

# COVID-19 ANTIGEN HOME TEST

## Instructions for Use

### EN

**Nasal Swab**  
For self-test use / Suitable for non-professionals

- A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens.
- For self-testing use.
- For In Vitro Diagnostic (IVD) use only
- This product has not been FDA tested or approved, but has been authorized under an Emergency Use Authorization (EUA)

(1) This test is intended to be used as an aid to the clinical diagnosis of a current COVID-19 infection. Do not use this test as the only guide to manage your illness.

(2) In USA -This product has not been FDA cleared or approved but has been authorized by FDA under an Emergency Use Authorization (EUA). This product has been authorized only for the detection of proteins from SARSE-CoV-2, not for any other virus or pathogens. The emergency use of this of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21U.S.C. § 360bbb - 3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

### Summary

SARS-CoV-2 is the causative virus to coronavirus disease 2019 (COVID-19). Since its emergence in December 2019, COVID-19

has posed a significant threat to people all over the world. SARS-CoV-2 spreads mainly through close contact among people. Air borne aerosols carrying the virus spread from one person to another through speaking, laughing, coughing, sneezing, and etc. Asymptotically infected people can also spread their viruses to the others. The most common symptoms of COVID-19 are fever, dry cough, and fatigue. Other symptoms that are less common and may affect some patients include: loss of taste or smell, nasal congestion, conjunctivitis (also known as red eyes), sore throat, headache, muscle or joint pain, different types of skin rash, nausea or vomiting, diarrhea, chills or dizziness. Without timely medical intervention, severe complications or even death may occur to COVID-19 cases.

### Intended Use

This product is suitable for people with symptoms similar to COVID-19, like cough, fever, fatigue and etc., to assist the early diagnosis of SARS-CoV-2 infection.

It can also be used to test people without COVID-19 symptoms to regularly monitor their health status.

### Test Principle

The COVID-19 Antigen Detection Kit is an immunoassay test kit for rapid detection of SARS-CoV-2 virus in nasal swab samples. The kit uses a pair of specific antibodies to detect the SARS-CoV-2 virus nucleocapsid protein. One antibody is coated on the colloidal gold particles to bind to the nucleocapsid protein in the sample, and the other antibody is immobilized on the nitrocellulose membrane to capture the colloidal gold particles bound to the nucleocapsid protein. In addition, the kit contains an internal control system that indicates whether the test is working properly. To conduct the test, three drops of sample solution is added into the sample loading well. The SARS-CoV-2 nucleocapsid protein in the sample will bind to the nucleocapsid antibody-coated colloidal gold particles, and migrate along the nitrocellulose membrane. The other nucleocapsid antibody coated on the nitrocellulose membrane will capture the colloidal gold particles, and immobilize them at the Test Line. As more and more

colloidal gold particles accumulate, a red band will appear at the Test Line and report a positive result. On the contrary, absence of red band at the Test Line reports a negative result. The Control Line should always appear to indicate that the test result is valid.

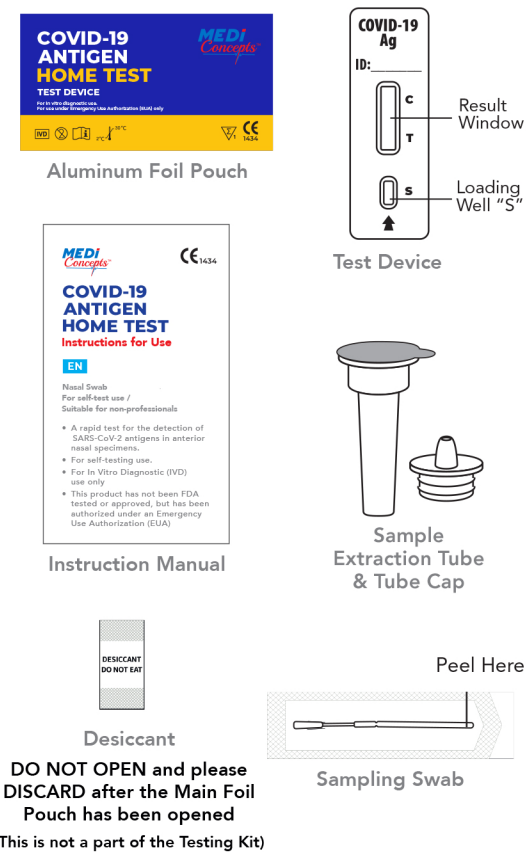
### Precautions Before Using The Product

