



**Fortress
Diagnostics**



Rapid COVID-19 Antigen Self-Test

INTENDED USE

The Rapid COVID-19 Antigen Self-Test is a lateral flow test for the qualitative detection of nucleocapsid protein antigen from SARS CoV-2 (Coronavirus, or “COVID-19”) from direct anterior nasal (nares) swab directly from individuals who are both symptomatic and asymptomatic. Nasal swab samples from individuals aged below 12 years or above 70 years should be collected by or under supervision of adults. This test is intended to aid in the rapid diagnosis of Coronavirus infections. If symptoms persist despite negative test results it is recommended to visit a healthcare professional to seek follow up care.

SUMMARY AND EXPLANATION

Coronavirus can cause an acute respiratory infectious disease known as COVID-19. Currently, people infected with coronavirus are the main source of infection; infected people can be a source of infection even if they do not show symptoms. Based on the current epidemiologic survey, the time between infection and disease onset is 1 to 14 days, most commonly 3 to 7 days. The main signs of infection include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, muscle pain and diarrhea are found in a few cases.

The Rapid COVID-19 Antigen Self-Test is for detection of nucleocapsid protein antigen of coronavirus. The antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Rapid diagnosis of coronavirus infection and subsequent care and treatment by healthcare professionals will help control the spread of coronavirus more efficiently and effectively.

BENEFITS

- Rapid testing for SARS-CoV-2 antigens within 15 minutes
- Simple, time-saving procedure
- High sensitivity and specificity
- Easy to store temperatures

Contact us

Address Fortress Diagnostics, Unit 9A The Technology Park, Belfast Road, Antrim, BT41 1QS,
Northern Ireland, United Kingdom

Email info@fortressdiagnostics.com

Website www.fortressdiagnostics.com



KIT CONTENTS

	COVSTN01	COVSTN05	COVSTN07	COVSTN15	COVSTN20
Test Device	1	5	7	15	20
Sterile Swab	1	5	7	15	20
Extraction Tube with Buffer and Tip	1	5	7	15	20
Workstation	1	1	1	1	1
Instruction for Use	1	1	1	1	1

MATERIALS REQUIRED BY NOT PROVIDED

- Clock, timer or stopwatch and plastic bag for waste.

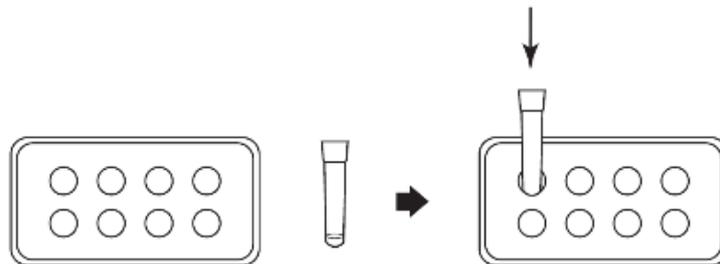
SPECIFICATION

Information	Detail
Results Time	15 minutes
Storage	2-30°C
Shelf Life	24 months
Specimen Type	Nasopharyngeal /Nasal Swab

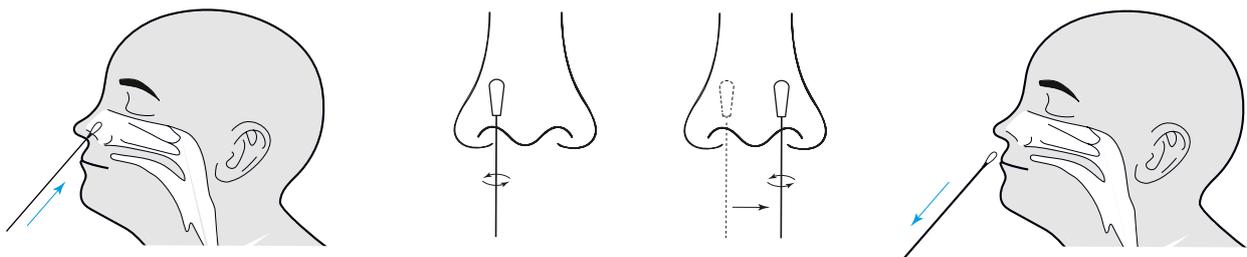
TEST PROCEDURE

Wash or sanitize your hands before performing the test. The test should be performed at room temperature (15-30°C). Allow the test to reach room temperature prior to use if any parts have been stored in a refrigerator.

