Hotgen

Coronavirus (2019-nCoV)-Antigen Test -

Instructions for Use

PRODUCT NAME Coronavirus (2019-nCoV)-Antigen Test -

PACKAGING SPECIFICATION 1T/Kit, 5T/ Kit, 20T/ Kit, 40T/ Kit,50T/ Kit

MODEL NUMBER E

INTENDED USE

The kit is used for the in vitro qualitative determination of the SARS-CoV-2-Virus antigen in a human anterior nasal swab samples. The test serves as a rapid examination for suspected cases of novel coronavirus, and can also serve as a confirmation method for nucleic acid tests in discharged patients. A positive test result indicates that the sample contains SARS-CoV-2-Virus antigen. A negative test result does not rule out the possibility of infection.

People are generally susceptible to COVID-19, an infectious and acute respiratory disease. Infected patients are currently the largest source of infection, and asymptomatically infected people are also a source of infection. The incubation period is 1 to 14 days, but mostly 3 to 7 days. The most important symptoms include fever, dry cough, fatigue, loss of smell and / or taste. Symptoms such as a blocked and / or runny nose, sore throat, muscle pains, and diarrhea can also occur.

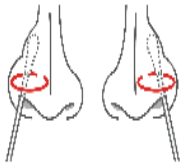
This test is for medical laypersons as a self-test at home and at work (in offices, for sporting events, airports, schools, etc.).

INSTRUCTIONS FOR IMPLEMENTATION:

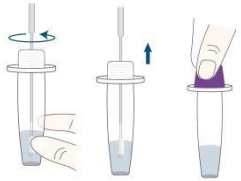
1. Read through all of these instructions before starting the test. Take the time to do it calmly and carefully. Find a clean and bright working surface with enough space for all utensils. Have a watch ready next to the test kit. Wash or disinfect your hands thoroughly before the start and after the completion of the test .

2. Check out the training video at:

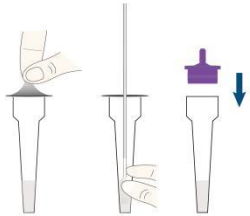
3. Take the swab out of the packaging without touching the wadding and carefully insert the cotton swab 1.5 cm into one of the nostrils until you feel a slight resistance. Do not insert the swab deeper if you feel strong resistance or pain. Using medium pressure, move the swab 4 to 6 times in a circular motion along the inner wall of the nose for at least 15 seconds in order to collect as many cells and mucus as possible. Repeat sampling with the same swab in the other nostril.



4. A. Open the large opening of the sampling tube and insert the used swab with the collected sample into the tube. The sample must be soaked in the sample extraction buffer liquid. The soak time for the swab is at least 15 seconds, the swab must be turned several times and the swab head must be pressed 3 times. Squeeze the swab on the sampling tube while removing the swab. The sampling tube is then closed with the cap. The liquid in the tube is the sample after the treatment.



Or B. Tear off the aluminum foil on the sampling tube and insert the used swab with the collected sample into the tube. The sample must be soaked in the sample extraction buffer liquid. The soak time for the swab is at least 15 seconds, the swab must be turned several times and the swab head must be pressed 3 times. Squeeze the swab on the sampling tube while removing the swab. The sampling tube is then closed with the cap. The liquid in the tube is the sample after the treatment.



5 Put the used swab in the enclosed plastic bag for contaminated waste.

6.If the test cassette and the sample have not been stored at room temperature (10 ~ 30 ℃), they should be stored at room temperature for 15 to 30 minutes.

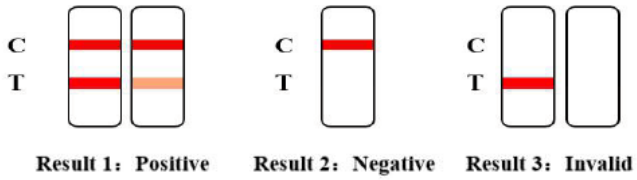
7. Open the silver aluminum pouch and place the test cassette on a flat surface. After opening the foil pouch, the test should be used within 30 minutes (temperature 10 ~ 30 ℃, humidity ≤70%).