1. Read the instructions carefully prior to first use.
2. For people who are not able to perform the test themselves, the test should be conducted by the legal guardians.
3. For children under the age of 15, the self-test should be conducted under adult supervision.
4. This test detects SARS-CoV-2 antigen in nasal cavity secretions, which is collected by sterile nasal swab.
5. For people who has recent nasal trauma or surgery, or has severe coagulopathy, gentle operation is required for nasal swab collection to avoid injuries to the nose.
6. Please use the components provided in the kit for testing. Do not use components from other sources.
7. Please use this product in a place with sufficient light, so as to interpret the results accurately.

### Precautions After Using The Product

1. If you get a positive result, please contact your family doctor, or seek help from a professional medical facility as soon as possible. You need a nucleic acid test to confirm viral infection.
2. A negative result cannot completely exclude the possibility of viral infection. Incorrect sampling or low viral load may also cause a false negative result.
3. When the test is completed, please disinfect the swabs, test cards, and other used components with a household bleach spray or a 70%-75% alcohol spray.
4. Wash the disinfected items and discard them in accordance with local regulations.
5. Wash the hands thoroughly after the test.

### 1. Product Components



### 2. Test Preparation

1. Put product components to room temperature (15-30°C or 59-86°F).
2. Blow nose to clear the nasal cavities.
3. Wash hands and keep them dry.
4. Read the instructions carefully or scan QR code to view the instructional video.
5. Check the expiration date after the symbol on the other side of aluminum foil pouch. DO NOT use expired test kits.
6. Use any available timer device such as a mobile phone or smart watch

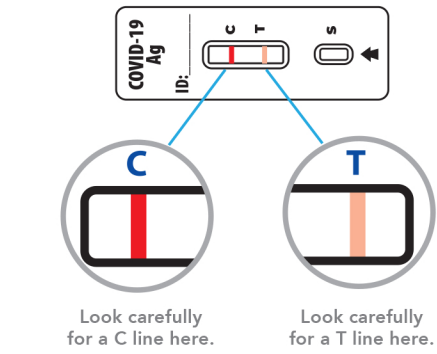
### 3. Test Procedures

1. Peel to open the package of sampling swab. DO NOT touch the swab tip
  2. Gently insert the swab tip 2-3cm into one nasal cavity
  3. Gently rotate the swab 5 rounds for 5 - 7 seconds to collect secretion in the nose. DO NOT force the swab, so as not to injure the nose
  4. Gently insert the same swab tip into the other nasal cavity. Gently rotate the swab 5 rounds for 5 - 7 seconds
  5. Peel off the top layer aluminum foil seal from the sample extraction tube.
  6. Place the swab into sample extraction tube. Stir the swab in the solution at least 5 rounds.
  7. Squeeze the tube with fingers. Move the swab up and down for at least 3 times to expel any sample solution from the swab. Take out the swab
  8. Insert the tube cap firmly on the sample extraction tube. Gently squeeze the tube for 3 times to mix the solution. Pull the tube still for 1 minute
  9. Peel to open the aluminum foil pouch. Take out the test card, and put it on the table
- Hold the tube upside down. Squeeze to add 3 drops of sample solution into the loading well "S" on the test card.
- Read the result after 15 minutes. The result is considered inaccurate and invalid after 30 minutes. DO NOT reload sample solution into the device itself

### 5. Read Result

Results should not be read after 30 minutes (Result shown at 2x magnification)

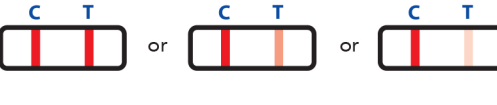
**Note : A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.**



**Note : The T line can be extremely faint.**

### 6. Test Result Explanation

#### POSITIVE RESULT



A **POSITIVE** result must show BOTH a C line and a T line.. A positive result means that viral antigens from COVID-19 were detected and the individual is positive for COVID-19.

Persons who test positive should self-isolate and seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary.