1. Insert the tube into the workstation. remove the lid from the top of the tube.



2. Open swab package where indicated. Pull the swab out by grasping the plastic end. Do not pouch the absorbent swab tip.
3. Carefully insert absorbent tip of the swab into your left nostril. Ensure that the entire swab tip is inside your nostril (2-4cm deep). Do not insert the swab further after you feel resistance.
4. Roll the swab at least 5 times against the insides of your nostril. Ensure good contact between the swab and the insides of your nostril.
5. Remove the swab and insert into your right nostril. Repeat Step 4 and 5.



Contact us

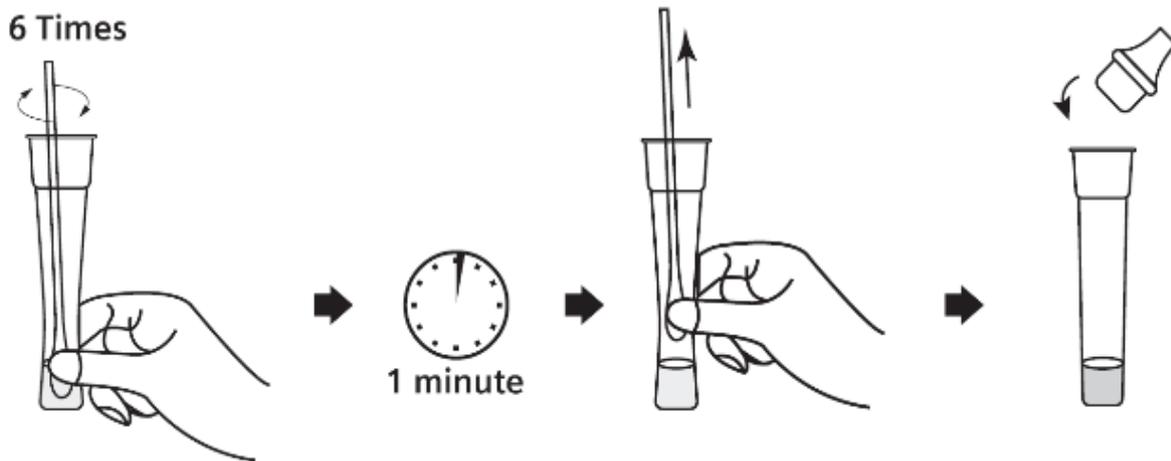
Address Fortress Diagnostics, Unit 9A The Technology Park, Belfast Road, Antrim, BT41 1QS,
Northern Ireland, United Kingdom

Email info@fortressdiagnostics.com

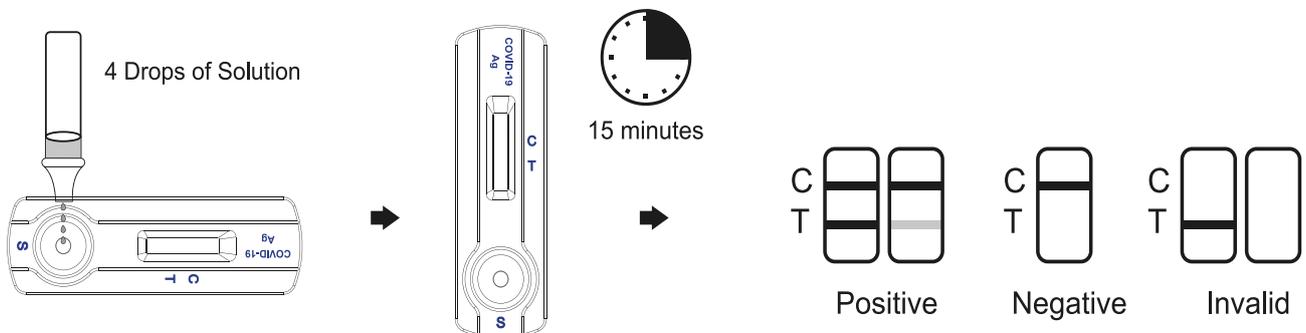
Website www.fortressdiagnostics.com



6. Remove the swab from your nostril and insert the swab into the tube in the workstation.
7. Mix well by rolling the swab at least 6 times while pressing the head of the swab against the bottom and sides of the tube.
8. Start timer . Leave the swab in the tube for 1 minute.
9. Squeeze the tube several times from the outside. Try to release as much solution from the swab as possible.
10. Remove swab and discard in a plastic bag.
11. Push the tip provided in the kit into the tube and ensure it fits tightly.