8. A. Open the sampling tube at the small front screw connection and put exactly 4 drops of the treated sample into the sample hole (S) of the test cassette.

Or B. Put exactly 4 drops of the treated sample into the sample hole (S) of the test cassette.

9. Observe the result after applying the drops at room temperature (10 to 30 ° C) for 15 minutes. The result displayed after 30 minutes is invalid.

10. Evaluation of the results



Result 1：Positive **Result 2：Negative** **Result 3：Invalid**

Positive: Two colored bands appear in the observation window, i.e. a red or magenta-colored line appears at the position of the C-line (control area) and at the T-line (detection line) as shown in result 10. The test result for the novel coronavirus antigen in the sample is positive. There is currently a suspicion of a COVID-19 infection. Immediately take self-isolation measures 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 the next steps will be explained to you..

Negative: If only a horizontal colored line is visible in the control area (C), this can mean that you are negative or that the viral load is too low to be recognized by the test. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, contact the nearest medical facility using the rules of your local authorities. 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!

Invalid: No line appears at position C (control area) in the observation window (as shown in Result 10), indicating that the test is invalid. This can be caused by a possibly incorrect test operation. Please repeat the test with a new test kit according to the instructions for use. If you have any further invalid test results, contact your doctor or a COVID-19 test center.

11. After the test, pack all the components of this test in the enclosed plastic bag for contaminated waste and dispose of this bag closed with the residual waste. Not reusable.

12. Wash or disinfect hands again.

COMPONENTS

1. SARS-CoV-2 antigen test cassette
2. Sample extraction buffer
3. Disposable virus specimen swab
4. Biohazard specimen bag
5. Instructions for use

STORAGE AND SHELF LIFE

1.The kit should be stored at 4 ~ 30 ° C and the shelf life is 18 months. Do not use the product after the expiration date. See label for the manufacture date and expiry date.

2.After opening the foil pouch, the test should be used within 30 minutes (temperature 10 ~ 30 ℃, humidity ≤70%), and it should be used immediately after opening at 30 ℃.

3. The sample extraction buffer should be used within 18 months after opening (temperature 10 ~ 30 ℃, humidity ≤70%)..

TEST PROCEDURE

If the test was carried out correctly, the control line appears because the reagents are reactive.

LIMITATIONS

1. The kit is a qualitative test that cannot quantify the concentration of SARS-CoV-2 antigen.

2. The test result of this kit is not the only confirmation indicator for clinical indications. If the test result does not match clinical evidence, it is recommended to perform additional tests to verify the result.

3. The test results of the samples are related to the quality of the sample collection, processing, transportation and storage. Any mistakes can cause inaccurate test results. If cross-contamination is not controlled during sample processing, false positive results can occur.

4. Children and young people under the age of 18 should be supported by an adult.

5. Clinical Performance: Nasal Swab Samples

The clinical performance of the novel coronavirus (2019-nCoV) antigen test (colloidal gold) is confirmed by self-tests in an examination of 108 positive and 115 negative samples for SARS-CoV-2 antigen (Ag). The sensitivity is 95.37% (95% CI: 89.62-98.01%) and the specificity is 99.13% (95% CI: 95.24-99.85%).

		PCR test results		
		Positive	Negative	Invalid
Results of the novel coronavirus (2019-CoV) antigen test (colloidal gold)	Positive	103	1	104
	Negative	5	114	119
	Invalid	108	115	223
		Sensitivity	Specificity	Overall percentage agreement
		95,37% [89.62%; 98.01%]	99,13% [95.24%; 99.85%]	97,31% [94.26%; 98.76%]

PRECAUTIONS

1. The kit is intended for in-vitro diagnostic use only. Please read the instructions for use carefully before test.

2. Please use the swab and sample extraction buffer included in this kit. Do not replace the sample extraction in this kit with components from other kits.

