

COVID-19 ANTIGEN RAPID TEST DEVICE

REF:COV-S23004H5

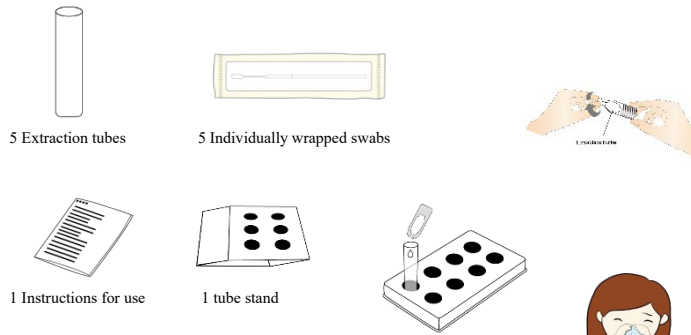
INTENDED USE

The COVID-19 antigen rapid test is an immunochromatographic in-vitro test for the direct and qualitative detection of viral SARS-CoV-2 nucleoprotein antigens in nasal swabs. This test is approved for personal use by people aged 18 and over who are suspected of having a COVID-19 infection. Children 2-15 years of age should be tested by an adult. Children aged 15 and over should be assisted by an adult. Do not use this test on children under 2 years of age.

PRINCIPLE

The rapid test detects the virus protein with the help of antibodies. One of the antibodies is color-coded and moves with the sample over the test strip. If the virus concentration is high enough, the antibody gets stuck in the area of the T-line, causing a colored line to appear. The result is positive. If the sample does not contain any virus or if the concentration of the virus is too low, no T-line appears. The result is negative. In either case, the test must show a C-line. This occurs regardless of the virus concentration and shows that the test is working properly. If the C-line is not displayed, the test result is invalid.

PACKAGE CONTENT



Additionally required



Clock

TEST PROCEDURE

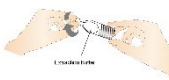
Prepare for the test

- The test should be used at room temperature (15 °C to 30 °C).
- If the test has been stored in a cool place (below 15 °C), allow the test to stand at room temperature for 30 minutes before use.
- Make sure that all packaging is intact. Do not use the test if the foil packaging is visibly damaged.
- Do not open the foil package until you are ready to perform the test.

Use the test within 1 hour of opening.

Test procedure

1. Before starting the test, clean the table surface.
2. Wash your hands thoroughly with soap and warm water or hand sanitizer for 20 seconds. If you do more than one test, clean the surface and wash your hands again between each test.
3. Just prior to performing the test, open the foil pouch, remove the test device, and place it on a clean, flat surface. For best results, the test should be performed within an hour.
4. Insert the extraction tube into the well on the tube stand.

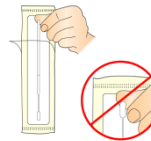


5. Open the ampoule of the extraction buffer. To do this, twist off the tip.

6. Pour all of the liquid into the tube

7. Take your nasal swab

- ① Gently blow your nose into a tissue to remove any excess mucus and toss the tissue into a closed container.
- ② Wash your hands with soap and water or use hand sanitizer for 20 seconds.
- ③ Open the swab packaging. To do this, pull the loose ends of the packaging apart. Remove the swab from the stem. Do not touch the padded tip of the swab



④ Sampling

- a) Insert the swab about 1-2cm into the nostril.
- b) Gently twist the swab 5 times against the nasal wall. The swab should remain in the nostril for 15 seconds.
- c) Pull the swab out of the nose while twisting it slightly.
- d) Repeat the process with the same swab in the other nostril, also for 15 seconds..



slightly.

This can feel uncomfortable. Do not insert the swab any deeper if you experience strong resistance or pain.

8. Process the swab sample

- a) Place the swab into the tube.
- b) Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is



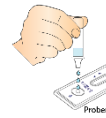
exerted on the tip of the swab.



c) Remove the swab. Squeeze the tube to squeeze as much liquid out of the swab as possible.



d) Place the dropper on the tube. Make sure it's tight.



