TEST IT for healthy generations

INSTRUCTIONS FOR USE

COVID-19 Ag HOME TEST

For the antigen of novel coronavirus detection in human nasal swabs

in vitro diagnostic test

In vitro diagnostic use only

Product Code: TICVH02005

BACKGROUND INFORMATION

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in some cases.

INTENDED USE

COVID-19 Ag Home Test for use by lay persons in a home environment, is intended for the in vitro qualitative detection of the nucleocapsid (N) protein antigen of the novel coronavirus in human nasal swabs.

METHOD

COVID-19 Ag Home Test is a rapid, qualitative, immunochromatographic assay for the detection of 2019-nCoV antigen in human nasal swabs. The sample will be under the capillary action to move forward along the test cassette; if the sample contains new coronavirus antigen at detectable level, the antigens will bind to the antibody, which is labeled with colloidal gold and form a colored line, which means the sample is coronavirus antigen positive. If the line does not display color, it means that the sample is SARS-CoV-2 antigen negative. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been used and membrane wicking has occurred.

FREQUENTLY ASKED QUESTIONS

Will this test hurt?
No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

What are the known and potential risks and benefits of this test?
Potential risks include:
• Possible discomfort during sample collection.
• Possible incorrect test results (see Interpretation of Results section).
Potential benefits include:
• The results, along with other information, can help your healthcare provider make informed recommendations about your care.
• The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What is the difference between an antigen test and molecular test?
There are different types of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. The antigen test has been developed specifically for this virus. But are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you are able to discontinue home isolation.

How Accurate is this Test?
Based on the interim results of a clinical study where the COVID-19 Ag Home Test was compared to an FDA authorized and CE certificated high sensitivity SARS-CoV-2 PCR kits, COVID-19 Ag Home Test correctly identified 92.71% of positive specimens and 99.54% of negative specimens.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging will remain stable until the expiry date if the storage conditions have been adhered to. The test device should be used within a maximum of 1 hour after the foil has been opened.

KIT COMPONENTS

5 Test cassette, 5 sterile swab, 5 sample extraction reagent tube and 1 insert with instructions for use.

Additional materials required but not provided: Timer, gloves, personal protection equipment.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
Learn how to perform the test by watching the application video of the test referred to on this insert.
3. Do not use test kit beyond expiry date. The test device is single use. Do not re-use any contents in the kit as they are single-use only.
4. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
5. Wash your hands with soap and water for at least 20 seconds, rinse, and dry before collecting the nasal sampling and after testing.
6. Wear disposable gloves while performing the test.
7. Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
8. The extraction agent contains the following substances: Purified water, $Na_2HPO_4.12H_2O$, $NaH_2PO_4.2H_2O$, Tween 20, Proclin 300.
If the extraction reagent contacts the skin or eye under the following conditions, please:
Eye contact: Immediately flush eyes thoroughly with water for at least 15 minutes. If the symptoms persist, get medical attention.
Skin contact: Immediately wash thoroughly with soap and water for 15 minutes. If the symptoms persist, get medical attention.
Inhalation: Move into fresh air immediately. If the symptoms persist, get medical attention.
9. Dispose of used specimens and test kit components in accordance with Federal, State, and Local requirements. Treat specimens and patient samples as well as used test kit components as potentially biohazardous materials.
10. Do not interchange kit contents from different lots.
11. The optimum is reached when swabs are eluted with the extraction reagent in the test kits. Using another reagent may result in wrong results.
12. Poor vision, color blindness or poor lighting may affect your ability to interpret the test correctly.
13. For lay users the minimum user age has been determined to be between 18 and 65 years of aged corresponding to this usability study. People under 18 years of age should be assisted by an adult. People over 65 years of age should, if necessary, seek the support of an asistant when performing the test and evaluating it.
14. Wear a safety mask or other face covering when collecting swabs from children or others.
15. Keep out of reach of children.

