BIO-SELF™ COVID-19 Antigen Home Test

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

www.bioteke-usa.com
User Instructions

IMPORTANT

Swabbing both nostrils is critical for obtaining an accurate result. If you do not swab both nostrils, the device will produce a false negative result.

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.*

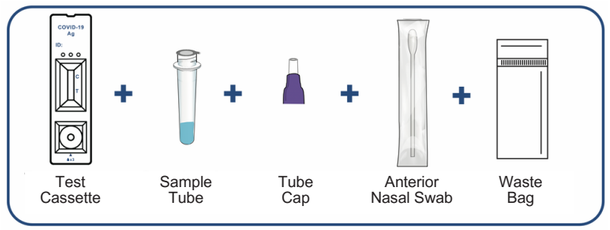
- For Anterior nasal specimens
- For *in-vitro* diagnostic use
- For use under emergency use authorization (EUA) only

Note: Repeat testing is needed if your first result is negative, please refer to the Result and Interpretation section.

Prepare for the Test

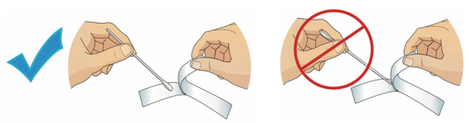
1 Wash your hands thoroughly for at least 20 seconds before the test.

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



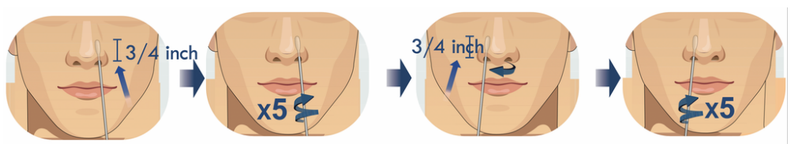
3 Locate sample tube and place in box holder. Gently peel off the aluminum foil seal.

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

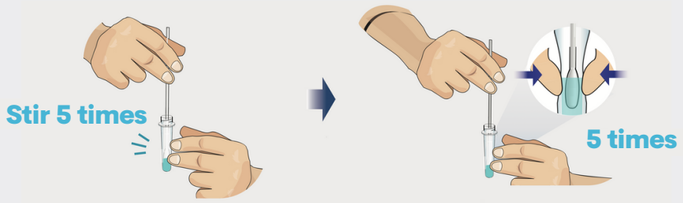
5 Gently insert the swab no more than 3/4 inch into the left nostril. Slowly rotate the swab at least 5 times in a circular path for a total of 15 seconds. Gently remove the swab from the left nostril and place into the right nostril. Repeat the process of rotating at least 5 times in a circular path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



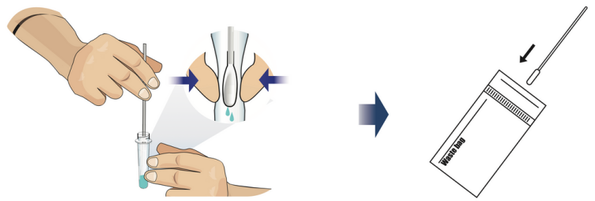
NOTE: With children, the maximum depth of insertion into the nostril may be less than 3/4 inch.

Test Procedure Continued

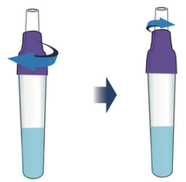
6 Insert the swab into the sample tube. Touch the bottom of the sample tube with the swab tip, and stir at least 5 times. Squeeze the swab in the tube through the outer wall of the tube by finger 5 times.



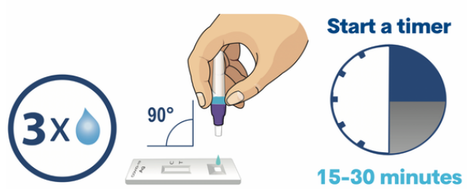
7 Remove the swab by rotating against the sample tube while squeezing the sides of the tube to release the liquid from the swab. Remove and discard the swab into waste bag provided.



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.

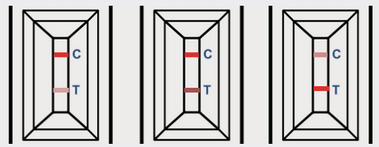


IMPORTANT

Please read the results between 15 - 30 minutes after the sample is dropped.

Result and Interpretation

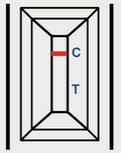
10 **NOTE: The test results should not be read after 30 minutes.**



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).

