Hotgen

Novel Coronavirus 2019-nCoV Antigen Test

Instructions for Use:

Product Name: Novel Coronavirus 2019-nCoV Antigen Test

Packaging Specification: 1 T/kit, 5 T/kit, 20 T/kit, 40 T/kit, 50 T/kit

Model: E

Intended Use

This kit is used for in vitro detection of SARS-CoV-2 antigen by nasal swabs. This kit can be used for both a rapid test of suspected cases of SARS-CoV-2 and a nucleic acid test after discharge from the hospital in patients infected with SARS-CoV-2. A positive test result indicates that the sample contains SARS-CoV-2 antigen. A negative test result indicates no infection with SARS-CoV-2.

COVID-19 is an infectious and acute respiratory disease that is highly contagious. At present, it seems that patients infected with SARS-CoV-2 are the main source of infection. However, the asymptomatic are also a potential source of infection. The incubation period may last for 1 - 14 days, and in most cases, the onset of symptoms occurs in 3 - 7 days in infected cases. Main symptoms include fever, dry cough, fatigue, anosmia, and/or ageusia. Infected cases may also suffer from nasal congestion and/or runny nose, sore throat, muscle pain, diarrhea, etc.

This kit is intended for self-testing of SARS-CoV-2 at home and in the workplace (offices, sporting events, airports, schools, etc.) instead of professional medical testing facilities. Minors (under 18 years old) are required to use this product under the supervision of an adult.

Instructions for Use

1. Before testing, you must read the Instructions for Use carefully and operate in strict accordance with the requirements. Select a clean and bright table for operation to provide enough space for the appliances. Prepare the timing tool before operation to determine the test time. Wash or disinfect your hands thoroughly before and after the test.

2. If this kit has not been stored at room temperature (10-30°C) before use, it should be placed at room temperature for 15 to 30 minutes before use.

3. Please watch the following videos carefully before use:

4. Remove the swab from the package and do not touch or contaminate the cotton wool on the front of the swab during this procedure. Gently insert the swab into the palate of the nasal passage to a depth of approximately 1.5 cm until slight resistance is felt. Do not insert the swab further into the nasal cavity if strong resistance or pain is felt while advancing into the nasal passage. Use moderate force to hold the swab in the nose for at least 15 s, gently rotate 4 - 6 times before removing the swab to ensure that the collected cells and mucus meet the test requirements. Collect samples from the other nostril in the same manner.

5. Hold the sample swab on one side and the sampling tube on the other. If the cap of the sampling tube is purple, it is tube A. If the cap of the sampling tube is a silver metal tongue-shaped cap, it is tube B.

Tube A: Unscrew the purple cap at the wide opening to open the sampling tube.

Tube B: Remove the silver tongue-shaped cap to open the sampling tube.

Put the sampling swab into the sampling tube.

The sampling swab head must be immersed in the sample solution for at least 15 s. Rotate the swab in the sampling tube several times and press the head 3 times. Squeeze the sampling tube while removing the swab. Then cover the sampling tube with the cap. At this time, the liquid retained in the sampling tube is the sample to be tested.

6. Used swabs should be sealed with a plastic bag specially designed for contaminants.

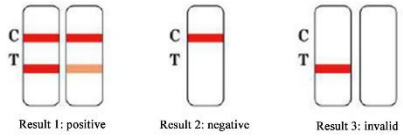
7. Open the silver aluminum foil bag and place the kit on a flat operation table. The aluminum foil bag should be used within 30 minutes after opening (10 – 30°C, humidity ≤ 70%).

8. Tube A: Open the small cap on the front of the sampling tube and accurately drip 4 drops of sample solution into the sample well (S) of the kit.

Tube B: Accurately drip 4 drops of sample solution into the sample well (S) of the kit.

9. Drip the sample solution at room temperature (10 - 30°C) and observe the test results after 15 minutes. The test results for 30 minutes after dripping the sample solution are not valid.

10. Result evaluation



Positive: Two lines appear in the observation region, i.e. red or magenta horizontal lines at the C-line (Control Region) and the T-line (test line) as shown in result 10. This represents a positive test for SARS-CoV-2 antigen in the sample. The tested person is suspected of SARS-CoV-2 infection and should immediately conduct self-quarantine according to local instructions and immediately contact the local health department or the appropriate responsible physician according to local government requirements.