LIMITATIONS

1. In the early stage of infection, the test result may be negative because the level of antigen in the sample is below the detection limit of the test.
2. A negative result does not exclude the possibility of COVID-19 infection, and should be treated as presumptive and confirmation through a molecular assay, if necessary for patient management, may have to be obtained.
3. The positive result should not be taken as a confirmed diagnosis. You should always discuss your test results with your healthcare provider. Judgment should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
4. As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.
5. Failure of the user to follow the test procedure correctly may adversely affect the test performance and/or invalidate the test result.
6. False negative results may occur if a specimen is improperly collected, transported, or handled.
7. Inappropriate sample collection, using other non-matching reagents with the test kits, leaving too long of a time period between sample transfer and test eluting (more than half an hour), adding too high a volume of reagent when eluting the swab, wrong application of test protocols for elution operation, a low virus titer in the sample, may all lead to false negative results.
8. There is also a chance that the test can give a positive result even if COVID-19 infection is not present (false positive).
9. Inappropriate sample collection, using other non-matching reagents with the test kits, wrong application of test protocols for elution operation, may all lead to false positive results.
10. Positive test results do not rule out co-infections with other pathogens.
11. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
12. This test can only qualitatively detect 2019-nCoV antigens in a human nasal swab. It cannot determine the exact amount of the viral concentration present in the specimen.

PERFORMANCE EVALUATION

1. Sensitivity and Specificity

COVID-19 Ag Home Test has been evaluated using clinical samples collected from both asymptomatic and symptomatic individuals/patients. RT-PCR methods were used to compare COVID-19 Ag Home Test and the following results were obtained.

• **Table 1.** Analysis of coincidence rate of COVID-19 Ag Home Test and RT-PCR Test in nasal samples:

COVID-19 Ag Home Test	RT-PCR Test		Total
	Positive	Negative	
Positive	295	3	298
Negative	23	759	782
Total	318	762	1080

Sensitivity: 92.77% [95% CI: 89.34% - 95.36%] **Specificity:** 99.61% [95% CI: 98.85% - 99.92%]
Accuracy: 97.59% [95% CI: 96.49% - 98.42%]

• **Table 2.** Analysis of coincidence rate of COVID-19 Ag Home Test in nasal samples and RT-PCR Test from nasopharyngeal samples:

COVID-19 Ag Home Test	RT-PCR Test		Total
	Positive	Negative	
Positive	252	2	254
Negative	20	323	343
Total	272	325	597

Sensitivity: 92.65% [95% CI: 88.87% - 95.45%] **Specificity:** 99.38% [95% CI: 97.79% - 99.93%]
Accuracy: 96.31% [95% CI: 94.47% - 97.68%]

Total:
Sensitivity: 92.71% [95% CI: 90.31% - 94.68%] **Specificity:** 99.54% [95% CI: 98.93% - 99.85%]
Accuracy: 97.14% [95% CI: 96.22% - 97.88%]
**95% Confidence Interval*

2. Interferences

COVID-19 Ag Home Test has been tested and no interference was observed in specimens containing; 10% Whole blood, 2% Mucin, 60 mg/ml Human albumin, 10 µg/ml Biotine, 5 µg/ml Tobramycin, 10 mg/ml Oseltamivir, 298 µmol/L Ascorbic acid, 3.7 mmol/L Acetylsalicylic acid, 5% Fluconazole, 12.1 µmol/L Captopril, 10% Sodium Chloride, 15% Oxymetazoline, 5% Fluticasone Propionate, 10 mg/ml Tamiflu, 100 µg/ml Amoxicillin, 802 ng/mL Human anti-mouse antibody and 10 mg/ml Mupirocin.

3. Cross-reactivity

Specimens which tested positive with the following various agents from patients were investigated with COVID-19 Ag Home Test. The concentration of virus samples is set to 10^6 pfu/ml or higher.

The results showed no cross-reactivity.

