Abbott

BinaxNOW™ COVID-19 ANTIGEN SELF TEST

For Use Under an Emergency Use Authorization (EUA) Only
For use with anterior nasal swab specimens

For ***in vitro*** Diagnostic Use Only

Instructions

Flip sheet over to view instructions prior to starting the test.

INTENDED USE

The BinaxNOW™ COVID-19 Antigen Self Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test is authorized for non-prescription home use with self-collected direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged two years or older.

The BinaxNOW COVID-19 Antigen Self Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient 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. The agent detected may not be the definite cause of disease. Individuals who test positive with the BinaxNOW COVID-19 Antigen Self Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

Negative results should be treated as presumptive, 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 decisions. 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 and confirmed with a molecular assay, if necessary, for patient management.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, 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 COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still 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. 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 (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The BinaxNOW COVID-19 Antigen Self 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 BinaxNOW COVID-19 Antigen Self Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

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 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 and Molecular 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 tests are 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. 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 should discontinue home isolation.

How Accurate is this Test?

Based on the interim results of a clinical study where the BinaxNOW™ COVID-19 Antigen Self Test was compared to an FDA authorized high sensitivity SARS-CoV-2 test, BinaxNOW COVID-19 Antigen Self Test correctly identified 91.7% of positive specimens and 100% of negative specimens.

Due to the relatively small sample size for the home use clinical study, the BinaxNOW COVID-19 Antigen Self Test is estimated to correctly identify between 73.0% and 98.9% of positive specimens as reflected in the 95% Confidence Interval. This is consistent with the performance established in a separate multi-site clinical study in the US, where the BinaxNOW COVID-19 Ag Card test was performed and results interpreted by test operators with no laboratory experience. In that study, BinaxNOW COVID-19 Ag Card test correctly identified 84.6% of positive specimens and 98.5% of negative specimens.

The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

Based on this information, negative results may require additional testing to confirm your result. Please talk to your healthcare provider to determine if you need additional testing.

What is Serial Testing?

COVID-19 Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection.

What do I need to know about Results from Serial Testing?

If your first test is negative, you should test again in 24-36 hours. If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your specimen and you likely have COVID-19. If you test positive with the BinaxNOW COVID-19 Antigen Self Test, you should self-isolate and seek follow-up care with your healthcare provider to determine the next steps you should take. You may need additional testing, depending on your personal health history and other factors.

If both your first and second tests are negative, you may not have COVID-19, however, you should follow-up with your healthcare provider if you are at high risk for COVID-19 infection or have known contacts with COVID-19. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19 or need other testing.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Wear safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
3. Use of gloves is recommended when conducting testing.
4. Keep testing kit and kit components out of the reach of children and pets before and after use.
5. This test has not been FDA cleared or approved but has been authorized by FDA under an EUA.
6. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
7. 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.
8. Proper sample collection and handling are essential for correct results.
9. Do not use a kit that has been opened and/or tampered with.
10. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
11. Do not dip the swab into the liquid reagent or other liquid before inserting the swab into the nose.
12. Do not touch swab tip when handling the swab sample.
13. Do not use kit past its expiration date.
14. Do not mix components from different kit lots.
15. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.
16. Dispose of kit components and patient samples in household trash.
17. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold bottle vertically, 1/2 inch above the swab well, and add drops slowly.
18. The Reagent Solution contains a harmful chemical (see table below). If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us or 1-800-222-1222

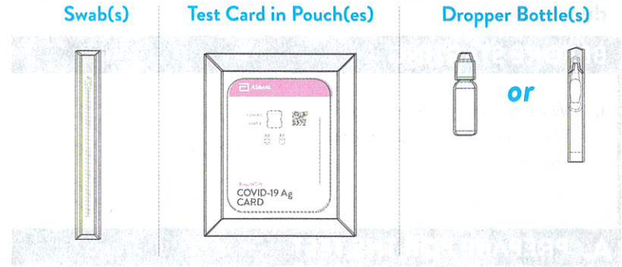
Chemical Name/CAS	GHS Code for each Ingredient	Concentration
Sodium Azide/26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.0125%

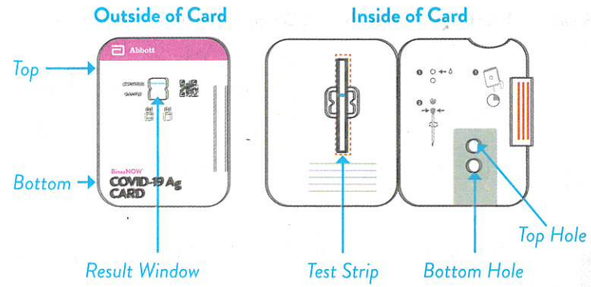
STORAGE and STABILITY

Store kit between 35.6-86°F (2-30°C). Ensure all test components are at room temperature before use. The BinaxNOW COVID-19 Antigen Self Test is stable until the expiration date marked on the outer packaging and containers.

KIT COMPONENTS OVERVIEW

! Do not touch before reading instructions (flip over sheet).