Negative: A single horizontal line in the Control Region (C) indicates that the sample has been tested negative or is unidentifiable because the viral load in the sample is too low. In case of headache, migraine, fever, anosmia/ageusia, etc., the tested person should contact the nearest medical institution according to local government regulations. In addition, a second test can be performed using a new test reagent. Since SARS-CoV-2 may not be detected early in infection, the test can be repeated one to two days later if there is still concern about infection.

Even if the test result is negative, hygiene regulations of the local government must be followed to maintain social distance.

Invalid: If there is no horizontal line at position C (control area) (as shown in result 10), the test result is invalid. This may be caused by an incorrect operation. At this time, please use a new test reagent and strictly follow the Instructions for Use to carry out the test again. For additional invalid test results, please contact the responsible physician or the local COVID-19 test center.

11. After the test, please put all parts used during the test in the plastic bag specially designed for contaminants and sealed with the residual contaminants for processing. All parts are prohibited for reuse.

12. Wash or disinfect hands thoroughly again after processing.

Components:

1. Novel Coronavirus 2019-nCoV Antigen Test
2. Sampling tube (sample solution)
3. Swab
4. Plastic bag specially designed for contaminants
5. Instructions for Use

There may be differences in the outer package design of the Novel Coronavirus 2019-nCoV Antigen Test, and the actual package shall prevail.

Storage and Shelf Life:

1. The kit should be stored at 4 - 30°C with a shelf life of 18 months. Do not use the product after the expiration date. See product label for manufacturing date and shelf life.

2. The aluminum foil bag should be used within 30 minutes after opening (10 - 30°C, humidity ≤ 70%).

3. The sample solution should be used within 18 months after unsealing (10 - 30°C, humidity ≤ 70%).

Test Validity

Due to the activity of the reagent, a horizontal line will appear in the controlled area if the test is performed correctly.

Limitation:

1. This kit is used for qualitative detection and cannot quantify the concentration of SARS-CoV-2 antigen.

2. The test method is simple with potential errors. Therefore, additional tests are recommended to assist in the demonstration of test results.

3. The test results are related to the collection, processing, transportation, and storage of the samples. Any incorrect operation may lead to inaccurate test results. If the sample is contaminated during processing, it may result in a false-positive test result.

4. The kit is only for sample testing by a nasal swab.

Through the testing of 108 positive SARS-CoV-2 antigen samples and 115 negative SARS-CoV-2 antigen samples, it is confirmed that this Novel Coronavirus 2019-nCoV Antigen Test (colloidal gold method) is with a sensitivity of 95.37% (95% CI: 89.62 - 98.01%) and a specificity of 99.13% (95% CI: 95.24 - 99.85%) in terms of clinical manifestations.

		PCR (Polymerase Chain Reaction) Test Results		
		Positive	Negative	Total
Test results of SARS-CoV-2 antigen (colloidal gold)	Positive	103	1	104
	Negative	5	114	119
	Total	108	115	223
		Sensitivity	Specificity	Total coincidence rate
		95.37% [89.62%; 98.01%]	99.13% [95.24%; 99.85%]	97.31% [94.26%; 98.76%]

Preventive Actions:

1. This kit is only used for in vitro detection of SARS-CoV-2 antigen. Please read the Instructions for Use carefully before testing.

2. Use the swab and sampling tube (sample solution) in this kit only for testing. Do not replace the sampling tube (sample solution) in this kit with parts from other kits.

3. Stop use if the kit or its components are damaged.

4. Operate in strict accordance with the Instructions for Use, and do not mix different batches of products for use.

5. Test the samples as soon as possible after sampling.

6. Positive and negative predictive values depend largely on prevalence. A positive test result may be false-positive when the activity of the SARS-CoV-2 is low/inactive and the disease prevalence is low. There is also a high possibility of false-negative test results at a high prevalence of disease caused by SARS-CoV-2.

