REF 41FK51/41FK71
41FK81/41FK91

EN

ENGLISH - INDIA

Panbio™

COVID-19 Antigen
SELF-TEST

For use with nasal swab specimens

Please scan the QR code to access a digital version of the instructions, additional technical support contacts, and download the NAVICA app from the Play Store/ App Store to report results. The app is available for the India market only. The Indian Council for Medical Research (ICMR) requires reporting of all COVID-19 Self-Test results.

INTENDED USE

The Panbio™ COVID-19 Antigen Self-Test is a single-use, *in vitro* (outside the body) visually read rapid immunoassay that uses a human nasal swab specimen for the qualitative detection of nucleocapsid protein SARS-CoV-2 antigen (Ag). The Panbio™ COVID-19 Antigen Self-Test is intended to be used manually by untrained lay users (self testing) in a private setting to aid in the diagnosis of an active SARS-CoV-2 infection. Children under 14 years should be supported by an adult.

SUMMARY

The novel coronaviruses belong to the β genus. 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. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

TEST PRINCIPLE

The Panbio™ COVID-19 Antigen Self-Test is a lateral flow test that detects the nucleocapsid protein antigen of the Coronavirus SARS-CoV-2 in a swab from the mid turbinate nasal region. The product includes a test device, a bottle with buffer solution, an extraction tube/cap and a nasal swab.

To use the test, buffer solution is added to the extraction tube, then a human nasal specimen is collected using the swab provided in the kit. After sample collection, the nasal swab is transferred to the extraction tube to extract the Coronavirus proteins. Next, 5 drops of extracted sample are applied to the round well on the test device. A line in the Control (C) line area within the result reading window will only become visible if the test was performed correctly. A line in the Test (T) line area within the result reading window will only become visible if Coronavirus proteins are detected. The presence of only a Control (C) line, without visible Test (T) line, indicates the coronavirus proteins are not present.

Active ingredients of the test device are antibodies specific to the SARS-CoV-2 nucleocapsid protein antigen.

CONTENTS

KIT SIZE	CONTENTS
1 Test	1 Instructions for Use, 1 Test Device, 1 Tube, 1 Blue Cap, 1 Buffer Bottle, 1 Swab, 1 Bag, 1 Tube Rack
4 Tests	1 Instructions for Use, 4 Test Devices, 4 Tubes, 4 Blue Caps, 4 Buffer Bottles, 4 Swabs, 4 Bags, 1 Tube Rack
10 Tests	1 Instructions for Use, 10 Test Devices, 10 Tubes, 10 Blue Caps, 10 Buffer Bottles, 10 Swabs, 10 Bags, 1 Tube Rack
20 Tests	1 Instructions for Use, 20 Test Devices, 20 Tubes, 20 Blue Caps, 20 Buffer Bottles, 20 Swabs, 20 Bags, 2 Tube Racks

Required but not included:

- Timing device

STORAGE AND STABILITY

1. Store the test kit in a cool, dry place (at 2-30 °C). Do not freeze the kit or its components.
2. Do not use the test kit beyond the expiration date as indicated on the outer package.
3. Perform the test immediately after removing the Test Device from the protective packaging.
4. Do not store the test kit in direct sunlight.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Read instructions prior to performing the test. Follow all instructions to achieve accurate results.
3. Do not eat or smoke while handling specimens.
4. Wash hands thoroughly before and after the test is completed.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Dispose of all specimens, reaction kits and potentially contaminated materials (i.e. Swab, Tube, Test Device) in bag provided.
7. Use only the liquid from the Buffer Bottle provided in the kit. Use of other liquids will lead to inaccurate results.
8. Keep the test kit out of reach of children.
9. To prevent contamination, only touch the sides of the Test Device and ensure the Swab end only touches the nasal cavity and inside of Tube.
10. The provided Swab should be used only for nasal (mid-turbinate) specimen collection.
11. Each single Test Device, Swab, Tube, Blue Cap, Buffer Bottle and Bag are single use. Do not reuse individual components. The Tube Rack is reusable.
12. Do not dip the Swab into buffer or other liquid before inserting the Swab into the nose.
13. The provided Buffer Bottle contains <0.1% sodium azide as a preservative which may be toxic if ingested. If you get buffer solution into your eyes rinse for at least 15 minutes under running water. If irritation persists, go to a doctor.
14. If you have stored the kit in the refrigerator, store the kit at room temperature (15 to 30°C) for 30 minutes before use.
15. Do not use the test kit if the pouch is damaged or the seal is broken.
16. Direct swab specimen should be tested immediately after collection.

