

# iHealth COVID-19 Antigen Self-Test Kit FAQs

## About the test

- **How does the iHealth Covid-19 Antigen Rapid Test Work?**

The iHealth<sup>®</sup> COVID-19 Antigen Rapid Test is an antigen test. When COVID-19 is present in the body, your nasal secretions can also contain the SARS-CoV-2 virus (the virus that causes COVID-19). The iHealth<sup>®</sup> COVID-19 Antigen Rapid Test is able to detect small parts of the SARS-CoV-2 virus, known as N protein or antigens, in your nasal secretions.

For a demonstration on how the test works, watch the instructional video [here](#).

- **Will this test detect COVID-19 variants?**

iHealth has completed testing on several heat inactivated variant strains and the iHealth<sup>®</sup> COVID-19 Antigen Rapid Test was able to detect the mutations. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

- **What are the difference between a COVID-19 antigen, molecular and antibody test?**

There are different kinds 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. Antigen test sare very specific for the 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. Another typeof test is an antibody test. A COVID-19 antibody test detects antibodies that have been made by your immune system in response to a previous COVID-19 infection or vaccination. Antibody tests are not suitable to diagnose an active COVID-19 infection.

For more information on COVID-19 testing, please see the following link:  
<https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics>

- **Is this iHealth COVID-19 Antigen Rapid Test Kit FDA approved or cleared?**

No. This test is not yet approved or cleared by the United States FDA. FDA can issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or authorization is revoked by FDA (after which the test may no longer be used).

- **What are the approved alternatives?**

There are no approved available alternative antigen tests. FDA has issued EUAs for other tests that can be found at:  
<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

- **What is the age range for test?**

This test is authorized for nonprescription home use with self-collected (unobserved) anterior nasal swab specimens from individuals aged 15 years and older or with adult-collected anterior nasal swab samples from individuals aged 2 years or older.

- **What is serial testing?**

Serial testing is when a single person is tested for COVID-19 more than once. Because antigen tests are less sensitive than other COVID-19 tests and false results may occur, repeated testing may identify individuals with COVID-19 more reliably than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of

infection. Additional testing with molecular COVID-19 test may be necessary, depending on your individual risk factors and test results. It is important that you work with your healthcare provider to help you understand the next steps you should take. Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

- **Do I always need to perform two tests?**

If you have COVID-19 symptoms and are within the first 7 days of symptom onset, you can use one single test of the iHealth® COVID-19 Antigen Rapid Test. You may also choose to perform two tests if you wish. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.

If you do not have COVID-19 symptoms or have been having symptoms for more than 7 days, you will need to perform two tests over two or three days with at least 24 hours and no more than 48 hours between tests.

- **Can this test be used as proof of a negative COVID – 19 tests for travel?**

No. Currently, the iHealth® COVID-19 Antigen Rapid Test cannot be accepted as proof of a negative COVID-19 test for travel.

- **Will the test work if I don't have symptoms?**

Yes. If you do not have COVID-19 symptoms, you will need to perform two tests over two or three days with at least 24 hours and no more than 48 hours between tests.

- **Should people who are vaccinated use this test?**

Individuals can utilize this test, as needed, regardless of vaccination status.

- **Is this test covered by insurance?**

The test is available for self-test at home without a prescription. Please consult with your health insurance to make sure if your test will be covered.

- **Is a prescription required to perform this test?**

You do not need a doctor's prescription to purchase and perform this test.

## Result and Accuracy

- **How accurate is the iHealth COVID-19 Antigen Rapid Test?**

Based on the results of a clinical study where the iHealth® COVID-19 Antigen Rapid Test was compared to an FDA authorized molecular SARS-CoV-2 test, iHealth® COVID-19 Antigen Rapid Test correctly identified 94.3% of positive specimens and 98.1% of negative specimens.

Additional asymptomatic individuals and individuals beyond the seven days of symptom onset were tested, but excluded from the primary performance calculations because they were not included in the intended use. A higher proportion of low positive specimens were observed in these populations, resulting in PPAs between of 85-88% in these individuals.

- **What does it mean if I have positive test results?**

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

The iHealth® COVID-19 Antigen Rapid Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

Test results are automatically reported through the “iHealth COVID-19 Antigen Rapid Test” App to relevant public health authorities in accordance with local, state, and federal requirements.

All healthcare providers must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

- **What should I do if my test result is positive?**

If your test result is positive with the iHealth® COVID-19 Antigen Rapid Test, you should self-isolate and seek follow-up care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms. The CDC currently recommends several Steps to help prevent the spread of COVID-19 if you are sick, detailed guidance could be found at: <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>

- **What does it mean if I have negative test results?**

A negative test result for this test means that antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids. The amount of antigen in a sample may decrease as the duration of illness increases. In

symptomatic patients, specimens collected after day 5 of illness may be more likely to be negative compared to a RT-PCR assay. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to CDC's Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings (Interim Guidance) (see links provided in "Where can I go for updates and more information" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected in between May and October 2021. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

- **What should I do if I have COVID-19 symptoms BUT my test result is negative?**

If you test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. 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 as well.

If you will not have an additional test to determine if you are contagious, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers)

AND

- Other symptoms of COVID-19 are improving (for example, when your cough or shortness of breath has improved) Note: Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation

AND

- At least 10 days have passed since your symptoms first appeared.

- **What does it mean if I have invalid test results?**

Invalid result means that the test is not performed correctly. You will need to retest with a new test kit.

## Using the test

- **Can the iHealth COVID-19 Antigen Rapid Test be used in children under two years old?**

No, DO NOT use it on anyone under 2 years old.

