COVID-19 Antigen Home Test

Catalog number: BTK-H2201, BTK-H2202, BTK-H2205, BTK-H2220

User Instructions

Prepare for the Test

1. Wash your hands thoroughly for at least 20 seconds before the test.

2. Unpack components, and place on a flat, clean surface.

3. Locate sample tube and place in box holder. Gently peel off the aluminum foil seal.

4. NOTE: Please blow your nose before collection. Remove the swab from its wrapper, being careful not to touch the fabric tip of the swab with your hands.

Test Procedure Continued

5. Gently insert the swab no more than 3/4 inch into the left nostril. Slowly rotate the swab at least 5 times in a circular path for a total of 15 seconds. Gently remove the swab from the left nostril and place into the right nostril. Repeat the process of rotating at least 5 times in a circular path for 15 seconds. Remove the swab from the right nostril.

6. Insert the swab into the sample tube. Touch the bottom of the sample tube with the swab tip, and stir at least 5 times. Squeeze the swab in the tube through the outer wall of the tube by finger 5 times.

7. Remove the swab by rotating against the sample tube while squeezing the sides of the tube to release the liquid from the swab. Remove and discard the swab into waste bag provided.

8. Screw the purple tube cap onto the sample tube and then unscrew the top white cap.

9. Take out the test cassette. Place it on a flat, dry and clean surface. Turn the sample tube upside down and slowly squeeze 3 drops onto the sample well of the test cassette.

Result and Interpretation

10. NOTE: The test results should not be read after 30 minutes.

11. All used test components should be disposed of in your household waste. After completing all steps, wash hands or use hand sanitizer.

Test Procedure

1. Read this instruction guide carefully prior to starting test.

2. Prepare a watch (or a clock/timer), tissue, hand sanitizer or soap and warm water.

3. Check the test kit contents. Make sure that nothing is missing, damaged, or broken.

Test

Cassette

Sample Tube

Waste Bag

NOTE: The test results should not be read after 30 minutes.

COVID-19 Positive [+]

If the Control (C) Line and the Test (T) Line are visible, the test is positive. Any faint visible pink/purple Test (T) Line with the Control (C) Line should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time. A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

COVID-19 Negative [-]

If the Control (C) Line is visible, but the Test (T) Line is not visible, the test is negative. To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

Invalid

If the Control (C) Line is not visible the test is invalid. Re-test with a new swab and new test device.

IMPORTANT

NOTE: With children, the maximum depth of insertion into the nostril may be less than 3/4 inch.
The Bio-Self™ COVID-19 Antigen Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (mucosal) swab specimens from individuals 14 years and older or adult collected anterior nasal (mucosal) swab specimens from individuals 2 years of older. This test is not intended for use in individuals who test negative and continue to experience COVID-like symptoms. You may need to purchase additional tests to perform this serial (repeat) testing if you have had symptoms longer than 7 days, you should be tested at least three times over five days with at least 48 hours between tests.

The Bio-Self™ COVID-19 Antigen Home Test does not differentiate between SARS-CoV-1 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detected in anterior nasal (mucosal) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigen, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or coinfection with other viruses and are not the definitive cause of disease. Individuals who test positive with the Bio-Self™ COVID-19 Antigen Home Test should self-isolate and seek follow-up care with their healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmatory with a molecular assay, if needed for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of the clinical history and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-like symptoms of illness may have SARS-CoV-2 infection and should seek follow-up care from their healthcare provider. Individuals who test positive and continue to experience COVID-like symptoms may apply to you, please refer to the performance data in the Healthcare Provider Instructions Document available at https://www.biote.com/usa.

What if I have a positive test result?
What if I have a negative test result?

If the test is positive, then proteins from the virus that causes COVID-19 have been detected in your sample and you likely have COVID-19.

If the test is negative, then proteins from the virus that causes COVID-19 have not been detected in your sample.

What does an invalid test result mean?

If the test is invalid, a new swab should be used to collect a new nasal specimen and follow the directions on the test kit.

An invalid result means the test was not able to tell if you have COVID-19 or not. The test result indicates that the test did not work properly. It will not tell you if you do not have COVID-19. If you have symptoms consistent with COVID-19, you may need to test COVID-19 with a molecular test.

What is the difference between an antigen and a molecular test?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Both antigen tests and molecular tests can be used to diagnose COVID-19.

Antigen tests use antibodies to detect antigens, proteins from the virus that causes COVID-19. Molecular tests use nucleic acid amplification to detect the genetic material of the virus that causes COVID-19.

What are the known and potential risks of the test?

Potential risks include:

1. Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:

1. The results of this test may help the potential spread of COVID-19 to others and your community. For more information on EULAs go to https://ecdc.europa.eu/en/technical-documentation/coronavirus-diagnostic-tests.

Hazardous Ingredients for Liquid Reagent

- The reagent solution contains harmful chemicals (see table below). If the solution comes into contact with your skin, eyes, nose, or mouth, flush with large amounts of water.