Potential Cross-Reactant		
Human coronavirus - OC43	MERS-coronavirus	Enterovirus
Human coronavirus - NL63	Human Metapneumovirus 3 (hMPV-3)	Escherichia Coli
Human coronavirus - 229E	Human Hepatitis B Virus (HBV)	Bacillus thuringiensis
Influenza A virus AH1	Pneumocystis jirovecii Recombinant	Klebsiella aerogenes
Influenza A virus H1N1	Staphylococcus aureas	Pseudomonas aeruginosa
Influenza A virus AH3	C. pneumoniae	Streptococcus dysgalactiae
Influenza A virus	L. pneumophila	Klebsiella quasipneumoniae
Influenza B virus	Metapneumovirus	Staphylococcus epidermidis
Respiratory syncytial virus	M. pneumoniae	Rotavirus
Human Parainfluenza	Rhinovirus	Adenovirus

SAMPLE COLLECTION AND PREPARATION

• The test can be performed using a human nasal swab. The samples should be used as soon as possible after they have been collected (within half an hour).
• If excessive mucus is detected in the nostril, the excess mucus should be cleaned off with a disposable tissue paper. In such a case, this disposable tissue paper should be thrown into the waste container due to the risk of infectiousness.
• Do not touch the swab head when handling the swab.
• Do not use any nasal sprays, gels, or creams before you collect a nasal sample.
• Both nostrils must be swabbed prior to running the test with the sterile swab.

TEST PROCEDURE

The samples should be used as soon as possible after they have been collected (within half an hour).
1- Before you start testing, wash your hands or use hand sanitizer. Make sure your hands are dry before starting.
2- It is recommended gloves (not provided) also be used during testing.
3- Open the kit box and take the kit components out. Bring the tests, reagents and samples to room temperature (15~30°C) prior to testing.
4- The cassette test must stay FLAT on the table for the duration of the entire test. Only open the foil pouch when you are ready to do the test. Open the pouch and take out the test cassette. Use the kit immediately after you open the aluminum test pouch, however; within a maximum of 60 minutes after you have opened it!
5- Unscrew the extraction reagent tube tip.
6- Remove the swab from the pouch. Keep fingers away from the swab end.
7- False negative results may occur if the nasal swab is not properly collected. Carefully insert the entire collection tip of the swab provided inside the nostril.
8- Slowly rotate the swab against the nostril wall into the nostril, and then slowly rotate it out while wiping.
9- Wipe the other nostril with the same swab, using the same method.
10- Hold the sample extraction reagent tube at a 45 degree angle. Place the swab specimen into the extraction reagent tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigens in the swab.
11-Squeeze the sample extraction reagent tube from over the swab head to remove as much liquid as possible from the swab.
Place the sample extraction reagent tube tip tightly on top of the test tube then break the tip of the extraction reagent tube lid.
12- Put 2 drops into the sample well of the test cassette, and start the timer.
13- **ATTENTION!** Read the test results promptly at between 20 and 30 minutes as shown below. Do not read the result before 20 minutes. Results forming after 30 minutes should be regarded as invalid.
14- Once your test is complete, put all of the used test kit contents in the additional plastic waste bag (not provided). Put in your general household waste.

INTERPRETATION OF RESULTS

INVALID NEGATIVE POSITIVE

INVALID:
To read the test results simply determine whether a line is present or absent in the Control **(C)** position. It does not matter how strong or weak a Control line **(C)** is.
If there is no Control line **(C)** or only a Test line **(T)** in the result window, the test did not run correctly and the results are not valid.

NEGATIVE:
Only one colored line appears, in the control region **(C)**. No apparent colored line appears in the test region **(T)**.

POSITIVE:
Two colored lines appear on the membrane. One line appears in the control region **(C)** and another line appears in the test region **(T)**.
NOTE: Look very closely! Low concentration of the virus antigens in the sample may cause a faint line in "T" area.
Even such a faint line in "T" area should be regarded as "positive".

In case of a positive test result:
• There is currently a suspicion of a SARS-CoV-2 infection.
• First and foremost, keep calm.
• You should self-isolate at home and wear a facemask.
• Stay in touch with your doctor. Call before you get medical care to avoid spreading the virus to others and tell the result of the serological test.
• Your doctor will provide you with further information and, if necessary, contact the responsible authorities and report your close contacts.
• Please follow local guidelines for self-isolation.

