The Panbio™ COVID-19 Antigen Self-Test is intended to be used manually by untrained users (self-testing) in a private setting to aid in the diagnosis of an active SARS-CoV-2 infection. Children under 18 months should be supervised by an adult.

SUMMARY

The coronavirus belongs to the βgenus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. Main manifestations are fever, cough, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

TEST LIMITATIONS

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigen from nasal swab samples. Other specimen types may lead to incorrect results and must not be used. Pulmonary infections that are caused by microorganisms other than SARS-CoV-2 are not diagnosed by this test.

2. Failure to follow the instructions for test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

4. A negative test result may occur if the specimen was collected, extracted or transported improperly. A negative test result may also occur if the test is performed after 12 days, or the coronavirus is not detectable in the very early phases of the infection. You are also advised to continue following local guidelines for self-testing and consult your doctor.

5. Do not use test solution on patients with other pathogens.

6. Reading the results earlier than 15 minutes or later than 30 minutes may give incorrect results.

7. The Panbio™ COVID-19 Antigen Self-Test is not intended to detect from defective (non-viral) factors in the virus during the later stages of viral shedding that might be PCR detected by other molecular tests. The test includes a test control to determine whether a person is infected.

8. Due to cross-reactivity with high concentrations of SARS-CoV-2 a false positive result may occur in the case of infection with SARS-CoV-2.

9. Read the test results following the testing window for an invalid result.

10. Test results are negative in the very later phases of infection and asymptomatic individuals.

FREQUENTLY ASKED QUESTIONS

What does the test do?

The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigen from nasal swab samples. Other specimen types may lead to incorrect results and must not be used. Pulmonary infections that are caused by microorganisms other than SARS-CoV-2 are not diagnosed by this test.

The Panbio™ COVID-19 Antigen Self-Test is not intended to detect the virus at later stages of the infection which may be detected by Molecular PCR.

Do I need to wear personal protective equipment?

The test can determine if you have an active COVID-19 infection.

What can I do if I have a positive result?

1. The results, along with other information, can help your healthcare provider make informed decisions about your treatment.

2. You can help limit the spread of COVID-19 by following local guidance for self-isolation and consult your doctor.

3. Possible symptoms will be discussed during the call.

What are the potential benefits and risks of this test?

Potential benefits:

- The test can determine if you have an active COVID-19 infection.

- You can help limit the spread of COVID-19 by following local guidance for self-isolation and consult your doctor.

Possible risks:

- You will need to receive help for isolation, quarantine, or other steps that may be required by your local health department.

What does it mean if I have an invalid result?

This may be a result of incorrect test procedure. Wrong sample product means you are not as significant as another test.

What does it mean if I have a negative result?

A negative test result means that it is unlikely that you have COVID-19 at the time of testing. The test does not detect any antigens in your nasal swab sample, but it is possible that your test gave a false negative test result. False negative test results can be caused by several factors:

- The amount of antigen in the sample may decrease over the duration of the infection.

- The test may be negative before you develop symptoms.

- The test may not perform the test correctly.

- Specimen collection, extraction or processing may not be performed correctly.

- If symptoms continue, you should repeat the test after 1-2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-testing and consult your doctor.

What are the differences between a COVID-19 Molecular, Antibody and Antigen test?

There are three main types of COVID-19 tests. Molecular tests are used to detect viral RNA. Antibody tests detect antibodies that are produced by the body’s immune system in response to a previous COVID-19 infection. Antibody tests cannot be used to diagnose active COVID-19 infection.

Antigén tests detect a protein of the virus. The Panbio™ COVID-19 Antigen Self Test which are detecting an active infection are key in the early stages of infection. Lower cycle threshold (Ct) values of samples, due to lower virus concentrations, may provide a more accurate diagnosis.

Negative test result means that it is unlikely that you have COVID-19 at the time of testing. The test does not detect any antigens in your nasal swab sample, but it is possible that your test gave a false negative test result. False negative test results can be caused by several factors:

- The amount of antigen in the sample may decrease over the duration of the infection.

