**Flowflex™ COVID-19 Antigen Home Test**

**Package Insert**

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. Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

**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.

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

**TEST PROCEDURE**

1. Remove the foil from the top of the extraction buffer tube.

2. 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. 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 ¾ of an inch, and you may need to have a second person to hold the child’s head while swabbing.

**SPECIMEN COLLECTION**

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

5. 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.

6. Immediately place the swab into the extraction buffer 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 ¾ 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 swab is not rotated five times.

9. Remove the swab while squeezing the tube. Dispose the swab in the trash. 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 ¾ of an inch, and you may need to have a second person to hold the child’s head while swabbing.

10. Note: A false negative result may occur if the swab is not rotated five times.

11. Remove the swab while squeezing the tube. Dispose the swab in the trash. 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 ¾ of an inch, and you may need to have a second person to hold the child’s head while swabbing.

12. Note: A false negative result may occur if the swab is not swirled at least 30 seconds.

**RESULT INTERPRETATION**

- **Negative**: Only the control line (C) and no test line (T) appears. This means that no SARS-CoV-2 antigen was detected.
- **Positive**: 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.
- **Invalid**: Control line (C) fails to appear. If a control (C) line is not visible, the test is invalid. Re-test with a new swab and new test cassette. If the problem persists, call (800) 838-9502 for assistance.

**SELF COLLECTION**

- **COLLECTION BY AN ADULT**
- **COLLECTION BY AN ADULT**

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.

**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.

www.flowflexcovid.com
FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY

This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.

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 IVDs for detection and/or diagnosis of COVID-19 by the percentage of positive results of at least six out of the first ten tests performed.

The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.

Do not use any of the test kit contents or packaging is damaged or open.

Test components are single use. Do not re-use. Do not use with multiple specimens.

Make sure there is sufficient light when testing.

Do not use needles or syringes after collecting a nasal sample.

Remove any pungency from the nose before starting the test.

Do not use anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the last six months.

False negative test results may occur if a specimen is incorrectly collected or handled.

Do not touch the swab tip when handling the swab.

The ACON FlexFlow COVID-19 Antigen Test was compared to an FDA authorized EUA. 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.

This product has been authorized only for the detection of proteins from SARS-CoV-2 nucleocapsid protein antigen. This antigen is generally found in anterior nasal swabs during the acute phase of infection.

Potential risks and benefits of this test include:

- Possible incorrect test results (see Warnings and Risk Interpretation section).
- 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 more information about the EUA please visit: https://www.fda.gov/emergency-preparedness-and-response/emergency-legal-and-policy-framework/emergency-use-authorization

For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

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

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 ACON FlexFlow 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 COVID-19 and should be discussed with your healthcare provider whether an additional test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with molecular tests. A negative result does not mean there is a higher chance this test will give you a negative result when you have COVID-19 than a molecular test would.

CQ: WHAT IS A POSITIVE TEST RESULT?

A: A positive test 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 IS A NEGATIVE TEST RESULT?

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 COVID-19 in all circumstances. 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.

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 provide all results obtained with this product to their healthcare provider for public health reporting.

Please visit www.flowflexcovid.com to obtain the complete instructions for use and fact sheet for healthcare providers.

IMPORTANT

This product is intended for veterinary use only.

This Antigen Home Test Package Insert should be read carefully before performing a test. Failure to follow directions may produce inaccurate test results.

The Test is intended for use by healthcare providers to perform a test on clients or patients. It is not intended for use by non-healthcare professionals or lay-persons.

The ACON FlexFlow COVID-19 Antigen Home Test Package was designed for self-administration by individuals 16 years of age and older.

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

The Reagent Solution contains a harmful chemical (see table below). To prevent adverse reactions, seek medical advice. https://www.poisonhelp.org or 1-800-222-1222

WARRANTS, PRECAUTIONS, AND SAFETY INFORMATION

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Index of Symbols

| Manufacturer | Date of manufacture |
| Contains sufficient for | <n> | REF | Catalogue number |
| In vitro diagnostic medical | | | Use-by date |
| Consult instructions for use | | | Batch code |
| Temperature limit | | | Do not reuse |
Flowflex® COVID-19 Antigen Home Test

The Flowflex COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19.

Contents:
• 5 Test Cassettes
• 5 Extraction Buffer Tubes
• 5 Disposable Nasal Swabs
• 1 Package Insert (En/Es)

Items necessary to use the kit, but not provided:
• Timer

Easy to Use
Quick Results

COVID-19 Test
A rapid test for the detection of COVID-19 antigens in nasal swab specimens.

For in vitro diagnostic use. For use under an Emergency Use Authorization (EUA) only.

This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test. For ages 2 to 13, an adult must collect and test the anterior nares specimen.

Scan to learn more about the test

5 TESTS

COVID-19 Antigen Home Test

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