In case of a negative test result:
• A negative result means the virus that causes COVID-19 was not found in your sample.
• Please continue to comply with all applicable rules regarding contact with others and protective measures.
• An infection may also be present if the test is negative.
• Contact a healthcare provider to discuss your results.
• Tell your healthcare provider whether you have symptoms or have no symptoms. Your healthcare provider may ask you to take additional medical tests to arrive at a diagnosis.
• In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be accurately detected in all phases of an infection.

In case of an invalid test result:
• It is important that you carefully follow the instructions for the test. You should test again with a new sample by using new test kit orderly to obtain accurate results.
• If the C line does not appear, the test is always invalid! Use another cassette and repeat the test again.
• If the test result is still invalid, contact a doctor or testing center.

CE 1434

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Manufacturer
Attention, see instruction for use
For single use only
Consult instruction for use
In vitro diagnostic medical device
Number of test
Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices
Do not use if packaging is damaged
Keep away from sunlight
REF Catalog number
Storage temperature
Indicate that you should keep the product dry

For swab manufacturer information please see IFU and swab label!
Sterile Swab:

CE 2292 RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER A.Ş. Plastikçiler Organize Sanayi Bölgesi (GEPOSB) Cumhuriyet Cad. No:3 Gebze / Kocaeli / Turkey

OR

CE 2292 ANT MEDİKAL İth. İhr. Paz. San. ve Tic. Ltd. Şti. Şerifali Mah. Emin Sok. No:15/1 34775 Ümraniye / İstanbul / Turkey

OR

CE 0123 HANGZHOU ROLLMED CO.,LTD. RM 913, Yuanmao Mansion. No.5, Wen Er West Road Xihu District. Hangzhou Zhejiang Province 310012 China

LOT Lot number
Expiry date

Instruction For Use Preparation Date: 23.11.2021 Rev.5
C08.TICVH.02

PROCEDURE CARD
COVID-19 Ag HOME TEST

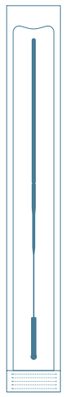
TEST IT for healthy generations

CHECK YOUR TEST KIT

KIT COMPONENTS

1

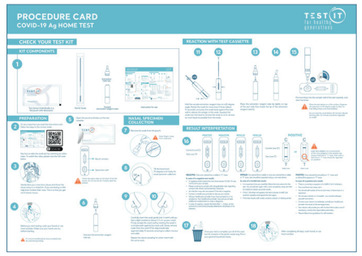
Test device (individually in a foil pouch with desiccant)



Sterile Swab

Extraction tube tips

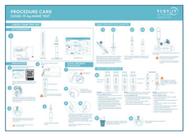
Sample extraction reagent tube



Instruction for use

PREPARATION

2 It's very important that you read the instructions and follow the steps in the correct order.



SCAN ME

Learn how to take the swab test by watching an online video. To watch the video, please scan the QR code below.

3

Gently blow your nose into a tissue and throw the tissue away in a closed bin. If you are testing a child help them to blow their nose. This is so that you get rid of excess mucus.

4

Before you start testing, wash your hands or use hand sanitizer. Make sure your hands are dry before starting.

It is recommended gloves (not provided) also be used during testing.

5 Open the pouch and take out the test cassette.

Check the expiry date at the back of the foil pouch. Do not use the kit if the expiry date has passed.

6

Unscrew the extraction reagent tube tip.

NASAL SPECIMEN COLLECTION

7 Remove the swab from the pouch.

Keep fingers away from swab end.

8

Tilt the head back 70 degrees, ready for nasal specimen collection.

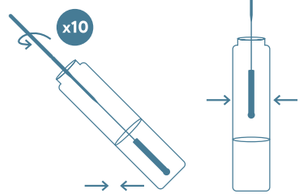
9 10

Carefully insert the swab gently into 1 nostril until you feel a slight resistance (about 2.5 cm up your nose). Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall. Slowly remove swab from the nostril (This step should take approximately 10 seconds, ensuring to collect mucous and cells).

Repeat the above sampling for other nostril with the same swab.