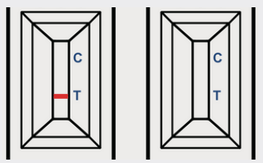


COVID-19 Negative [-]

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.**

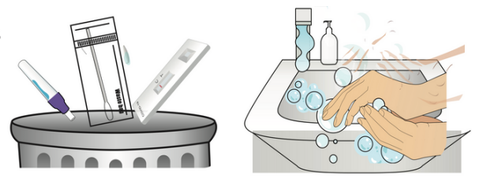
A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results 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.

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



Result and Interpretation Continued

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Report your test result(s) at MakeMyTestCount.Org – this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

Intended Use

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 (nares) swab samples from individuals aged 14 years or older or adult- collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests and for individuals without symptoms or other epidemiological reasons to suspect COVID-19 when 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 and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, 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 co-infection with other viruses and the agent detected may not be 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 physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary 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 an individual's recent exposures, 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 fever, cough and/or shortness of breath may have SARS-CoV-2 infection and should seek follow-up care from their healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LVID) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The Bio-Self™ COVID-19 Antigen Home Test is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting. The Bio-Self™ COVID-19 Antigen Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

How to Use This Test

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Warnings, Precautions and Safety Information

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing. If you have had symptoms longer than 7 days, you should consider testing at least three times over five days with at least 48 hours between tests.**
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Ensure that there is sufficient lighting for testing and interpretation.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting anterior nares swab specimen from a child or another individual.
- Wash hands thoroughly for at least 20 seconds before and after handling nasal swab samples.
- Immediately use the test kit after opening.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Test components are single-use. Do not re-use.
- Keep the test device on a flat surface during testing.
- Keep testing kit and kit components away from children and pets before and after use.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false-positive result.
- Inadequate or inappropriate sample collection, storage, and transport can result in false results. If specimen storage is necessary, swabs can be placed into the extraction vial for up to three hours. Specimens should not be stored dry.
- When collecting a nasal swab sample, use only the anterior nasal swab provided in the kit.
- Keep foreign substances and household cleaning products away from the test during the testing process. Contact with foreign substances and household cleaning products may result in an incorrect test result.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Handle all specimens as though they contain infectious agents.
- Do not operate your test outside of storage conditions.
- Do not interpret the test result before 15 minutes or after 30 minutes of starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Do not use if any of the test kit contents or packaging is damaged.
- Do not touch the tip (specimen collection area) of the swab.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not interchange kit contents from different lots.
- Eye and skin contact with extraction solution should be avoided.
- Extraction solution should not be ingested.
- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and- response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization.
- For the most up to date information on COVID-19, please visit: http://www.cdc.gov/COVID19.

Hazardous Ingredients for Liquid Reagent

Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts 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 Harm for Each Ingredient	Concentration
Triton X-100	May cause skin irritation (H315) May cause serious eye irritation (H319)	0.50%
ProClin 300	May cause an allergic skin reaction (H317) Causes mild skin irritation (H316)	0.10%

Frequently Asked Questions

What are the known and potential risks and benefits of the test?

Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community. For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/ mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

What is the difference between an antigen and molecular test?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the Bio-Self™ COVID-19 Antigen Home Test, detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

How accurate is this test?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at https://www.bioteke-usa.com/.

What if I have a positive test result?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

What if I have a negative test result?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS- CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

What does an invalid test result mean?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

Important

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

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 in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between May 2022 and July 2022. The clinical performance has not been established for 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.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus 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. Because these lines can be very faint, users with conditions affecting their vision such as far sightedness, glaucoma, or color blindness are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person).
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

Storage

Store the Bio-Self™ COVID-19 Antigen Home Test between 2 - 30°C (35.6 - 86°F). Ensure all kit contents are at room temperature before use. Kit contents are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date. The test card must remain in the sealed pouch until use.

Symbols

Date of manufacture.
Indicates the date when the medical device was manufactured.

Do not re-use.
Indicates a medical device that is intended for one use, or uses on a single patient during a single procedure.

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

Caution.
Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

2°C 30°C — Temperature limit.
Indicates the temperature limits to which the medical device can be safely exposed.

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

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

Consult instructions for use.
Indicates the need for the user to consult the instructions for use.

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

REF — Catalog number.
Indicates the manufacturer's catalog number so that the medical device can be identified.

Bio-Self™

Manufactured for: BioTeke USA, LLC
900 Brickell Key Boulevard, Suite 2304
Miami, FL 33131
www.bioteke-usa.com | 1-800-240-3944

Version 1.0
May 2023

BIO-SELF™

COVID-19 ANTIGEN HOME TEST

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

- 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
- For in vitro diagnostic use.