9. Invert the tube and add 3 drops of the solution to the sample well by gently squeezing the tube.

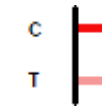


10. Look at the clock. You can read the result after 15 minutes. After more than 20 minutes, the result is no longer valid.

Note:

1. Use only the swab provided.
2. Do not use specimens that are obviously contaminated with blood as this may affect the test.

INTERPRETATION OF RESULTS



Positive test result: two colored stripes appear on the membrane. One stripe appears in the control area (C) and another stripe appears in the test area (T).

The intensity of the color in the test area (T) can vary. However, any shade in the test area should be considered positive. Note that this is a qualitative test only and the virus concentration in the sample cannot be determined. If you get a positive result, it indicates a possible SARS-CoV-2 infection. A positive result also means you are at risk of infecting others, please contact a doctor, family doctor or local health department immediately for a confirmatory PCR test.

Note:

Please follow local guidelines for self-isolation.



Negative test result: Only one colored stripe appears in the control area (C). No stripe appears in the test area (T).

Negative results do not completely rule out SARS-CoV-2 infection. Please continue to comply with all applicable rules regarding contact with others and protective measures. An infection can also be present if the test is negative. In case of suspicion, repeat the tests after 1-2 days, as the coronavirus cannot be accurately detected in all phases of an infection.



INVALID: Control strip does not appear.

Results of tests that do not show a control strip in the control area (C) after 15 minutes are invalid. This may have been caused by an incorrect test execution. Please read the instructions carefully and repeat the test. If the test results remain invalid, contact a doctor or a COVID-19 test center.

NOTE:

Insufficient sample size, incorrect application procedure, or expired tests are the most likely reasons for the missing control strip.

PRECAUTIONS

- Read the instructions for use before use. The instructions for use must be read carefully and followed.
- Do not test or components after their expiration date use.
- Do not use if the pouch is damaged or open.
- The test components are packed in foil pouches to protect them from moisture during storage. Check each foil pouch before opening it. Do not use any component that has holes in the film or the pouch has not been completely sealed. Improper storage of test items or components can lead to incorrect results.
- Do not use the extraction buffer if it becomes discolored or cloudy. Discoloration or cloudiness can indicate microbial contamination.
- If samples and test components are not brought to room temperature before the test, the test sensitivity may be reduced. Incorrect or unsuitable sampling and storage can lead to false negative test results.
- Avoid eye, skin and mucous membrane contact with the buffer. In the event of contact with buffer, rinse with plenty of water.
- Do not use this test on anyone under 2 years of age.
- Keep out of the reach of children. Small test components can pose a choking hazard.
- Use only the supplied test components. Do not replace the buffer with any other liquid.
- Keep the swab clean. Do not touch the swab tip and make sure it does not touch any surfaces before use. Place the swab in the buffer immediately after collecting the sample.
- Do not insert the swab into your nose if it has come into contact with the extraction buffer and do not take the extraction buffer orally. Only a clean swab should be inserted into your nose.
- Use a separate test for each person.
- If you have a nose piercing, dab the other nostril. If pierced on both sides, remove the piercing on one side before wiping it off.
- This test is for human use only.
- Do not touch the sample well or test strip before or during the test. Use the test only to examine nasal swabs.

STORAGE AND SHELF LIFE

- Store the test at 2 to 30 ° C when not in use.
- DO NOT FREEZE.
- The test is stable until the expiry date stated on the outer packaging.
- Keep out of the reach of children.

QUALITY CONTROL

Internal procedural controls

The test has an internal control. If the colored stripe is present in the “C” area, it indicates that the test was performed correctly and the result is valid.

