



SARS-CoV-2 Antigen Rapid Test

(Nasal Swab) Package Insert For Self-testing

REF: INCP-502H | English

Number: 146642600
Effective Date: 2022-01-04

INTENDED USE

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in nasal swab specimen.
For self-testing *in vitro* diagnostic use.

SUMMARY

The novel coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough, Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases¹.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human swab specimen.

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 AND STABILITY

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.

MATERIALS

Materials Provided

- Test cassette
- Package insert
- Sterile swab
- Extraction buffer
- Biosafety bag

Materials required but not provided

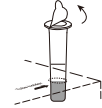
- Timer

PROCEDURE

Wash your hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

1

Remove the cover of the tube with Extraction buffer and place the tube in the tube holder in the box.



2

Nasal swab specimen Collection

1. Remove the sterile swab from the pouch.
2. Insert the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it along the insides of your nostril for 5-10 times against the nasal wall.

Note:

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.

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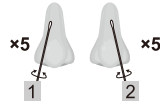
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If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

3. Gently remove the swab.

4. Using the same swab, repeat step 2 in your other nostril.

5. Withdraw the sterile swab



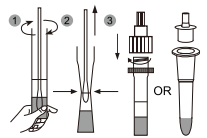
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Specimen Preparation

1. Place the swab into the Extraction tube, ensure it is touching the bottom and stir the swab to mix well. Press the swab head against to the tube and rotate the swab for 10-15 seconds.

2. Remove the swab while squeezing the swab head against the inside of the Extraction tube. Place the swab in the biosafety bag.

3. Close the cap or fit the tube tip into the tube.



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Testing

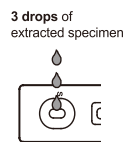
1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

Place the test cassette on a flat and level surface.

2. Invert the specimen extraction tube and add 3 drops of extracted specimen to the sample well(S) of the test cassette and start the timer. Do not move the test cassette during test developing.

3. Read the result at 15 minutes. Do not read the result after 20 minutes.

Note: After test is completed, place all the components into plastic Biosafety Bag and dispose according to local regulation.



READING THE RESULTS

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



POSITIVE: Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T).

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

A positive result means it is very likely you have COVID-19, 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: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).

You are unlikely to have COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 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 cannot be precisely detected in all phases of an infection.

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



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 test center.

LIMITATIONS

1. Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
2. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 antigens in the specimen.
3. If the test result is negative or non-reactive and clinical symptoms persist, it is because the very early infection virus may not be detected. It is recommended to test again with a new kit or test with a molecular diagnostic device to rule out infection in these individuals.

4. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
5. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
6. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
7. Failure to follow these procedures may affect test performance.
8. False negative results may occur if a specimen is improperly collected or handled.
9. False negative results may occur if inadequate levels of viruses are present in the specimen.

INDEX OF SYMBOLS

	For <i>in vitro</i> diagnostic use only
	Store between 2-30°C
	Do not use if package is damaged
	Manufacturer
	Catalog #
	Tests per kit
	Use by
	Lot Number
	Consult Instructions For Use
	Do not reuse

Hangzhou AllTest Biotech Co.,Ltd.
#550, Yinhai Street,
Hangzhou Economic & Technological Development Area,
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

Statement: Information about manufacturer of sterile swab is placed on the packaging.

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