#### NEGATIVE RESULT



A **NEGATIVE** result will show ONLY a C line. A negative result means that viral antigens from COVID-19 were not detected and that the individual is presumed negative for COVID-19.

- Please note the negative results do not rule out COVID-19.
- In case of negative test result: Continue to follow all social distancing recommendations and take protective measures. If suspicions of infection persist and/or your first test is negative, repeat the test after 1-2 days and consult your healthcare

provider or local COVID-19 center.

- Note: A negative result is presumptive and confirmation with a molecular assay. If necessary, for patient management may be performed. Individuals without symptoms that test negative should be tested again with at least 24 hours and no more than 48 hours between tests. Additional confirmatory testing with a molecular test for negative results may be necessary after second negative result for asymptomatic patients. If there is a high likelihood of SARS -Cov-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

#### INVALID RESULT



If there is NO LINE or if there is ONLY a T line, the test is INVALID. Invalid result means that the test did not function correctly. You will need to retest with a new test kit. If upon retesting, the test result is still invalid, contact your doctor or local COVID-19 center. An invalid result does not indicate if the individual did or did not have COVID-19 and should be repeated.

### 7. Dispose the Test Kit

After test is completed, dispose the kit components in trash.

- Use a sanitizer to disinfect used product components
- Put used Test Kit in a plastic bag. Close bag and put it in another plastic bag. Dispose bag properly with a household garbage.
- Wash hands thoroughly.

### Storage and Stability

	Store at 2°C to 30°C		Expire in 24 months (see package label)
	Keep away from sunlight		Keep dry
	Keep out of the reach of children		Do not use if package is damaged

### Warning And Precautions

1. People who are not able to perform the test alone should be tested by their legal guardians.
2. This product is applicable to nasal swab samples. Using other sample types may cause inaccurate or invalid test results.
3. Test within two hours after sample collection. Stale samples may cause inaccurate results.
4. Please make sure that a proper amount of sample is added for testing. Too much or too little sample amount may cause inaccurate results.
5. If the sample extraction solution comes into contact with the skin or eyes, please rinse with running water.
6. DO NOT drink the sample extraction buffer. Seek medical attention if you feel uncomfortable.
7. Please wait 15 to 30 minutes after sample loading, and then read the test results. Incorrect waiting time may cause inaccurate results.
8. If the test line or control line is out of the test window, do not use the test card. The test result is invalid. Retest the sample with another test card.
9. This product is disposable. DO NOT recycle used components.
10. Disinfect used products, samples, and other consumables with a household bleach spray, or a 70% - 75% alcohol spray.
11. Wash the hands thoroughly before and after the test.

### Product Performance

**Limit of Detection (LoD)** : the LoD of this product is about 0.05 ng/ SARS-CoV-2 nucleocapsid protein solution.

**Cross-Reactivity with Other Pathogens**  
No cross-reactivity observed with the

following pathogens: Staphylococcus aureus, Streptococcus pneumoniae, Measles virus, Mumps virus, Adenovirus type 3, Mycoplasma pneumoniae, Parainfluenza virus 2, Metapneumovirus, SARS-CoV, MERS-CoV, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, Bordetella pertussis, Influenza B virus (Victoria Lineage), Influenza B virus (strain B/Yamagata/16/1988), 2009 pandemic influenza A (H1N1) virus, Influenza A (H3N2) virus, Avian influenza A (H7N9) virus, Avian influenza A (H5N1) virus, Epstein-Barr virus, Enterovirus CA16, Rhinovirus, Neisseria meningitidis, and Respiratory syncytial virus.

### Interference Test

No interference observed with the following materials: Abidol, Aluminum hydroxide, Azithromycin, Beclomethasone, Bilirubin, Budesonide, Ceftriaxone, Dexamethasone, Flunisolide, Fluticasone, Hexamethalin, Histamine hydrochloride, Levofloxacin, Lopinavir, Meropenem, Mometasone, Mucin, Oseltamivir, Oxymetazoline, Paramivir, Phenylephrine, Ribavirin, Ritonavir, Sodium bicarbonate, Sodium chloride, Tobramycin, Triamcinolone acetonide, Zanamivir, alpha-interferon.