TEST LIMITATIONS

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigen from nasal swab. Other specimen types may lead to incorrect results and must not be used. Pulmonary infections that are caused by microorganisms other than by SARS-CoV-2 coronavirus are not detected 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.
3. A confirmed diagnosis should only be made by a health care professional after all clinical and laboratory findings have been evaluated.
4. A negative test result may occur if the specimen was collected, extracted or transported improperly. 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-isolation and consult your doctor.
5. Positive test results do not rule out co-infections with other pathogens.
6. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.
7. Panbio™ COVID-19 Antigen Self-Test is not intended to detect from defective (non-infectious) virus during the later stages of viral shedding that might be detected by PCR molecular tests.
8. Due to cross-reactivity with high concentrations of SARS-CoV, a false positive result may occur in the case of infection with SARS-CoV.
9. Wait 4 hours before repeating the test following an invalid result.

FREQUENTLY ASKED QUESTIONS

What does this test do?

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

Does this test hurt?

The nasal swab may cause slight discomfort. It is important to follow the nasal swab collection steps as indicated in the procedure. Discomfort may occur if the swab is inserted beyond the recommended depth. If painful, slightly withdraw the swab to finish the sample collection process.

What is the best time to read the results?

15 minutes.

What are the potential benefits and risks of this test?

Potential benefits:

- The test can determine if you have an active COVID-19 infection.
- The results, along with other information, can help your healthcare provider make informed decisions about your treatment.
- You can help limit the spread of COVID-19 by knowing your infection status and taking appropriate social distancing measures.

Possible risks:

- Slight discomfort during the nasal sample collection.
- Possible false test results may occur, 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-isolation and consult your doctor.

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

There are three main types of COVID-19 tests. Molecular tests (also known as PCR tests) detect the genetic material of the coronavirus. The Panbio™ COVID-19 Antigen Self-Test is an antigen test. Antigen tests detect coronavirus proteins. Antibody tests detect antibodies produced by your body's immune system in response to a previous COVID-19 infection. Antibody tests cannot be used to diagnose an active COVID-19 infection.

How accurate is the Panbio™ COVID-19 Antigen Self-Test?

The Panbio™ COVID-19 Antigen Self-Test has been shown in clinical evaluations, performed by professional health care persons, to correctly identify 99.8% (403 out of 404) of SARS-CoV-2 negative nasal samples with a confidence interval of 98.6% to 100.0% (known as test specificity). The test correctly identified 98.1% (102 out of 104) SARS-CoV-2 positive nasal samples with a confidence interval of 93.2% to 99.8% (known as test sensitivity).

In a clinical evaluation of 483 asymptomatic patients the Panbio™ COVID-19 Antigen Self-Test showed a sensitivity of 93.8% (confidence interval: 79.2% to 99.2%) of SARS-CoV-2 positive samples at lower Ct (cycle threshold, values of ≤30) which corresponds to higher virus concentrations. In this study, the specificity was 100.0% (433 out of 433) with a confidence interval of 99.2% to 100.0%. All samples were confirmed positive and negative by a RT-PCR test approved by the US FDA for emergency use.

In clinical evaluations with 102 self-test users, the Panbio™ COVID-19 Antigen Self-Test correctly identified 100.0% (81 out of 81) of SARS-CoV-2 negative samples with a confidence interval of 95.5% to 100.0%, and 95.2% (20 out of 21) of SARS-CoV-2 positive samples with a confidence interval of 76.2% to 99.9%.

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

Which cross-reactivities can occur?