- If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name
Labelling of Horn for Each Concentration

<table>
<thead>
<tr>
<th>Compound</th>
<th>EULAC</th>
<th>CAS Number</th>
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<tbody>
<tr>
<td>Reagent solution</td>
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Storage

Store the Bio-Self™ COVID-19 Antigen Home Test between 2 - 30°C (56 - 86°F). Expose all strips to room temperature before use. Kit contents are not required to be cool, but they should not be exposed to extremes of temperature. The expiration date printed on the outer packaging. Do not use beyond the expiration date. The test kit must be used within one year of expiration date.

Symbols

Indicates the manufacturer's batch code so that the batch or lot can be identified.

Indicates a medical device that is intended for one use, or uses on a single patient during a single procedure.

Indicates the date after which the medical device is not to be used.

Indicates the number of patients that the medical device can be used on.

Indicates a medical device that should not be used if the package has been damaged or opened.

Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.

Limitations

There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result than if you test positive with a molecular test.

The performance of this test was established based on the evaluation of a limited number of samples from individuals who tested positive or negative for COVID-19. The clinical performance has not been established for all circulating variants but is expected to be reduced if the variant circulates in at the time of the location of the clinical evaluation. Performance of the test may vary depending on infection control measures, including, newly emerging variants of SARS-CoV-2 and their prevalence, which change over time.

All results from the test that causes COVID-19 have been found in the sample and you likely have COVID-19.

These test results are shown as lines of color. Since these lines can be very faint, users with conditions affecting their vision such as nearsightedness,远视, or color blindness are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).

Inadequate or inappropriate sample collection, storage, and transport can result in an invalid test result. If the test is invalid, a new swab should be used to collect a new nasal specimen and follow the directions on the test kit.

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Easy - Simple
Nasal Swab
COVID-19 ANTIGEN HOME TEST
Self-Test at Home
For Use With
Or Without
Symptoms
Fast - Results
in 15 Minutes
Contains
Two Tests
Place
Tube
Here
TM
15
MINUTES
TM
TM
TM
TM
TM
TM
For In Vitro Diagnostics Use Only
For Ages 2 and Up
For self-testing
For self-testing
For Emergency Use Authorization (EUA) only.
This test can be used at home for self-testing.
For Symbol Glossary, refer to Instructions for Use.
Items necessary to use the kit, but not provided: Timer
COMPONENTS:
2 Test Cassettes
2 Sample Tubes
2 Tube Caps
2 Anterior Nasal Swabs
2 Waste Bags
1 Quick Reference Instructions
COVID-19 ANTIGEN HOME TEST
Manufactured for: Bioteke USA, LLC
900 Brickell Key Boulevard, Suite 2304
Miami, FL 33131
www.bioteke-usa.com 1-800-240-3944
Store between 35.6-86° F (2-30° C) until use
BTK-H2202
* In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. 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/or 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.
Easy - Simple  Nasal Swab  COVID-19 ANTIGEN HOME TEST  Self-Test at Home  For Use With  Or Without  Symptoms  Fast - Results  in 15 Minutes  Contains  Two Tests  Place Tube Here  TM  15 MINUTES  TM  For In Vitro Diagnostics Use Only  For Ages 2 and Up  For self-testing  For self-testing  J  J  J  J  J  For Emergency Use Authorization (EUA) only.  This test can be used at home for self-testing.  For Symbol Glossary, refer to Instructions for Use.  Items necessary to use the kit, but not provided: Timer +.  COMPONENTS: 2 Test Cassettes 2 Sample Tubes 2 Tube Caps 2 Anterior Nasal Swabs 2 Waste Bags 1 Quick Reference Instructions  COVID-19 ANTIGEN HOME TEST  TM  Manufactured for: Bioteke USA, LLC  900 Brickell Key Boulevard, Suite 2304 Miami, FL 33131  www.bioteke-usa.com  1-800-240-3944  Store between 35.6-86° F (2-30°C) until use  BTK-H2202  

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For self-testing
Easy - Simple
Nasal Swab
COVID-19 ANTIGEN HOME TEST
Self-Test at Home
For Use With
Or Without
Symptoms
Fast - Results
in 15 Minutes
Contains
Five Tests
TM
15 MINUTES
For In Vitro Diagnostics Use Only
For Ages 2 and Up
Place Tube Here
For Emergency Use Authorization (EUA) only. This test can be used at home for self-testing. For Symbol Glossary, refer to Instructions for Use.
Components:
5 Test Cassettes
5 Sample Tubes
5 Tube Caps
5 Anterior Nasal Swabs
5 Waste Bags
1 Quick Reference Instructions
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COVID-19 ANTIGEN HOME TEST

For In Vitro Diagnostics Use Only
For Ages 2 and Up

Easy - Simple Nasal Swab
Fast - Results in 15 Minutes
Contains Twenty Tests

Self-Test at Home

For self-testing

COMPONENTS:
20 Test Cassettes
20 Sample Tubes
20 Tube Caps
20 Anterior Nasal Swabs
2 Waste Bags
1 Quick Reference Instructions

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