No interference observed with the following respiratory pathogens: Staphylococcus aureus, Streptococcus pneumoniae, Measles virus, Adenovirus type 3, Mycoplasma pneumoniae, Parainfluenza virus 2, Metapneumovirus, SARS-CoV, MERS-CoV, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Human coronavirus HKU1, Influenza B virus (Victoria Lineage), Influenza B virus (strain B/Yamagata/16/1988), 2009 pandemic influenza A (H1N1) virus, Influenza A (H3N2) virus, Avian influenza A (H7N9) virus, Avian influenza A (H5N1) virus, Epstein-Barr virus, Enterovirus CA16, Rhinovirus, Respiratory syncytial virus.

### Sensitivity, Specificity & Total Accuracy

The product performance was evaluated with clinical specimens, using commercial RT-PCR kit as the reference method.

Nasal Swab	RT-PCR		Total
	Positive	Negative	
Positive	218	219	219
Negative	7	466	466
Total	225	460	685
	<b>Sensitivity</b>	<b>Specificity</b>	<b>Total Accuracy</b>
	96.9%	99.8%	98.8%
	95% CI : (93.7% - 98.7%)	95% CI : (98.8% - 99.9%)	95% CI : (97.7% - 99.5%)

### Index Of Symbols

	Manufacturer		Date of Manufacture
	Authorized representative in the European Community		Consult instructions for use
	Contains sufficient for >= 3 tests		In vitro diagnostic medical device
	Batch Code		Use-by date
	Product Code		Store between 2-30°C
	Do not re-use		Do not use if package is damaged
	Keep away from sunlight		Keep dry

# FAQ

### 1. What is the MediConcepts Covid-19 Antigen Detection self test?

The MediConcepts Covid-19 is a rapid antigen test that detects the SARS-CoV-2 antigen in nasal swabbed specimens. This compact, portable test is intended for at-home or on-the-go self-testing use. This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens;

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and / XXor diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

### 2. What type of test is this?

This test uses a nasal swab in both nostrils to take a sample and test for the presence or lack of presence of Covid-19 antigens. For a demonstration on how this test works, please watch the instructional video at [www.medicconcepts.net](http://www.medicconcepts.net)

### 3. How many times must I test with the MediConcepts Covid-19 Antigen Detection At-Home Test Kit?

The MediConcepts Covid-19 Antigen Detection At-Home Test Kit is designed to give you accurate results with 1 test. It is suggested for you to test again if your test is Invalid and re-test again if you show symptoms after the first test being Negative.

### 4. Is there an age requirement to take this test.

This test is acceptable for use on people 2 years old or older with adult supervision. It is recommended that a person be above the age of 14 before administering this self test alone.

### 5. If I do not have Covid-19 symptoms, will the test work?

Anyone is eligible to take this test whether they are symptomatic or have no visible symptoms of Covid-19 at all.

### 6. Do I have to swab my nasal passages or can I swab my throat or my ear?

Please only swab your nose to collect a sample and follow all instructions. This test does not work if you swab your ear or throat.

### 7. If I lose the swab that comes in my kit can I use another type of cotton swab like a Q-Tip?

The swab provided with the kit is packed in a sealed package. Please do not use any other swab except the one that is included in your kit. If you need customer assistance email the helpdesk at: [Contact@MediConcepts.net](mailto:Contact@MediConcepts.net)

### 8. How deep do I insert the swab into my nostril?

The test is designed for you to insert the swab one half inch to three quarters of an inch into your nostril. This may be shorter for small children. PLEASE NOTE: If the swab is not inserted deep enough it could result in a false-negative reading.

### 9. Do I have to swab both nostrils?

Yes. To ensure an accurate result, please swab both nostrils according to the instructions.

### 10. How long do I swab each nostril?

Firmly rub and rotate the swab in a circular motion around the inside wall of the nostril 5 full rotations. Make sure that you collect any nasal drainage with the swab. For a more detailed guide to this process please read the instruction manual together with an instruction video on this website : [www.medicconcepts.net](http://www.medicconcepts.net)

### 11. There are parts missing from my Medi-Concepts Covid-19 Self Test. What do I do?

If you cannot find any part that should be included in your kit, please contact the company you purchased from or email the helpdesk at [Contact@MediConcepts.net](mailto:Contact@MediConcepts.net)

### 12. What do I do if I spill my solution?

If you spill your solution, please do not use your test. Please buy or use a new test kit .