The following 45 cross-reactants and 21 other microorganisms had no impact on the performance of the Panbio™ COVID-19 Antigen Self-Test:
Adenovirus Type 1, 5, 7, and 11, Enterovirus (EV68), Echovirus 2 and 11, Enterovirus D68, Human herpesvirus (HSV) 1 and 2, Mumps Virus Ag, Influenza virus A (H1N1) Strains (A/ Virginia/ATCC1/2009, A/WS/33 and A/California/08/2009/pdm09), Influenza virus B Strain (B/Lee/40), Parainfluenza Type 1, 2, 3 and 4A, Respiratory syncytial virus (RSV) type A and B, Rhinovirus A16, HCoV-HKU1, HCoV-NL63, HCoV-OC43, HCoV-229E, MERS-CoV Nucleoprotein, Human Metapneumovirus (hMPV) 16 Type A1, Adenovirus Type 2, 3 and 4, Enterovirus C, Influenza virus A (H3N2) Strain (A/Hong Kong/8/68), Influenza virus A (H5N1), Influenza virus B Strain (Victoria), Rhinovirus 14 and 54, Human cytomegalovirus, Norovirus, Varicella-zoster virus, Measles virus, EB virus, Influenza virus (H7N9), Influenza virus B Strain (Yamagata), Rotavirus, *Staphylococcus saprophyticus, Neisseria sp.(Neisseria lactamica), Staphylococcus haemolyticus, Streptococcus salivarius, Hemophilus parahaemolyticus, Proteus vulgaris, Moraxella catarrhalis, Klebsiella pneumoniae, Fusobacterium necrophorum, Mycobacterium tuberculosis, Streptococcus pyogenes, Mycoplasma pneumoniae, Staphylococcus aureus, Escherichia coli, Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Streptococcus pneumoniae, Bordetella pertussis, Pneumocytis jirovecci*, Pooled human nasal wash.

Panbio™ COVID-19 Antigen Self-Test has cross-reactivity with Human- SARS-coronavirus Nucleoprotein (SARS-CoV) at a concentration of 25 ng/ml or more because SARS-CoV has high homology to the SARS-CoV-2.

Which interferences can occur?

The following 43 potentially interfering substances / factors had no impact on the performance of the Panbio™ COVID-19 Antigen Self-Test:
Mucin, Hemoglobin, Triglycerides, Icteric (Bilirubin), Rheumatoid factor, Anti-nuclear antibody, Pregnant, Guaiacol glyceryl ether, Albuterol, Ephedrine, Chlorpheniramine, Diphenhydramine, Ribavirin, Oseltamivir, Zanamivir, Phenylephrine hydrochloride, Oxymetazolin hydrochloride, Amoxicillin, Acetylsalicylic acid, Ibuprofen, Chlorothiazide, Indapamide, Glimepiride (Sulfonylureas), Acarbose, Ivermectin, Lopinavir, Ritonavir, Chloroquine phosphate, Sodium chloride with preservatives, Beclomethasone, Dexamethasone, Flunisolide, Triamcinolone, Budesonide, Mometasone, Fluticasone, Sulfur, Benzocaine, Menthol, Mupirocin, Tobramycin, Biotin, HAMA.

What does it mean if I have an invalid result?

This may be a result of incorrect test procedure. Wait 4 hours before repeating the test.

What does it mean if I have a positive result?

A positive test result means that proteins of the virus that causes 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 coinfection with other pathogens. Please follow local guidelines for social distancing to limit the spread of the virus and contact your doctor or local health department immediately.

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 did 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 swab sample may decrease over the duration of the infection.
- The test may be negative before you develop symptoms.
- The test was not performed per the instructions.
- Specimen collection, extraction or transport was not preformed correctly.

If the rapid antigen test results are negative and symptoms continue, individuals should immediately be tested by RT-PCR per ICMR Advisory. You are also advised to continue following local guidelines for self-isolation and consult your doctor. Ministry of Health & Family Welfare, Government of India (https://www.mohfw.gov.in)

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Please scan QR code for additional toll-free numbers and technical support contacts.

GLOSSARY OF SYMBOLS

2°C 30°C	Store between 2-30°C		Do not reuse
IVD	*In vitro* diagnostic device	LOT	Batch code
	Consult instructions for use	STERILE R	Sterilized using irradiation
	Use by date	STERILE EO	Sterilized using ethylene oxide
	Date of manufacture		Do not resterilize
	Manufacturer		Keep dry
Σ	Contains sufficient for <n> test		Keep away from sunlight
	Caution	REF	Catalog number
	Do not use if package is damaged	CE	CE mark
MD	Medical device	EC REP	Authorized representative in the European Community/ European Union

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1, D-07743 Jena, Germany
www.globalpointofcare.abbott

Date issued: 2021.06
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Nasal Swab Manufacturers

Jiangsu Changfeng Medical Industry Co., Ltd.
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CE 0197 MD

EC REP **Llins Service & Consulting GmbH**
Obere Seegasse 34/2, 69124 Heidelberg, Germany

FA INC.
10-5, Myeonghaksandanseoro, Yeondong-myeon,
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CE 1639 MD

EC REP **MT Promedt Consulting GmbH**
Altenhofstrasse 80, 66386 St. Ingbert, Germany

Turn Over

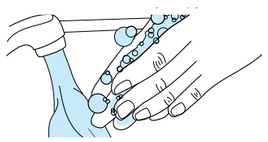
Carefully read these instructions prior to using Panbio™ COVID-19 Antigen Self-Test kit to ensure accurate results.
Children under 14 should be supported by an adult.