WHAT YOUR RESULTS MEAN

Positive Result

A positive test result means it is very likely you have COVID-19 and it is important to be under the care of your healthcare provider. It is also likely that you may be placed in isolation to avoid spreading the virus to others. 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 with the BinaxNOW COVID-19 Antigen Self Test, you should self-isolate and seek follow-up care with your healthcare provider. 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.

Negative Result

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test 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. Please consult your healthcare professional if you develop symptoms, symptoms persist or become more severe. Your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19.

If the presence of a faint line and/or the presence of a line is uncertain, additional confirmatory testing should be conducted. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Invalid Result

An invalid result means this test was unable to determine whether you have COVID-19 or not. A new test is needed to get a valid result. Please contact Technical Support at +1 833-637-1594.

Abbott Rapid Diagnostics
Technical Support

US
+1-833-637-1594

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Scarborough, Maine 04074 USA
www.binaxnow-selftest.abbott

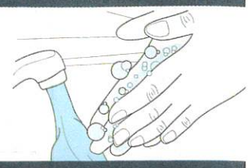
Turn Over

INSTRUCTIONS - START HERE

Carefully read instructions prior to starting test. It is recommended gloves (not provided) also be used during testing.

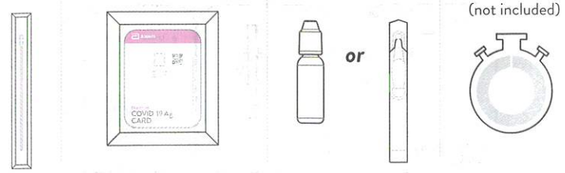
BEFORE STARTING

1. Wash or sanitize your hands. Make sure they are dry before starting.



A. PREPARE FOR THE TEST

1 Swab | 1 Test Card in Pouch | 1 Dropper Bottle | Timing Device (not included)



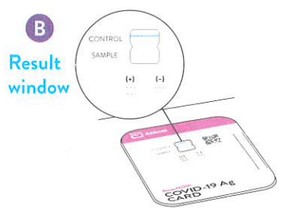
! **DO NOT touch any parts on the inside. Handle card only by edges.**

! **Card must stay FLAT on table for entire test.**

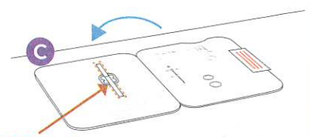
2. Remove test card from pouch and lay flat on table.

   The card must stay flat on the table for the entire test.

   Make sure the **blue control line** is present in the result window. If a blue line is not present, **do not** use this card.



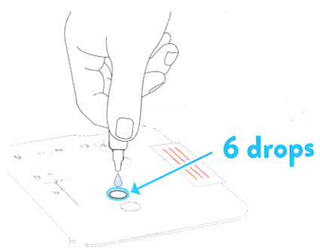
   Open card flat on table. You may bend the spine in the opposite direction to help the card lay flat.



3. Remove dropper bottle cap.

   Hold dropper bottle straight over **top hole**, not at an angle.

   Put 6 **drops** into **top hole**. Do not touch card with tip.

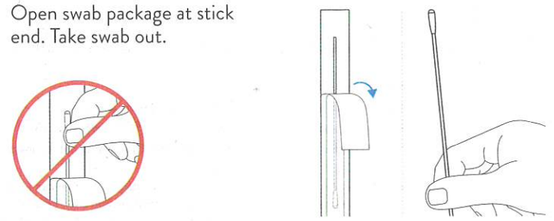


Note: False negative result may occur if less than 6 drops of fluid are put in the hole.

B. COLLECT NASAL SAMPLE

! **Keep fingers away from the swab end.**

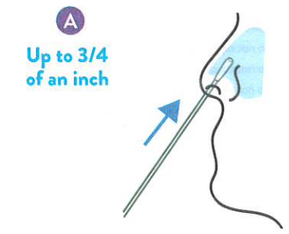
4. Open swab package at stick end. Take swab out.



5. **Swab both nostrils carefully as shown.**

   Insert the entire soft tip of the swab into a nostril (usually 1/2 to 3/4 of an inch).

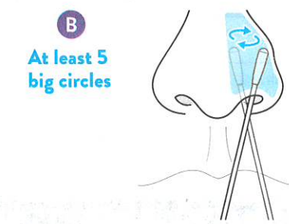
   You do not need to go deeper.



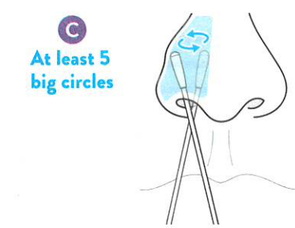
   Using medium pressure, rub the swab against all of the inside walls of your nostril.

   Make at least **5 big circles.** **Do not** just spin the swab.

   Each nostril must be swabbed for about **15 seconds.**



   Using the same swab, repeat step 5 in your other nostril.



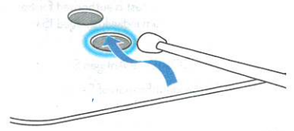
STOP **Check:** Did you swab BOTH nostrils?

Note: False negative result may occur if the nasal swab is not properly collected.