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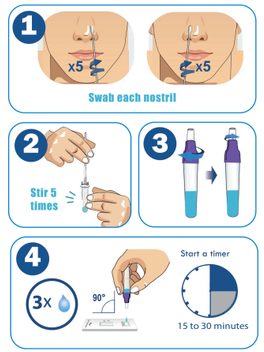

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Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

BIO-SELF™ *For self-testing*

Store between 35.6-86°F (2-30°C) until use

IVD

2°C-30°C

BIO-SELF™

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

15 MINUTES

Contains Two Tests

2 TESTS

Place Tube Here

LOT

REF BTK-H2202

Self-Test at Home

BIO-SELF™

For self-testing

BIO-SELF™ COVID-19 ANTIGEN HOME TEST

BIO-SELF™

COVID-19 ANTIGEN HOME TEST

COMPONENTS:
1 Test Cassette
1 Sample Tube
1 Tube Cap
1 Anterior Nasal Swab
1 Waste Bag
1 Quick Reference Instructions

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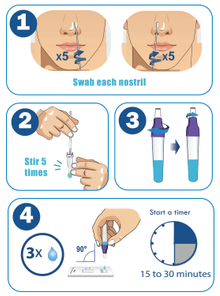

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BIO-SELF™ *For self-testing*

Store Between 35.6-86°F (2-30°C) until use

2°C 30°C IVD

LOT

REF BTK-H2201

Place Tube Here

Contains 1 TEST One Test

Fast - Results in 15 MINUTES Minutes

Easy - Simple Nasal Swab

For In Vitro Diagnostics Use Only
For Ages 2 and Up

COVID-19 ANTIGEN HOME TEST

BIO-SELF™

Self-Test at Home

BIO-SELF™ *For self-testing*

BIO-SELF™ COVID-19 ANTIGEN HOME TEST

BIO-SELF™

COVID-19 ANTIGEN HOME TEST

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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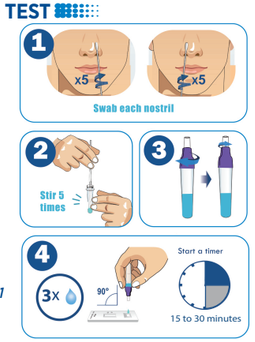

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Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-test

COVID-19 ANTIGEN HOME TEST
BIO-SELF™

For self-testing

2°C–30°C IVD

Store Between 35.6-86°F (2-30°C) until use

BIO-SELF™

Self-Test at Home

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 Five Tests
Place Tube Here

BIO-SELF™
COVID-19 ANTIGEN HOME TEST
For self-testing

BIO-SELF™

REF BTK-H2205

LOT

COVID-19 ANTIGEN HOME TEST

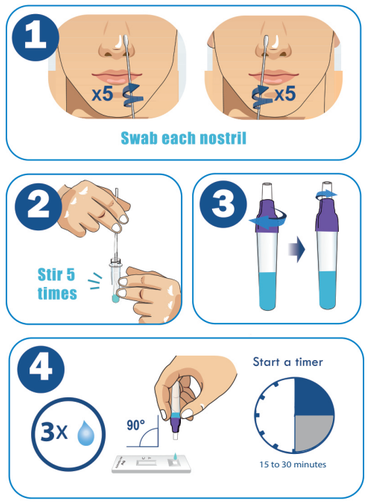
BIO-SELF™

COVID-19 ANTIGEN HOME TEST

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

- 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
- For in vitro diagnostic use.

Manufactured for: BioTeke USA, LLC
900 Brickell Key Boulevard, Suite 2304 Miami, FL 33131
www.bioteke-usa.com 1-800-240-3944



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BIO-SELF™

COVID-19 ANTIGEN HOME TEST

For self-testing

Store between 35.6-86°F (2-30°C) until use

IVD

2°C 30°C

For self-testing

BIO-SELF™

COVID-19 ANTIGEN HOME TEST

BIO-SELF™

COVID-19 ANTIGEN HOME TEST

For self-testing

For In Vitro Diagnostics Use Only
For Ages 2 and Up

Easy - Simple Nasal Swab

Fast - Results in 15 Minutes

15 MINUTES

Contains Twenty Tests

20 TESTS

Place Tube Here

BIO-SELF™

Self-Test at Home

BIO-SELF™

COVID-19 ANTIGEN HOME TEST

REF BTK-H2220

LOT