The following instructions are the test procedure to complete a single test. The 4 Test, 10 Test and 20 Test kits include components to complete multiple tests. If more than one individual will be tested, separate the test components to avoid confusion.

BEFORE STARTING

Scan the QR code on page 1 to download the NAVICA app.
Open the app and **follow the prompts** to complete the test.

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



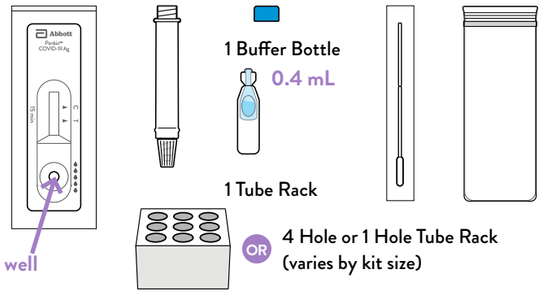
A. PREPARE FOR THE TEST

1. Check the expiration date on the box. Do not use if the kit is expired.

2. Ensure kit is at room temperature for at least 30 minutes prior to use.

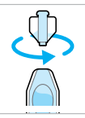
   Open the box and remove 1 each of the components shown below to perform a single test.

   Do not open individual components until instructed.



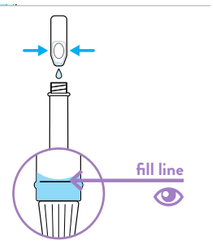
Note: A timing device (clock, timer, etc.) is required, but not provided.

3. Keep Buffer Bottle upr ght, twist and pull tab to op n bottle.

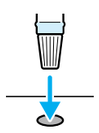


4. Squeeze the liquid from the Buffer Bottle into the Tube. You will need to squeeze at least twice.

   Note: Check the liquid level. Liquid should be at or slightly above the fill line on the side of the Tube.



5. Put the Tube into the Tube Rack before proceeding to the next step.



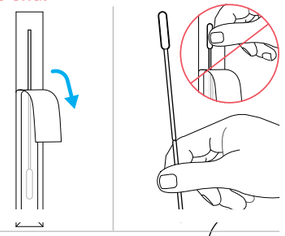
Note: Be careful not to spill the Tube contents.

B. COLLECT THE NASAL SAMPLE

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

6. Open Swab protective package at stick end.

   Take Swab out.

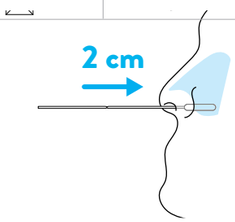


7. **Swab both nostrils.**

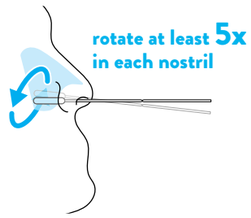
   Insert the soft end of the Swab straight back into your nostril until resistance is felt (about 2cm).

   Slowly rotate the Swab, gently rubbing it along the insides of your nasal passage at least 5 times.

   Remove Swab from nostril.



8. Using the same Swab, repeat step 7 in your other nostril.

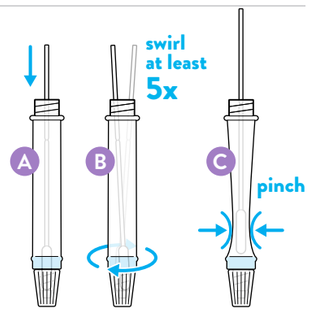


STOP **Check: Did you swab BOTH nostrils?**

9. Insert the Swab into the Tube.

   Swirl in the fluid 5 or more times while pushing against the wall of the Tube.

   Pinch the Swab tip through the Tube to remove any remaining fluid.

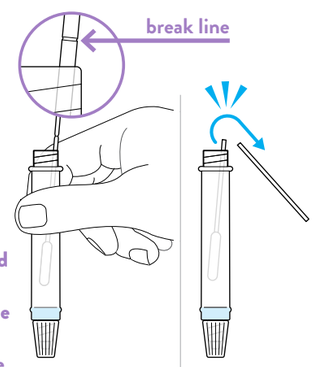


10. Hold the Tube firmly with one hand. Lift the Swab and locate the break line.

    Snap the Swab handle at the break line.