### 13. How long do I stir the swab in the test solution?

You should insert the swab into the solution and rotate the swab in the solution for 5 rotations. Then squeeze the extraction tube with your fingers and move the swab up and down three times to wring out any sample solution from the swab. After that, remove the swab and discard it.

### 14. How much solution do I put into the loading well – marked S – on the testing device?

After firmly putting the tube cap on the sample extraction tube, gently squeeze the tube and add 3 drops of the sample solution into the loading well - marked S.

### 15. How long do I wait before I get the results?

Your results will be available in 15 minutes. PLEASE NOTE: You must check for results between 15 and 20 minutes. Results after 30 minutes may not be accurate and is considered as INVALID RESULTS.

### 16. Is this test painful?

This test is not painful and should not cause pain in any way. The unfamiliar feeling of the swab inside your nostril may cause some discomfort. If for any reason you do feel pain, please stop the test and seek advice from a healthcare professional.

### 17. Who should NOT use this test?

This test is not to be used on children under 2 years old. Also, any individual who is prone to nosebleeds or has had head injuries or surgeries in the past 6 months should use caution or avoid using the test.

### 18. Are there any known risks or benefits of this test?

The potential benefits of using this test are: The test, along with other information, can help you and your healthcare provider make informed decisions about your care, and the information you receive from this test may help you take the necessary steps to help prevent the spread of Covid-19.

### 19. If the test result on the device is very light or pinkish is the test result still valid?

If you see a red, pink, or very light line at the T-line, the test result is positive and the test is still valid.

### 20. What is the difference between Antigen, Molecular, and Antibody tests?

There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as the MediConcepts COVID-19 Antigen Home Test detect proteins from the virus. Antigen tests are very specific for the COVID-19 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 is necessary and if you should con-tinue isolating at home.

Another type of test is an antibody test. A COVID-19 antibody test detects antibodies that have been produced by your immune system in response to a previous COVID-19 infection or vaccination. Antibody tests are not suitable for diagnosing an active COVID-19 infection.

### 21. What does a positive test result mean?

A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19. There is a very small chance that this test can give a positive result that is wrong (a false-positive result).

If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at [www.cdc.gov/coronavirus](http://www.cdc.gov/coronavirus). Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s), medical history and symptoms.

### 22. What does a negative test result mean?

A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (a false-negative result) in some people with COVID-19. Negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative.

If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow-up care with your healthcare provider immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow-up testing, please contact your healthcare provider.

### 23. What if my test result is invalid?

If you do not get a line at the C-line on your test device, you have an invalid test. An invalid test result indicates that not enough specimen volume was collected or incorrect test operation are the likely reasons for an invalid result. Please review the instructions again and repeat the test with a new test kit.

### 24. What is a false-positive and a false-negative test result?

A false positive is a test result that indicates a person has a specific disease or condition when the person actually does not have the disease or condition. A false-negative test result indicates a person does not have a specific disease or condition when the person actually does have the disease or condition. Incorrect specimen collection and sample preparation can result in false-negative and false-positive test results. Therefore, before you begin the test, it is very important to watch the instructional video on our website [www.medicconcepts.net](http://www.medicconcepts.net) and read the instructions provided in the test package, and closely follow all instructions.

### 25. Is this test acceptable for travel? Can I use it for proof of Negative Covid-19 Test?

The type of testing and documentation required for your international or domestic air travel may or may not be acceptable based on your travel destination, airline, and state requirements. We recommend you contact your airline carrier or visit the CDC/TSA website, and view your local health department's website for the latest requirements on the type of acceptable testing and documentation required for where you are traveling to.

### 26. I was vaccinated. Will this test work for me?

Yes. The MediConcepts™ COVID-19 Antigen Home Test is designed to detect Covid-19 Antigens whether you are symptomatic or not. It does not matter if you are vaccinated or not.

### 27. Can I reuse this test?

No, the MediConcepts™ COVID-19 Antigen Home Test is a single use test and should not be reused.