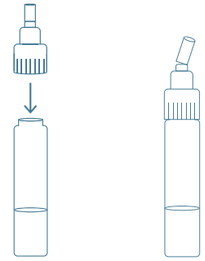
REACTION WITH TEST CASSETTE

11 12



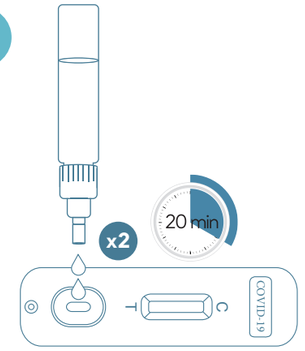
Hold the sample extraction reagent tube at a 45 degree angle. Rotate the swab for more than 5 times (about 10 seconds), and press the swab head against the tube wall to release the antigen in the swab. Squeeze the swab over the head to remove the swab so as to remove as much liquid as possible from the swab.

13 14



Place the extraction reagent tube tip tightly on top of the test tube then break the tip of the extraction reagent tube lid.

15



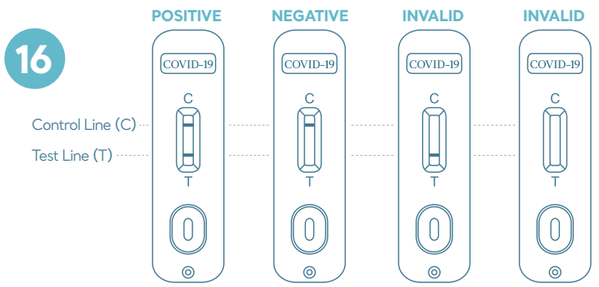
Put two drops into the sample well of the test cassette, and start the timer.

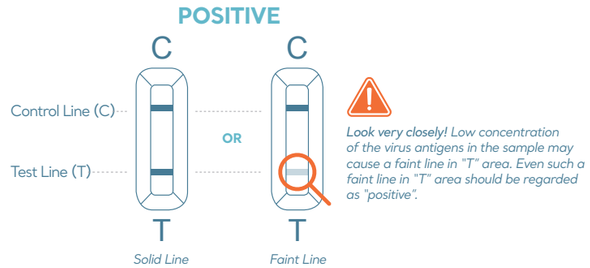
Place the test device on a flat surface. Dispense the specimen at a 90 degree angle to allow for free falling drops and to avoid bubbles.

Do not read the result before 20 minutes. Results forming after 30 minutes should be regarded as invalid.

RESULT INTERPRETATION

16





Look very closely! Low concentration of the virus antigens in the sample may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".

NEGATIVE: Only one colored line is visible in the "C" area.

In case of a negative test result:

- A negative result means the virus that causes COVID-19 was not found in your sample.
- Please continue to comply with all applicable rules regarding contact with others and protective measures.
- An infection may also be present if the test is negative.
- Contact a healthcare provider to discuss your results.
- Tell your healthcare provider if you have symptoms or no symptoms. Your healthcare provider may ask you to take additional medical tests to arrive at a diagnosis.
- In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be accurately detected in all phases of an infection.

INVALID: No colored line is visible or only one colored line is visible in the "T" area; test should be repeated using a new test device.

In case of a invalid test result:

- It is important that you carefully follow the instructions for the test. You should test again with a new sample by using a new test kit properly to obtain accurate results.
- If the C line does not appear, the test is always invalid! Use another cassette and repeat the test again.
- If the test result is still invalid, contact a doctor or testing center.

POSITIVE: One colored line should be in the "C" area and a colored line appears in the "T" area.

In case of a positive test result:

- There is currently a suspicion of a SARS-CoV-2 infection
- First and foremost, keep calm.
- You should self-isolate at home and wear a facemask.
- Stay in touch with your doctor. Call before you get medical care to avoid spreading the virus to others and tell the result of the serological test.
- Your doctor will provide you with further information and, if necessary, contact the responsible authorities and report your close contacts.
- Please follow local guidelines for self-isolation.

17

Once your test is complete, put all of the used test kit contents in the plastic waste bag. Put in your general household waste.

18

After completing all steps, wash hands or use hand sanitizer.