- The test may be negative before you develop symptoms.

- The test may not perform the test correctly.

- Specimen collection, extraction or processing may not be performed correctly.

- If symptoms continue, you should repeat the test after 1-2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-testing and consult your doctor.

What are the cross-reactivity of COVID-19?

The Panbio™ COVID-19 Antigen Self-Test was confirmed to detect SARS-CoV-2. The test gives negative test result with known variants as of August 31, 2021. Please scan the QR code for the Panbio™ COVID-19 Antigen Test and Emerging Virus Information Sheet for the most recently analyzed variants.

What is the sensitivity of Panbio™ COVID-19 Antigen Self-Test?

The Panbio™ COVID-19 Antigen Test has been shown in clinical evaluations, performed by professional healthcare personnel, to correctly identify 99.9% (483 out of 483) of SARS-CoV-2 negative nasal swabs with a confidence interval of 99.9% (100.0%).

In a clinical evaluation of 483 symptomatic patients the Panbio™ COVID-19 Antigen Test shows a sensitivity of 99.9% (483 out of 483) and a specificity of 99.9% (0 out of 4). The specificity was 100% (433 out of 433) with 95% confidence interval of 99.9% (100.0%). All samples were confirmed negative by RT-PCR test approved by the US FDA for emergency use.

In a comparative evaluation with Panbio™ COVID-19 Antigen Self-Test correctly identified 99.9% (483 out of 483) of SARS-CoV-2 negative nasal swabs with a confidence interval of 99.9% (100.0%) and 99.9% (483 out of 483) of SARS-CoV-2 positive nasal swabs with a confidence interval of 99.9% (100.0%).

All samples were confirmed as positive and negative by Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal).

What does it mean if I have a negative result?

A negative result may occur if the specimen was collected, extracted or transported improperly. A negative test result may also occur if the test is performed after 12 days, or the coronavirus is not detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-testing and consult your doctor.

What does it mean if I have a positive result?

A positive test result means that proteins of the virus that cause COVID-19 have been found in your nasal swab sample. It is likely that you will need to perform self-isolation at home to prevent the spread of COVID-19. A positive result does not rule out confusion with other pathogens.

Please follow local guidelines for social distancing to limit the spread of the virus. All positive results must be confirmed with a laboratory PCR test.

What does it mean if I have a negative result?

A negative test result means that it is unlikely that you have COVID-19 at the time of testing. The test does not detect any antigens in your nasal swab sample, but it is possible that your test gave a false negative test result. False negative test results can be caused by several factors:

- The amount of antigen in the sample may decrease over the duration of the infection.

- The test may be negative before you develop symptoms.

- The test may not perform the test correctly.

- Specimen collection, extraction or processing may not be performed correctly.

- If symptoms continue, you should repeat the test after 1-2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-testing and consult your doctor.
C. PERFORM THE TEST

10. Hold the Tube firmly with one hand. Lift the Swab and locate the break line.

11. Secure the Blue Cap on the top of the Tube. Return the Tube to the Tube Rack before proceeding to the next step.

D. READ TEST RESULT

12. Remove the Test Device from its protective package and place on a well-lit, flat surface.

13. Check liquid for bubbles. Wait for any bubbles to disappear as they can lead to inaccurate results.

14. Squeeze 5 drops of liquid from the Tube into the well on the Test Device. Secure white cap back on Tube and wait 15 minutes.

Note: After 20 minutes the result might become inaccurate.

Note: Be careful not to spill the Tube contents.

15. Keep Test Device flat on table. Read the result at 15 minutes. Do not read the result earlier than 15 minutes or after 20 minutes.

Note: A Control (C) line may appear in the result window within a few minutes but a Test (T) line may take as long as 15 minutes to appear.

16. Place Swab, Tube and Test Device into the Bag.

E. DISPOSE THE TEST KIT

17. Seal the Bag tightly.

18. Throw away the Bag in waste bin.