Coretests®

CE 1434 IVD

* Please carefully read the instructions before use

COVID-19 Ag Test

For self-testing

Format: Cassette

Specimen: Nasal swab(anterior nasal area) specimen

• INTENDED USE

COVID-19 Ag Test is the chromatographic assay test used for qualitative detection of the COVID-19 nucleoprotein antigen in nasal swab specimen from suspected patients may infected COVID-19. It is intended to be used in self-testing. COVID-19 Ag Test provides preliminary test results. And negative results don' t preclude COVID-19 Ag infection. The test kit cannot be used as the sole basis for treatment or other management decision. For in vitro diagnostic use only.

People under the age of 15 should be tested by a guardian, and people over 70 years old should seek help from others for swab specimen collection. If the test result is negative but still with the present symptoms, it is recommended to consult a doctor for confirmation in time.A nasal swab sample can be self-collected by an individual aged 15- 70 years. People are unable to collect samples by themselves may be assisted by other adults. Infants or small children should be tested by medical staff.

The test is suitable for symptomatic and asymptomatic patients. It is recommended for symptomatic patients.

• PRINCIPLES

This test kit uses COVID-19 monoclonal antibody and goat anti-mouse IgG polyclonal antibodies that are respectively immobilized on a nitrocellulose membrane. It uses colloidal gold to label sufficient COVID-19 monoclonal antibody. Using nano-colloidal gold technology and applying highly specific antibody-antigen reaction and immunochromatographic analysis technology principle.

When testing, the COVID-19 antigen in the sample combined with the colloidal gold-labeled COVID-19 monoclonal antibody to form a complex, which was then combined with the COVID-19 monoclonal antibody coated in the T line during chromatography. At this time there is one red line in the T area .When the samples do not contain COVID-19 antigen, colloidal gold-labeled COVID-19 monoclonal antibody cannot combined with COVID-19 monoclonal antibody in the T line region, so there is no red colored line in the T area. Regardless of the presence of COVID-19 antigen in the sample, a red line will form in the quality control area (C). The red line appears in the quality control area (C) serves as: 1 verification that sufficient volume is added. 2 that proper flow is obtained 3. and as a control for the reagents.

• MATERIALS PROVIDED

Test contains the following items to perform the assay:

1. Test cassette
2. Instruction for use
3. Sampling swab
4. Biohazard specimen bag
5. Sample collection tube containing sample processing solution
6. Tube rack

• MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Mask
3. Disposable gloves

• WARNING AND PRECAUTIONS

1. Read instruction for use carefully before performing this test.
2. For in vitro diagnostic use only.
3. Do not use the test cassette beyond the expiration date.
4. The test cassette should remain in the sealed pouch until use. Do not use the test cassette if the pouch is damaged or the seal is broken.
5. Do not reuse the cassette and swab.
6. Do not mix and interchange different specimens.
7. You need to use the swab provided in the kit for sampling.
8. The testing process must follow SPECIMEN PREPARATION and TEST PROCEDURE.
9. After the test,collect and put used product components in a plastic bag. Close the bag and put it in another plastic bag. Dispose of the bag with household garbage. Or collected and processed according to the requirements of the local epidemic prevention department.
10. Do not touch the swab head when handling the swab.
11. Insufficient sampling or wrong sampling process may lead to wrong results.
12. Keep test kit and materials out of the reach of children and pets before and after use.
13. Wear safety mask or other face covering when collecting swabs from children or others.
14. That used materials and device should be treated as infectious even if the result of test is valid and negative.
15. If the test result is negative but still with the present symptoms, it is recommended to consult a doctor for confirmation in time.

• SPECIMEN PREPARATION

1. Cleaning preparation before test

Wash or sanitize your hands, and dry completely.

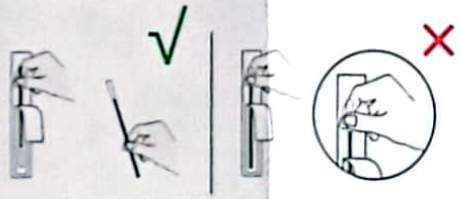
2. Swab sample collection

NOTE: 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.

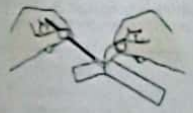
NOTE: Failure to swab properly may cause false negative results.

NOTE: Please wash your hands before and after the test.

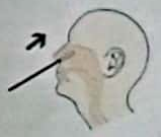
NOTE: Do not touch the tip(specimen collection area) of the swab.



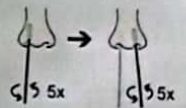
① Remove a nasal swab from the pouch.



② Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met.



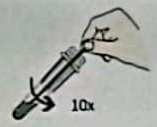
③ Roll the swab 5 times in a circular motion around the inside wall ensure that both mucus and cells are collected.Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.



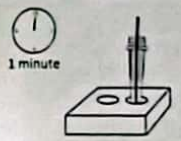
④ Unscrew sample collection tube.

3. Swab sample processing

⑤ Insert the swab in collection tube to the bottom, rotate and squeeze the swab 10 times.



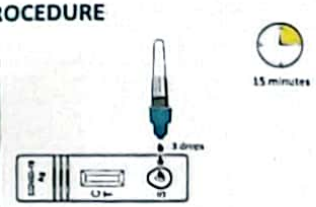
⑥ Leave the swab in the collection tube for 1 minute.



⑦ Rotate and squeeze the tube several times with fingers from outside of the tube to unwater the swab. Remove the swab.

⑧ Screw the cap on the sample tube, break off the top of the cap and begin the test procedure.

• TEST PROCEDURE



Read the instruction first prior to testing. Bring the pouched test to room temperature prior to testing. Do not open the pouch until ready to begin testing.

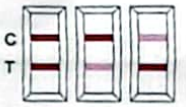
1. Remove the test from the sealed pouch. Lay it on a flat, clean and dry surface.
2. Reverse the sample collection tube, and add 3 drops of test sample by squeezing the collection solution tube into (S) the sample well.
3. Read results at 15 minutes.

NOTE: *The test is intended to be read at 15 minutes. If the test is read before this or is read more than 30 minutes after the indicated read time, results may be inaccurate (false negative, false positive, or invalid) and the test should be repeated.*

4. Collect all the package components and seal in biohazard specimen bag. Discard bag according with local legislation.

Careful: *NO MATTER TEST RESULT IS POSITIVE OR NEGATIVE OR INVALID, this procedure must be done.*

• INTERPRETATION OF RESULTS



POSITIVE

Positive: Control line (C) and T line appear in the show window. Regardless of whether the color of the T line is dark or light, it should be interpreted as a positive result.

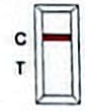
A positive test result means that proteins from the virus that causes COVID-19 were found in your sample and it is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give you a positive test result that is wrong (false positive.)

If you test positive with the COVID-19 Ag Test:

- you should self-isolate,

- and seek follow-up care with doctor/family physician or the local public health department as additional testing may be necessary. Doctor/family physician or the local public health department provider will work with you to determine how best to care for you based on your test result along with your medical history, and your symptoms.

- have a PCR confirmatory test performed.



NEGATIVE

Negative: Only one line appears in Control area (C), no line appears in T area.

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.