LIMITATIONS OF THE TEST

1. The test is suitable for personal use and may only be used for the qualitative detection of the SARS-CoV-2 antigen.
2. As with all diagnostic tests, a clinical diagnosis must not be based on the results of a single test, but rather be made by the doctor after all clinical and laboratory results have been evaluated.
3. Failure to follow the TEST PROCEDURE and INTERPRETATION OF RESULTS may negatively affect and / or falsify the test result.
4. Negative results do not completely rule out an infection with SARS-CoV-2.

PERFORMANCE CHARACTERISTICS

Analytical sensitivity (detection limit):

The detection limit was determined with a SARS-CoV-2 virus and is 2×10²⁻⁴ TCID₅₀ / ml.

The detection limit was also determined with a recombinant SARS-CoV-2 nucleoprotein and is 0.4 ng / ml.

Clinical evaluation:

Clinical examinations were performed to compare the results obtained with the COVID-19 Antigen Rapid Test and an RT-PCR comparison test. There is no cross-reactivity of the following pathogens with the COVID-19 antigen rapid test.

The results are shown below:

		RT-PCR		Total
		Positive	Negative	
COVID-19 Antigen	Positive	96	0	96
	Negative	6	243	252
Total		102	243	345

Relative sensitivity: 94.1% (87.8% ~ 97.3%)* (Ct<30)

Relative specificity: 100.0% (98.4% ~ 100.0%)*

Overall agreement: 98.3% (96.3% ~ 99.2%)*

*95% Confidence Interval

Cross reactivity:

One study investigated whether the test would give a false-positive result in the presence of other pathogens (cross-reactivity). The following pathogens were examined: HCoV-HKU1, HCoV-OC43, HCoV-NL63, HCoV-229E, Measles virus, Streptococcus pneumonia, Epstein-Barr virus, Bordetella parapertussis, Influenza A (H1N1) pdm09, Influenza A (H3N2), Influenza A (H5N1), Influenza A (H7N9), Influenza A (H7N7), Influenza B Victoria lineage, Influenza B Yamagata lineage, Respiratory syncytial virus,

Adenovirus, Parainfluenza 1/2/3 virus, Human metapneumovirus, Rhinovirus, Coxsackie virus A16, Norovirus, Mump virus, Legionella pneumophila, Mycoplasma pneumonia, Chlamydia pneumonia, Streptococcus pyogenes, Streptococcus agalactiae, Group C Streptococcus, Staphylococcus aureus. All results were negative. This means a positive result with high probability of SARS-CoV-2 and not is due to another pathogen.

Interfering substances:

The following substances, which occur naturally in respiratory samples or which can be artificially introduced into the airways, have been evaluated at the concentrations listed below. None of them affect the test performance of the COVID-19 Antigen Rapid Test.

Substance	Concentration	Substance	Concentration
4-acetamidophenol	10 mg/ml	Mucin	1%
Acetylsalicylic acid	20 mg/ml	Mupirocin	250 µg/ml
Albuterol	20 mg/ml	Oxymetazoline	10 mg/ml
Chlorpheniramine	5 mg/ml	Phenylephrine	10 mg/ml
Dexamethasone	5 mg/ml	Phenylpropanolamine	20 mg/ml
Dextromethorphan	10 mg/ml	Relenza® (zanamivir)	20 mg/ml
Diphenhydramine	5 mg/ml	Rimantadine	500 ng/ml
Doxylaminesuccinate	1 mg/ml	Tamiflu® (oseltamivir)	100 mg/ml
Flunisolide	3 mg/ml	Tobramycin	40 mg/ml
Triamcinolone	14 mg/ml	Guaiacol glyceryl ether	20 mg/ml

GLOSSARY OF SYMBOLS

ρ	Catalog	Ø	Temperature limitation
I	In-vitro diagnostics	Λ	Batch code
μ	Manufacturer	ε	Use by
▽	Contains sufficient for <n> tests	σ	Do not reuse
ι	Consult instructions for use	Α	Authorized representative in the European

U

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