SARS-CoV-2 ANTIGEN RAPID TESTS

REF: COV-S23004H1

INTENDED USE

The SARS-CoV-2 Antigen Rapid Tests is a rapid visual immunoassay for the direct and qualitative detection of viral SARS-CoV-2 nucleoprotein antigens in nasal swabs. This test is intended for personal use by people aged 18 and over who are suspected to be infected with COVID-19. 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. The SARS-CoV-2 Antigen Rapid Tests is for self-testing use. The test procedure is not automated. Test results should not be used as a sole basis for diagnosis but should always be interpreted by a physician in the clinical context.

PRINCIPLE

The rapid test detects the virus protein with the help of antibodies. One of the antibodies is color- conjugated and moves with the sample over the test strip.

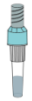
If the virus concentration is high enough, the antibody gets stuck in the area of the T-line, causing a colored line to appear. The result is positive.

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 CONTENTS

1 Test Device



1 Extraction buffer

1 Instruction for use

1 Individually wrapped swab

1 Plastic garbage bag

1 Desiccant

Additionally required

Clock

TEST PROCEDURE

Prepare for the test

- **The test should be used at room temperature (15℃ to 30 ℃).**

If the test has been stored in a cool place (below 15 ℃), 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.**

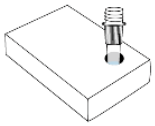
Use the test within 1 hour of opening.

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 testshould be performed within an hour.

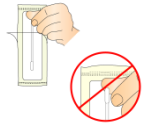


4.Insert the extraction buffer into the well on the packaging and unscrew the blue cap.

5. Take your nasal swab

①Gently blow your nose into a tissue to remove any excess mucus and toss the tissue into a closed container.

②Wash 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. (Collect the anterior nasal swab specimen)

b) Gently twist the swab 5 times against the nasal wall. The swab should remain in the nostril for 15 seconds.

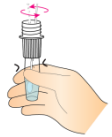
c) Pull the swab out of the nose while twisting it slightly.

d) Repeat the process with the same swab in the other nostril, also for 15 seconds.

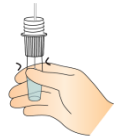
This can feel uncomfortable. Do not insert the swab any deeper if you experience strong resistance or pain.

6.Process the swab sample

a) Place the swab into the tube.

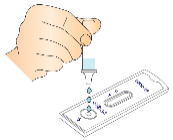


b) Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is exerted on the tip of the swab.



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

d) Screw the blue cap back onto the extraction tube and unscrew the top white cap



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

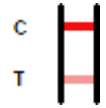
8.Look at the clock. You can read the result after 15 minutes. After more than 20 minutes, the result is no longer valid.

9.When your test is finished, put all of the contents of the test kit you used in the waste bag provided. Dispose of the closed waste bag with household waste.

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



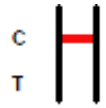
Positive test result: two colored stripes appear on the membrane. One stripe appears in the control area (C) and another stripe appears in the test area (T).

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:

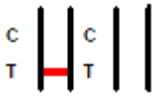
Please follow local guidelines for self-isolation.



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 $2\times10^{2.4}$ $TCID_{50}$ / mL.

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

Clinical evaluation:

The SARS-CoV-2 Antigen Rapid Tests was evaluated with clinical specimens whose status was confirmed using RT-PCR tests approved by FDA-EUA. (DTPM COVID-19 RT-PCR Test or TaqPath™ COVID-19 Combo Kit).

A total of 345 clinical specimens were collected. 102 positive specimens (Ct value range: 14~30) and 243 negative specimens were confirmed by RT-PCR. The results are shown below:

		RT-PCR		Total
		Positive	Negative	
SARS-CoV-2 Antigen Test	Positive	96	0	96
	Negative	6	243	249
Total		102	243	345

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

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, Bordetellaparapertussis, 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 virusA16, 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 notis 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 SARS-CoV-2 Antigen Rapid Tests.

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

Reproducibility

Reproducibility has been determined by using the precision panel containing negative(assay buffer), low positive (1X LOD), and high positive (5X LOD). Three different lots have been tested using these specimens by 3 operators over 5 days. The results are consistent between the different lots, sites and operators.

Repeatability

Assays were carried out to determine assay repeatability using replicates of 10 tests for one lot using the precision panel containing negative(assay buffer), low positive (1X LOD), and high positive (5X LOD). The results are consistent for one lot products.

LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).

2. Ithete, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).

GLOSSARY OF SYMBOLS

REF	Catalog		Temperature limitation
IVD	In-vitro diagnostics	LOT	Batch code
	Manufacturer		Use by
	Contains sufficient for <n> tests		Do not reuse
	Consult instructions for use	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

IVD

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CE 0197 EC REP

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CE 0197 EC REP

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