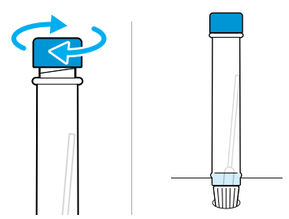
    Leave the Swab in the Tube and discard stick.

    Note: After the swab is inserted in the buffer, the inactivation properties of the buffer plus the physical barrier of the closed extraction tube, help neutralize the COVID-19 virus.



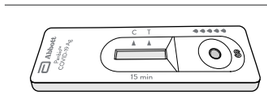
11. Secure the Blue Cap on the top of the Tube.

    Return the Tube to the Tube Rack before proceeding to the next step.



C. PERFORM THE TEST

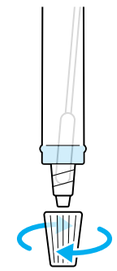
12. Remove the Test Device from its protective package and place on a well-lit, flat surface.



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

    Keep Tube vertical with the white cap pointed down.

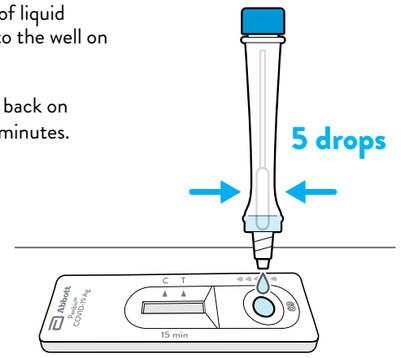
    Remove the white cap.



! **Do not move the Test Device until the test is finished.**

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: If clogging occurs, gently tap the bottom of the Tube to release the blockage.

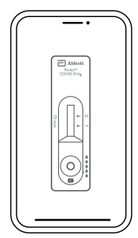
! **Do not touch the Test Device during this period.**

15. Keep Test Device flat on table.

    After 15 minutes, use the NAVICA app to take a photo of the Test Device and submit your result.

    The app will automatically submit your result to ICMR and display your test result.

    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.

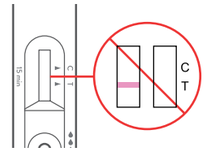
Note: After 20 minutes the result might become inaccurate.

D. READ TEST RESULT

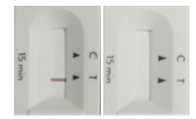
INVALID RESULT (test did not work)

Find the result window. If **NO** Control (C) line is present, the test did not work and is considered **Invalid**.

This may be the result of an incorrect test procedure and the test should be repeated.



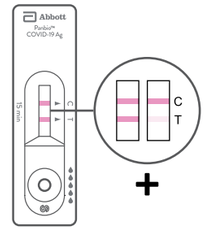
These are examples of invalid tests:



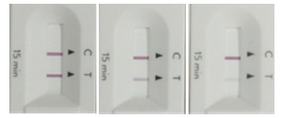
POSITIVE RESULT

Find result window and look carefully for two lines.

Positive Result: If you see two lines, Control (C) line and Test (T) line, this means **COVID-19 was detected.**



These are examples of positive tests:



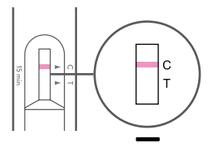
Look closely! The presence of any Test (T) line, no matter how faint is a positive result.

If positive, please contact your doctor or local health department immediately and follow local guidelines for self-isolation.

NEGATIVE RESULT

Find result window and look for a single line in window.

Negative Result: If you see **only** the Control (C) line is present, this means **COVID-19 was not detected.**

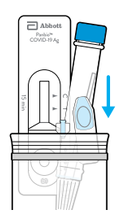


This is an example of a negative test:

If the rapid antigen test results are negative and symptoms continue, individuals should immediately be tested by RT-PCR per ICMR Advisory.
You are also advised to continue following local guidelines for self-isolation and consult your doctor. Ministry of Health & Family Welfare, Government of India (https://www.mohfw.gov.in)

E. DISPOSE THE TEST KIT

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



17. Seal the Bag tightly.

18. Throw away the Bag in waste bin.

Product - Panbio™ COVID-19 Ag Self-Test / IFU **Size** - A3	 **CMYK**	**Rev. No.** 41FK-ST-01-EN-IN-A1 **Rev. Date** - 2021. 06. 18