- **Is the iHealth COVID-19 Antigen Rapid Test reusable?**

No. All the components of iHealth® COVID-19 Antigen Rapid Test Kit are not reusable and can only be used once.

- **Will the 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.

- **How far do I need to insert the Nasal Swab?**

Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.

With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.

- **Why must I swab both nostrils?**

In some cases, it has been observed that only one nostril has the detectable virus. Swabbing both nostrils is important because it gives you the best chance of a collecting sufficient sample to generate an accurate result.

- **Can I perform the test if I don't have a blocked or runny nose?**

Yes. The iHealth<sup>®</sup> COVID-19 Antigen Rapid Test can be used with or without any noticeable symptoms of COVID-19 (including a blocked or runny nose).

- **How much fluid should I squeeze into the sample port of the test card?**

3 drops.

- **Within how much time should the test card be used, after the foil pouch is opened?**

Once the Test Card is removed from the pouch, perform the test as soon as possible. Use the Test Card within 1 hour after opening the foil pouch.

- **Do I have to wait for 15 minutes to read the results?**

Yes. After adding the sample to the sample port, do NOT confirm your result before your 15-minute timer is up. The positive indicating line would take as long as 15 minutes to appear, so you may get an incorrect result (false negative) if you do not wait for 15 minutes.

- **What are the known and potential benefits and risks for the home test?**

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

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.

- **Do I have to use the app?**

No. Use of app is optional. You can follow the paper instructions to perform the test if you wish. However, we do recommend you use the iHealth COVID-19 Test App as step-by-step instructional videos are available in the app for more intuitive understanding of how to perform the test correctly. In addition, the health pass and group testing features in the app would benefit you in your daily life.

- **Why is the iHealth COVID-19 Test App asking me for my personal information?**

The iHealth COVID-19 Antigen Rapid Test app saves your test results if you select and submit your results within the App. This record can be shared with your healthcare professional as proof of COVID-19 testing. Your date of birth and zip code, together with test results, are the information required as they are shared with the relevant health authorities to support monitoring of COVID-19 infection and test positivity rates across the country.

- **Can I leave or exit the iHealth COVID-19 Test App while the test is still running?**

If you leave the iHealth COVID-19 Antigen Rapid Test app during test without exiting it, you may be able to return to the same screen. If you exit the app during your test or if the app was force quit by accident, a button to continue your test will be available on the home page once you re-open the app. However, we recommend keeping the app on the screen until you get your result to avoid any possibility of interrupting the test.

- **What devices are compatible with the iHealth COVID-19 Test App?**

The iHealth COVID-19 Test App is compatible with most smartphones with operation systems iOS 12 or above, android 6.0 or above. Below is the full list of compatible smartphones.

Apple iPhones: iPhone 7, iPhone 7 plus, iPhone 8 plus, iPhone 10, iPhone 11, iPhone 11 Pro, iPhone 12, iPhone 12 max, iPhone 12 pro max, iPhone SE, iPhone SE2, iPhone X, iPhone X, iPhone XR, iPhone XS, iPhone XS MAX

Android Phones: LG Stylo 5X, Moto G8 Power, Moto G7 Plus, Samsung Galaxy Note8, Samsung Galaxy Note9, Samsung Galaxy S10, Samsung Galaxy S20, Samsung Galaxy S6, Samsung Galaxy S8, Samsung Galaxy S9, Google Pixel 4a, Huawei P20

## Health

- **Who is considered high risk for severe disease?**

The following people are considered high risk for severe disease:

- People aged 65 and older
- People in nursing homes or long-term care facilities
- People of all ages with underlying medical conditions, particularly if they are not well controlled
- Cancer
- Chronic obstructive pulmonary disease
- Chronic kidney disease
- Immunosuppressed following solid organ transplant
- Obesity (BMI >30)
- Serious heart conditions such as heart failure, coronary artery disease or cardiomyopathies
- Sickle cell disease
- Type II Diabetes

People may be at increased risk due to the following conditions:

- Asthma (moderate-severe)
- Cerebrovascular disease (affecting blood vessels to the brain)
- Cystic fibrosis
- High blood pressure
- Immunocompromised (weakened immune system) from blood or bone marrow transplants, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medications
- Neurologic conditions such as dementia

- Liver disease
  - Pulmonary fibrosis
  - Smoking
  - Thalassemia
  - Type I Diabetes
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- **Can I injure myself using the swab?**

The Swab is sterile and safe to use. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril (Note: With children, you may not need to insert the swab as far into the nostril.). You may experience some discomfort when swabbing your nose, but this is to be expected. Do not insert the Swab any further if you experience sharp pain.
  - **I have a nosebleed after swabbing my nose. What should I do?**

In the unlikely event your nose starts bleeding, do not insert the Swab again. Apply pressure to your nose until the bleeding stops and consult a healthcare professional.

## Troubleshooting

- **I inserted the nasal swab into the tube before I swabbed my nose. Can I re-use the swab?**

No. You will need to obtain a new test kit. The swab with Extraction Reagent cannot be used for sample collection, the Extraction Reagent contains harmful chemicals (refer to Hazardous Ingredients for Reagent Solution part of Instructions for Use).
- **What Should I do if some of the liquid splashes onto my phone or anywhere else except the sampling port?**

The liquid should be wiped off your phone or surface immediately as per the recommendations of your phone manufacturer. Please note that you may not have sufficient liquid remaining to perform the test and may need to obtain a new test kit.

- **I received an invalid result when I performed the test and I need to use a new test kit. Can I use the same sample I used in the previous test?**

No, do not reuse any test components. Please obtain a new test kit and perform a new test.