The instructions may result in inaccurate test results. A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. For self-testing use. For use under an Emergency Use Authorization (EUA) only.

**TEST PROCEDURE**

1. Wash or sanitize your hands. Make sure they are dry before starting the test. Read the instructions.

2. Remove the foil from the top of the extraction buffer tube. Punch through the perforated circle on the kit box to form a tube holder. Place the tube in the tube holder. For 25 test quantity kit box the tube holder is provided.

3. Check your kit contents and make sure you have everything. Check the expiration date printed on the cassette foil pouch. Do not use if the pouch is damaged or open.

4. Open the pouch and lay the cassette on a clean, flat surface. Locate the Result Window and Sample Well on the cassette.

5. Remove the swab while squeezing the tube. Dispose the swab and new test swab and new test cassette in the trash.

6. Immediately place the swab into the extraction buffer tube. Swirl at least 30 seconds. Rotate the swab 5 times while squeezing the tube. Note: A false negative result may occur if the swab is not swirled at least 30 seconds.

7. Gently insert the entire absorbent tip of the swab into 1 nostril (½ to ¾ of an inch). With children, the maximum depth of insertion into the nostril may be less than ½ of an inch, and you may need to have a second person to hold the child’s head while swabbing.

8. Note: A false negative result may occur if the nasal swab specimen is not properly collected.

9. Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril.

10. Gently squeeze the tube and dispense 4 drops of solution into the Sample Well. Gently squeeze the tube and dispense 4 drops of fluid are added to the Sample Well. Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes. Dispose the test cassette in the trash. Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

**RESULT INTERPRETATION**

<table>
<thead>
<tr>
<th></th>
<th>C</th>
<th>T</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invalid</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Only the control line (C) and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected. A negative test result indicates that antigens from the virus that causes COVID-19 were not detected from the specimen. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19. If you test negative and continue to experience COVID-19-like symptoms, see your healthcare provider.

Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected. **NOTE:** Any faint red or pink line in the test line region (T) should be considered positive. 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

**PREPARATION**

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

2. Read the instructions.

3. Check your kit contents and make sure you have everything. Check the expiration date printed on the cassette foil pouch. Do not use if the pouch is damaged or open.

**SPECIMEN COLLECTION**

4. Open the pouch and lay the cassette on a clean, flat surface. Locate the Result Window and Sample Well on the cassette.

5. Remove the swab while squeezing the tube. Dispose the swab and new test swab and new test cassette in the trash.

6. Immediately place the swab into the extraction buffer tube. Swirl at least 30 seconds.

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**Flowflex Web App**

The Flowflex Web App allows you to track and report your COVID-19 test results:

- The Web App is optional and not required to run a COVID-19 test. It assists you in interpreting your visual test result and report your result to local health authorities.
- Ensure you have an internet connection and scan the Flowflex QR code or go to www.flowflexcovid.com prior to starting the test.
- Ensure you are using a compatible web browser (Chrome, Firefox, Edge, or Safari) and your electronic device has a camera.
- Click on “Report Your Test Result.”
- Create an account.

To perform a COVID-19 test:

1. Log in to the Flowflex Web App - Ensure you are connected to the internet during your test.
2. Answer a few questions on the Web App.
4. Read result.

**COLLECTION BY AN ADULT**

A nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

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A nasal swab sample can be self-collected by an individual aged 14 years and older. Children aged 2 to 13 years should be tested by an adult.

Follow up care with your health care provider.

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To perform a COVID-19 test:

1. Log in to the Flowflex Web App - Ensure you are connected to the internet during your test.
2. Answer a few questions on the Web App.
4. Read result.
Q: WHAT IF YOU TEST POSITIVE?
A: 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. Your healthcare provider will work with you to determine how best to care for you based on your test result, medical history, and symptoms.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. However, negative results do not rule out SARS-CoV-2 infection. 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. For example, you may get a false negative result if you did not perform the test correctly or if the level of antigen from the virus causing COVID-19 was below the test limits. The amount of antigen in a sample may decrease the longer you have had symptoms of infection. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath, you should seek medical care. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: An invalid test result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new sample should be used within 60 minutes. Follow the Flowflex COVID-19 Antigen Home Test instructions for use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time.

Individuals should report the test result through the Flowflex Web App or provide all results obtained with this product to their healthcare provider for public health reporting.

For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcr-legal-regulatory-and-policy-framework/emergency-use-authorization

For the most up to date information on COVID-19, please visit: www.cdc.gov/coronavirus

For detailed instructions, please visit: www.flowflex.com

This test is intended to be used as an aid in the clinical diagnosis of active COVID-19. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time.

Individuals should report the test result through the Flowflex Web App or provide all results obtained with this product to their healthcare provider for public health reporting.

Q: WHAT IS COVID-19?
A: COVID-19 is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Symptoms may include fever, coughing, shortness of breath, fatigue, muscle pain, headache, chills, loss of taste or smell. People infected with COVID-19 can spread the virus to others even before they show symptoms. A full list of symptoms of COVID-19 can be found at the CDC site here: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Q: CAN SELF-TESTING REDUCE THE SPREAD OF COVID-19?
A: This test was not able to tell if you have COVID-19 or not. If the test is invalid, a new sample should be used within 60 minutes. Follow the Flowflex COVID-19 Antigen Home Test instructions for use.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the virus that causes COVID-19. Molecular tests detect genetic material from the virus, Antigen tests, such as the Flowflex COVID-19 Antigen Home Test, detect proteins from the virus. Antigen tests are very specific for the SARS-CoV-2 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. In a clinical study conducted between March 2021 and May 2021 with 172 nasal swabs self-collected or paired with a molecular test, the antigen test correctly identified 93% of positive specimens and 100% of negative specimens.

Q: WHAT IS THE PERFORMANCE OF THE FLOWFLEX COVID-19 ANTIGEN HOME TEST?
A: A laboratory study conducted between March 2021 and May 2021 with 172 nasal swabs self-collected found that Flowflex COVID-19 Antigen Home Test correctly identified 98% of positive specimens and 100% of negative specimens. Possible incorrect test results (see Warnings and Risk Interpretation section). The results of this test may help limit the spread of COVID-19 to your family and others in your community. Possible discomfort during sample collection. Possible incorrect test results (see Warnings and Risk Interpretation section). Possible discomfort during sample collection.

This test is intended to be used as an aid in the clinical diagnosis of active COVID-19. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time.

Individuals should report the test result through the Flowflex Web App or provide all results obtained with this product to their healthcare provider for public health reporting.