7. Five days after showing symptoms of SARS-CoV-2 for the first time, the sensitivity of this kit is lower than that of the RT-PCR for SARS-CoV-2 antigen testing.

8. The kit should be used within 30 minutes after opening (10 - 30°C, humidity ≤ 70%). Unopened kits must be sealed and stored in a dry place.

9. All wastes and sample residues generated during the test should be treated as infectious substances. These substances should be put into the garbage bag and then disposed of as domestic wastes.

10. Do not drink any liquid from the sampling tube. Do not eat, drink or smoke in the testing area. If swallowed, rinse your mouth thoroughly immediately and then drink plenty of water. In case of any discomfort, please consult your physician immediately. The Safety Data Sheet can be found at the following website:

11. If the sample solution comes into contact with the skin or eyes, wash/rinse the affected area immediately with plenty of water. In case of irritation, please consult your physician immediately.

12. Take off the contaminated clothing (if any) immediately and make sure to not contact the eyes.

Identification Description:

	Shelf life		Batch		Pay attention to the Instructions for Use
	Contents sufficient for testing		Temperature limitation		Catalog No.
	Manufacturing date		Caution		Do not reuse
	For self-testing		Authorized by the European Community		Manufacturer
	For in vitro detection		Keep away from light		Keep dry
	Do not use if the product is damaged				

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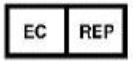

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Approval and Revision Dates of the Instructions for Use:

Approved in May 2021;

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Frequently Asked Questions(FAQ):

● When can I perform self-testing?

You may perform self-testing at any time. However, it should be noted that the test result only indicates that you have not been infected with SARS-CoV-2 at the time. Therefore, repeated tests should be performed as required by the regulatory authority.

● What should I pay attention to for an accurate test result?

You need to strictly follow the Instructions for Use. The sample should be tested immediately after collection. The sample solution in the sampling tube should be accurately dripped into the sample well of the kit. Four drops should be dripped. Too much or too little may result in an inaccurate test result.

● What is the testing principle?

The N protein of SARS-CoV-2 reacts with the coating of the test line and leads to a color change, i.e. a red line. If the sample does not contain any N protein of SARS-CoV-2, the test line (T) will not turn red.

● What may result in a too deep color of the test line? Or what did I do wrong?

Too deep color in the test line is due to too much sample solution dripped into the sample well of the kit. The sample well of the kit can only accommodate limited sample solution. If the color of the control line does not change or if the color of the test line has changed significantly, please retest with a new kit according to the Instructions for Use.

● What should I do if the color of the control line does not change after the test?

In this case, the test result is invalid. This may be caused by improper operation.

Please retest with a new kit according to the Instructions for Use. If the test results continue to be invalid or other abnormal test results occur, please contact the responsible physician or the local COVID-19 test center.

● What should I do if I cannot confirm the test result?

If you are unsure of the test result, please contact the nearest medical institution according to local government regulations.

● What should I do if the test result is positive?

If your test result shows colored horizontal lines in both the Control Region (C) and the Test Region (T), then the test result is positive and you may be infected with SARS-CoV-2. Please immediately conduct self-quarantine according to local epidemic prevention requirements. Your test result will be confirmed by a PCR test, please follow the steps of the PCR test for subsequent operation.

● What should I do if the test result is negative?

If your test result shows only one colored horizontal line in the Control Region (C), the test result is negative or unidentifiable by the kit because the viral load in the sample solution is too low. In case of headache, migraine, fever, anosmia/ageusia, etc., you should contact the nearest medical institution according to local government regulations. In addition, a second test can be performed using a new test reagent. In addition, a second test can be performed using a new test reagent. Since SARS-CoV-2 may not be detected early in infection, the test can be repeated one to two days later if there is still concern about infection. Even if the test result is negative, hygiene regulations of the local government must be followed to maintain social distance.

● Can the kit be reused or shared by many people?

The kit is disposable and cannot be reused or shared.

● Where should I discard the product?

The kit can be disposed of with ordinary domestic wastes.

Self-testing - Comply with Article 11 "Special Regulations Regarding Placing on the Market and Putting into Service" in German Medical Devices Act (BfArM GZ: 5640-S-057/21)