swab tip is touching the nostril walls as you rotate. Take approximately 15 seconds to collect the sample.
7. Remove the swab from the nostril.
8. Using the same swab, repeat Step 6 to Step 7 in another nostril. **It is important to collect samples from BOTH nostrils using the same swab.**
9. After the sample collection is complete, proceed to the assay procedure as soon as possible. Do NOT place the swab back into the packaging after sample collection is complete.



<p>1</p> <p>Remove and discard the cap from the extraction buffer tube.</p>	<p>2</p> <p>Immerse the control swab into the extraction buffer tube. Roll the swab at least ten-twenty (10-20) times while pressing the head against the bottom and side of the extraction buffer tube.</p>	<p>3</p> <p>Leave the swab in the extraction buffer tube for 30 seconds.</p>	<p>4</p> <p>When removing, roll the swab head toward the inside of the extraction buffer tube and squeeze the sides of the tube to extract the liquid from the swab. Dispose of the used swab in your biohazardous waste.</p>
<p>5</p> <p>Press the attached cap tightly onto the extraction buffer tube containing the processed sample.</p>	<p>6</p> <p>Add 3-5 drops (100 µL) of the processed sample into the sample well.</p>	<p>7</p> <p>Visual interpretation at 15-20 minutes. Some positive results may appear sooner. CAUTION: Do not read the results after 20 minutes. It may provide false results.</p>	

Interpretation of Results

<p>Positive</p>		<p>⊕ Positive result</p> <p>There are two colored lines on the test cassette.</p> <p>Both colored test and control lines appear on the test cassette.</p> <p>Within the specified observation time, a weak coloured T line should be judged as a positive result.</p>
<p>Negative</p>		<p>⊖ Negative result</p> <p>Only the colored control line appears on the test cassette.</p> <p>The absence of the test line indicates a negative result.</p>
<p>Invalid Assay</p>		<p>⊗ Invalid result</p> <p>There should always be a colored control line in the control region regardless of the test result.</p> <p>If the control line is not seen, repeat the assay with a new test cassette.</p>
<p>Negative / High CT value</p>		<p>Negative / High CT value</p> <p>Within a specified observation time a very weak colored on T line should be judged as negative or high CT value, please refer to RT-PCR result.</p>

Frequently Asked Questions

Q: Will this test hurt?

A: No, the nasal swab is not sharp and the part touching the nasal wall is soft. Sometimes you can expect some discomfort, there should not be a sharp pain. Do not insert the swab any deeper if you feel strong resistance or pain.

Q: What do I have to do if the test is negative?

A: This means that the virus was not found or the virus count was not high enough to be detected in your sample at that particular moment. However, it is only a snapshot. Hygiene rules should still be followed and if you feel sick, please contact your doctor.

Q: What do I have to do, if the result is unclear?

A: If the result is unclear, you should consult your doctor to take further steps.

Q: What do I have to do if the test is positive?

A: If your test result is positive, you and your household must self-isolate according to the Government guidelines and call your doctor.

Q: Can I use the test, if the test is expired?

A: Do not use any accessory past the expiration date.

Q: Can I read the results after 20 minutes?

A: No. All results after 20 minutes are not valid.

Q: What are the known and potential risks and benefits of this test?

Potential risks include:

Possible incorrect test result (see INTERPRETATION OF RESULTS section)

You may feel uncomfortable during specimen collection.

Potential benefits include:

Slow the spread and help protect the most vulnerable in our families and communities.

The results, along with other information, can help your doctor make informed recommendations about your care.