

A rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid Protein, Influenza A and Influenza B nucleoproteins antigens present in nasal swab specimen.

For self-testing *in vitro* diagnostic use..

## TESTING PROCEDURE

<p><b>01</b></p> <p>Wash hands thoroughly before testing.</p>	<p><b>02</b></p> <p>Remove the cover of the tube containing the extraction buffer. Place the tube in the tube holder.</p>	<p><b>03</b></p> <p>Remove the swab from the pouch. Do not touch the "cotton" tip.</p>	<p><b>04</b></p> <p>Insert the swab into your nostril. Do not exceed 2 cm. Firmly rub the swab in a circular motion around the inside wall of each nostril 5-10 times.</p> <p><b>Note:</b> This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain. When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended. If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.</p>	<p><b>05</b></p> <p>Immediately insert the swab into the bottom of tube containing the extraction buffer. Stir the swab to mix well. Press the tip of the swab in the tube. Rotate the swab for <b>10-15 seconds</b>.</p>	<p><b>06</b></p> <p>Pull out the swab while pinching the tube. Release the sample on the swab in the tube as much as possible.</p>
<p><b>07</b></p> <p>Close the cap or fit the tube tip onto the tube.</p>	<p><b>08</b></p> <p>Remove the test cassette from the sealed foil pouch and use it within one hour. Place the test cassette on a clean and level surface.</p>	<p><b>09</b></p> <p>Invert the tube and add 3 drops of solution to each specimen well(S) of the test cassette and start the timer. Do not move the test cassette during test.</p>	<p><b>10</b></p> <p>Read the result at 10 minutes. Do not interpret the result after 20 minutes.</p>	<p><b>11</b></p> <p>After the test is completed, place all the components of the test kit in a plastic bag and tightly sealed, then dispose of them according to the local regulations. Do not reuse any used components of the kit.</p>	<p><b>12</b></p> <p>Wash hands thoroughly after test disposal.</p>

## READ RESULTS

Please share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.



Positive

**POSITIVE SARS-CoV-2:**\* Two colored lines appear in the left window. One colored line should be in the control region (C) and another colored line should be in the Test region (T).

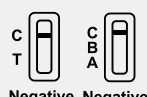
**POSITIVE Influenza A:**\* Two colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A).

**POSITIVE Influenza B:**\* Two colored lines appear in the right window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B).

**POSITIVE Influenza A and Influenza B:**\* Three colored lines appear in the right window. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B).

**\*NOTE:** The intensity of the color in the test line region (T/B/A) will vary based on the amount of SARS-CoV-2 and / or Influenza A+B antigen present in the sample. So any shade of color in the test region (T/B/A) should be considered positive.

A positive results means it is very likely you have COVID-19 and / or Influenza A/Influenza B, but the positive samples should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner/doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.



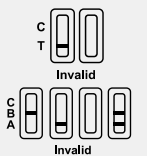
Negative Negative

**NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T/B/A).**

You are unlikely to have COVID-19 and / or Influenza A/Influenza B. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19 and / or Influenza A/Influenza B. This means you could possibly still have COVID-19 and / or Influenza A/Influenza B even though the test is negative.

In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus/Influenza virus cannot be precisely detected in all phases of an infection.

Even with a negative test result, distance and hygiene rules must be observed, migration/traveling, attending events and etc. should follow your local COVID/Influenza guidelines/requirements.



Invalid

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test or contact with a COVID-19 and / or Influenza test center.

## WARNINGS AND PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For self-testing *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not drink the buffer in the kit. Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Test for children should be under the guidance of an adult.
- Wash hands thoroughly before and after handling.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.

## STORAGE

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date. Keep dry.