3. Use only undamaged test kits.

4. Operation should be strictly according to the instructions and different batches should not be mixed.

5. The user should test the sample as soon as possible as the clinical performance assessment of a frozen sample may differ from a fresh sample.

6. Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.

7. The sensitivity of the test after the first five days of symptom onset has been shown to be decreased when compared to the RT-PCR SARS-CoV-2 assay.

8. After opening, the test cassette must be used within 30 minutes (temperature 10～30 ℃, humidity ≤70%) and it should be used immediately after opening at room temperature (10 - 30 ℃). The unused test cassette must be sealed and stored in a dry place.

9. DO NOT drink any liquid in the sampling tube. In the event of accidental ingestion, rinse your mouth thoroughly, the extraction liquid is not toxic.

10. The waste or excess samples generated during the test should be inactivated according to the treatment for infectious agents.

EXPLANTION OF IDENTIFICATION

	Use by date	LOT	Batch		Consult Instruction for use
	Content Sufficient For <n> Tests		Temperature limit	REF	Catalog number
	Manufacturing date		Attention		Do not reuse
	For self-test	EC REP	Authorized representative in the European Community		Manufacturer
IVD	For use in in vitro diagnostics		Keep away from sunlight		Keep dry

Beijing Hotgen Biotech Co., Ltd.

9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District, Beijing, 102600, P.R. China.

EC REP

MedNet GmbH

Borkstrasse 10, 48163 Muenster, Germany

Distribution:

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DE-71083 Herrenberg,Germany
www.asid-bonz.de

APPROVAL DATE AND REVISION DATE OF THE INSTRUCTION

Approved on March. 2021;

Version number:V. 2021-01.01[Eng.]

IVD

FREQUENTLY ASKED QUESTIONS (FAQ)

- **When can I test myself?**

You can always test yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated in accordance with the requirements of the responsible authorities..

- **What do I have to pay attention to in order to get the most exact test result possible?**

Always follow the instructions for use exactly. Perform the test immediately after collecting the sample. Put the drops from the sample tube only into the designated well of the test cassette. Dispense four drops from the sample tube. Too many or too few drops can lead to an incorrect or invalid test result.

- **How does the test work?**

The N-protein of the SARS-CoV-2 virus reacts with the coating of the test line and leads to a color change, i.e. a red line appears. If the sample does not contain any virus proteins or antigens, no red test line (T) appears.

- **The test strip is very discolored. Why is this or what am I doing wrong?**

The reason for a clearly visible discoloration of the test strip is that too large a quantity of drops has been dispensed from the test tube into the test cassette well. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is severely discolored, please repeat the test with a new test kit according to the instructions for use.

- **What should I do if I did the test but don't see a control line?**

In this case the test result is to be considered invalid. This can be caused by a possibly incorrect test operation. Please repeat the test with a new test kit according to the instructions for use. If you have any further invalid test results, contact your doctor or a COVID-19 test center.

- **I am unsure of the interpretation of the results. What should I do?**

If you cannot clearly determine the result of the test, contact the nearest medical facility using the rules of your local authority.

- **My result is positive. What should I do?**

If a horizontal colored line is visible in the control area (C) as well as in the test area (T), your result is positive. There is currently a suspicion of a COVID-19 infection. Immediately take self-isolation measures 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 the next steps will be explained to you.

- **My result is negative. What should I do?**

If only a horizontal colored line is visible in the control area (C), this can mean that you are negative or that the viral load is too low to be recognized by the test. If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility using the rules of your local authority. 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. Distance and hygiene rules must still be observed.

- **Can this test cassette be reused or used by more than one person?**

This test cassette is for single use and cannot be reused or used by more than one person.

- **Where do I dispose of the product ?**

The test kit can be disposed of with normal household waste..

The product will be placed on the market for the first time in Germany for a limited period in accordance with section §11 paragraph 1 MPG