12. Remove the test device from the pouch and lay it on a flat clean surface.
13. Add 4 drops of the solution into the sample well of the test device by gently squeezing the tube.
14. Start timer and wait 15 minutes. It is important to read the results at 15 minutes.
15. Read your results (See interpretation of results section).



Contact us

Address Fortress Diagnostics, Unit 9A The Technology Park, Belfast Road, Antrim, BT41 1QS,
Northern Ireland, United Kingdom

Email info@fortressdiagnostics.com

Website www.fortressdiagnostics.com



INTERPRETTION OF RESULTS

There are three possible types of results.

1. POSITIVE:

If the test device looks like either of the positive result windows as displayed above, you have a current COVID-19 infection. Please call your doctor or your local health department and make sure you adhere to local guidelines for self-isolation. Re-testing with other test methods such as a PCR test may be required.

2. NEGATIVE:

If the test device looks like the negative result window as displayed above, no COVID-19 infection could be detected. In a suspected case, repeat the test after 1-2 days since the virus cannot be accurately detected in all phases of an infection. Despite a negative test result, you still have to comply with all applicable rules regarding contact with others and protective measures.

3. INVALID:

If your test result looks different, meaning there is no line visible or only one line at T, the result is invalid. This may be a result of the test execution, and the test should be repeated. If invalid test results continue, please contact your doctor or a COVID test centre.

FREQUENTLY ASKED QUESTIONS

Will this test hurt?

The nasal swab may cause slight discomfort. To obtain an accurate test result it is important to swab the nostril as instructed in the test procedure. Discomfort may be increased if swab is inserted beyond recommended depth. If sharp pain is experienced, do not swab the nostril any further.

What are the potential benefits and risks of this test?

Potential benefits:

- The test can determine if you have COVID-19.
- The results, along with other information, can help your healthcare provider make informed decisions about your care.
- You can help limit the spread of COVID-19 by knowing your infection status with this test.

Potential risks:

- Possible discomfort during swabbing.
- Possible incorrect test results (see interpretation of results and limitations sections).

What are the differences between COVID-19 molecular, antigen, and antibody tests?

There are three main types of COVID-19 tests available, and there are significant differences between them. Molecular tests (also known as PCR tests) detect the genetic material of the Coronavirus. The Rapid COVID-19 Antigen Self-Test is an antigen test. Antigen tests detect for proteins, which are small pieces, belonging to the Coronavirus. Antibody test detects anti-bodies that the immune system in your body produces in response to previous COVID-19 infection. Antibody tests cannot be used to diagnose active COVID-19 infection.

How accurate is the Rapid COVID-19 Antigen Self-Test?

The Rapid COVID-19 Antigen Self-Test identified 97.25% of COVID-19 positive samples and 100% of COVID-19 negative samples. The overall accuracy of the Rapid COVID-19 Antigen Self-Test is 98.73%. The samples used to determine the performance of this test were collected during a clinical study conducted in the USA. The samples were confirmed positive and negative by a USFDA emergency use authorized PCR test.

What does it mean if I have a positive result?

A positive test result means that proteins from the virus that causes COVID-19 was found in your swab sample. It is likely that you may be required to self-isolate at home to prevent the spread of COVID-19. Please also observe the relevant rules for spread control and contact your doctor or local health department.

In this case, it is recommended to have the result confirmed with an alternative test method such as a PCR test.

Contact us

Address Fortress Diagnostics, Unit 9A The Technology Park, Belfast Road, Antrim, BT41 1QS,
Northern Ireland, United Kingdom

Email info@fortressdiagnostics.com

Website www.fortressdiagnostics.com