C. PERFORM THE TEST

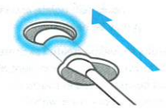
! **Keep card FLAT on table.**

6. Insert swab tip into **bottom hole.**



   Firmly push the swab tip from the bottom hole until it is visible in the **top hole**.

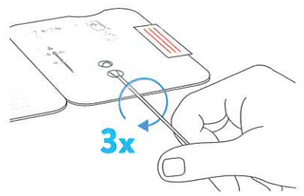
   Do not remove the swab from the card.



7. Turn swab to right 3 times to mix the swab with the drops.

   Do not skip this step.

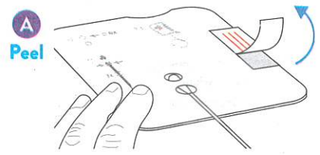
   Leave the swab in the card for the remainder of the test.



Note: False negative result can occur if swab is not turned.

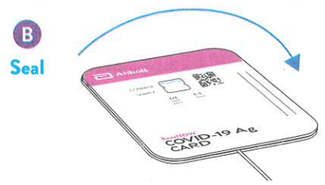
! **DO NOT remove swab.**

8. Peel adhesive liner off. Be careful not to touch other parts of card.



   Close left side of card over swab. Press firmly on the two lines on right edge of card to seal.

   Keep card face up on table.



! **DO NOT move or touch the card during this time.**

9. **Wait** 15 minutes.

   Read the result at 15 minutes.

   Do not read the result before 15 minutes or after 30 minutes.

Note: A control line may appear in the result window in a few minutes but a sample line may take as long as 15 minutes to appear.

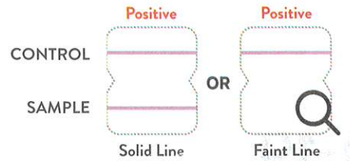
Note: Results should not be read after 30 minutes.

D. INTERPRET RESULTS

A. Check for Positive COVID-19 Result

Find result window and look carefully for two pink/purple lines.

Positive Result: If you see two pink/purple lines (one on the top half and one on the bottom half), this means **COVID-19 was detected.**



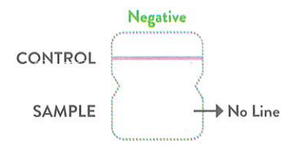
Look very closely!
The bottom line can be very faint. Any pink/purple line visible here is a Positive Result.

Below are photos of actual positive tests. On the right, note how faint the bottom line can get.

B. Check for Negative COVID-19 Result

Find result window and look for a single pink/purple line in window.

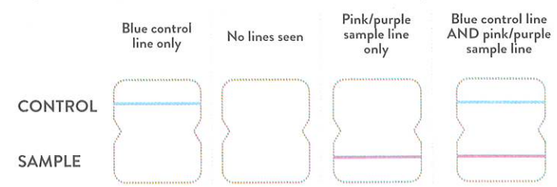
Negative Result: If you see **only** one pink/purple line on the top half, where it says "Control" this means **COVID-19 was not detected.**



C. Check for Invalid Result

If you see any of these, the test is invalid. An invalid result means this test was unable to determine whether you have COVID-19 or not. A new test is needed to get a valid result.

Please contact Technical Support at + 1 833-637-1594



Note: See other side to read about what your results mean.

E. DISPOSE THE TEST KIT

Throw away all used test kit components in the trash.

F. REPORT YOUR RESULTS

Please share your test result with your health care provider.
A second test should be obtained over three days with at least 36 hours between tests.

See other side for important information.

FACT SHEET FOR INDIVIDUALS

Abbott Diagnostics Scarborough, Inc.
BinaxNOW™ COVID-19 Antigen Self Test

March 31, 2021

Coronavirus Disease 2019 (COVID-19)

You are provided this Fact Sheet because you obtained the BinaxNOW™ COVID-19 Antigen Self Test for testing yourself or dependants for the proteins from the virus that causes COVID-19. The intended use of this test is for testing twice over three days with at least 36 hours between tests.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the detection of proteins from the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:
https://www.cdc.gov/COVID19

What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link:https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the BinaxNOW™ COVID-19 Antigen Self Test?

The BinaxNOW™ COVID-19 Antigen Self Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in anterior nasal swabs.

The BinaxNOW COVID-19 Antigen Self Test is intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms tested twice over three days with at least 36 hours between tests.

What are the known and potential risks and benefits of the 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.

What does it mean if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. 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 with the BinaxNOW COVID-19 Antigen Self 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.

What does it mean if I have a negative test result?

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. In symptomatic people, specimens collected after you have had symptoms for more than five days may be more likely to be negative compared to a molecular assay.

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. For example, 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.

Where can I go for updates and more information? The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

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 more individuals with COVID-19 infection than a single test. By repeating testing, it may be possible to more quickly identify cases of COVID-19 infection 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.

What are the differences between antigen tests and other COVID-19 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 detect proteins from the virus. Antigen tests are 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.

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 should discontinue home isolation. 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) **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.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID-19 if you are sick:

https://www.cdc.gov/coronavirus/2019-ncov/downloads/sick-with-2019-nCoV-fact-sheet.pdf

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. FDA may 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 the 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.

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. 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#2019-ncov.

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