WHO Emergency Use Assessment SARS-CoV-2 IVDs PUBLIC REPORT

Product: Panbio COVID-19 Antigen Self-Test

Manufacturer: Abbott Rapid Diagnostics Jena GmbH

EUL Number: EUL 0692-032-00

Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and the Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety, and performance data. The EUL procedure includes the following:

- Quality Management Systems Review and Plan for Post-Market Surveillance: a desktop review of the manufacturer's Quality Management System documentation and specific manufacturing documents.
- Product Dossier Review: assessment of the documentary evidence of safety and performance.

Panbio COVID-19 Antigen Self-Test, product codes 41FK51, 41FK71, 41FK81, and 41FK91, CE marked and TGA regulatory versions, manufactured by Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, 07743 Jena, Germany, was listed on 12 September 2022.

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
2.0	The shelf life of the Panbio COVID-19 Antigen Self-Test shall be extended to 24 months.	7 August 2024.

Intended use:

According to Abbott Rapid Diagnostics Jena GmbH's claim of intended purpose, *"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."

Specimen type that was validated:

Nasal swab specimens.

Test kit contents:

Component	1 Test(T) (41FK51)	10 T (41FK71)	20 T (41FK81)	4 T (41FK91
Instructions for use	1	1	1	1
Test device	1	10	20	4
Buffer tube	1	10	20	4
Swab	1	10	20	4
Bag	1	10	20	4
Tube rack	\	1	2	\

Items required but not provided

Timing device

Storage

2-30°C.

Shelf-life upon manufacture

24 months.

Warnings/limitations

Refer to the instructions for use (IFU).

Product dossier assessment

Abbott Rapid Diagnostics Jena GmbH submitted a product dossier for Panbio COVID-19 Antigen Self-Test as per the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 nucleic acid or antigen (PQDx_0347)"*. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and an external assessor appointed by WHO.

Post listing Commitments for EUL:

As commitments to listing, Abbott Rapid Diagnostics Jena GmbH committed to,

1. Assess the traceability of the materials used in validating the product (including estimation of LoD) with the WHO SARS-CoV-2 antigen International Standard when available.
2. Partake in an independent performance evaluation conducted by a laboratory commissioned by WHO. Any such performance evaluation testing will be performed using the protocol and technical criteria established by WHO.
3. Include the clinical performance data for specimens with Ct values > 30 and additional stratification by days post symptom onset in the next issue of the IFU.

Risk-benefit assessment is acceptable.

Quality Management Systems Review

To establish eligibility for WHO procurement, Abbott Rapid Diagnostics Jena GmbH was asked to provide up-to-date information about the status of its quality management system.

Based on the review of the submitted quality management system documentation by WHO staff, it was established that Abbott Rapid Diagnostics Jena GmbH provided sufficient information to fulfil the requirements described in the "*Instructions for Submission Requirements: In vitro diagnostics detecting SARS-CoV-2 nucleic acid or antigen (PQDx_347)*".

The quality management documentation assessment is acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting, and acting on adverse events, product problems, non-conforming goods and processes is critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-EUL activities are required to maintain the EUL listing status:
1. Notification to WHO of any planned changes to a EUL product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic" (document number PQDx_121*); and
2. Post-market surveillance activities, in accordance with "*Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics"* (ISBN 978-92-4-001531-9).

Abbott Rapid Diagnostics Jena GmbH is also required to submit an annual report that details sales data and all categories of complaints in a summarized form. Certain categories of complaints and changes to the product must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensuring that post-emergency use listing safety, quality and performance monitoring activities are in accordance with WHO guidance "*Guidance for*

post-market surveillance and market surveillance of medical devices, including in vitro diagnostics" (ISBN 978-92-4-001531-9).[1]

Scope and duration of procurement eligibility

Panbio COVID-19 Antigen Self-Test, product codes 41FK51, 41FK71, 41FK81, and 41FK91, manufactured by Abbott Rapid Diagnostics Jena GmbH, is considered eligible for WHO procurement for 12 months from the day of listing. The assay may detect the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) antigen. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO prequalified.

As part of the ongoing requirements for listing as eligible for WHO procurement, Abbott Rapid Diagnostics Jena GmbH must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality, and performance requirements. Abbott Rapid Diagnostics Jena GmbH is required to notify WHO of any complaints, including adverse events related to the use of the product, within 7 days and any changes to the product.

WHO reserves the right to rescind eligibility for WHO procurement if additional information on the safety, quality, and performance during post-market surveillance activities and if new data becomes available to WHO that changes the risk-benefit balance.

Labelling

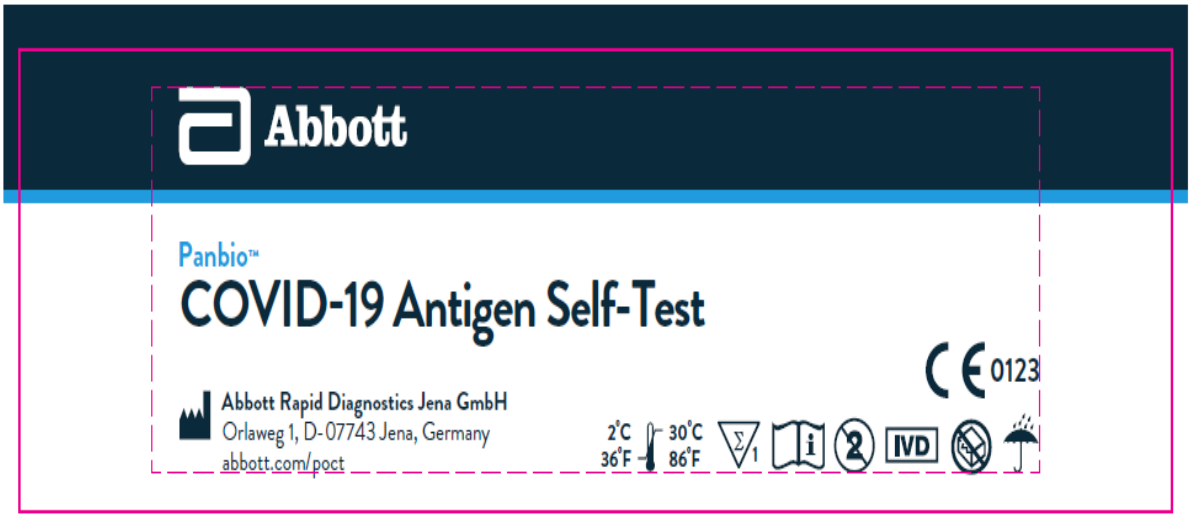
1.0 Labels

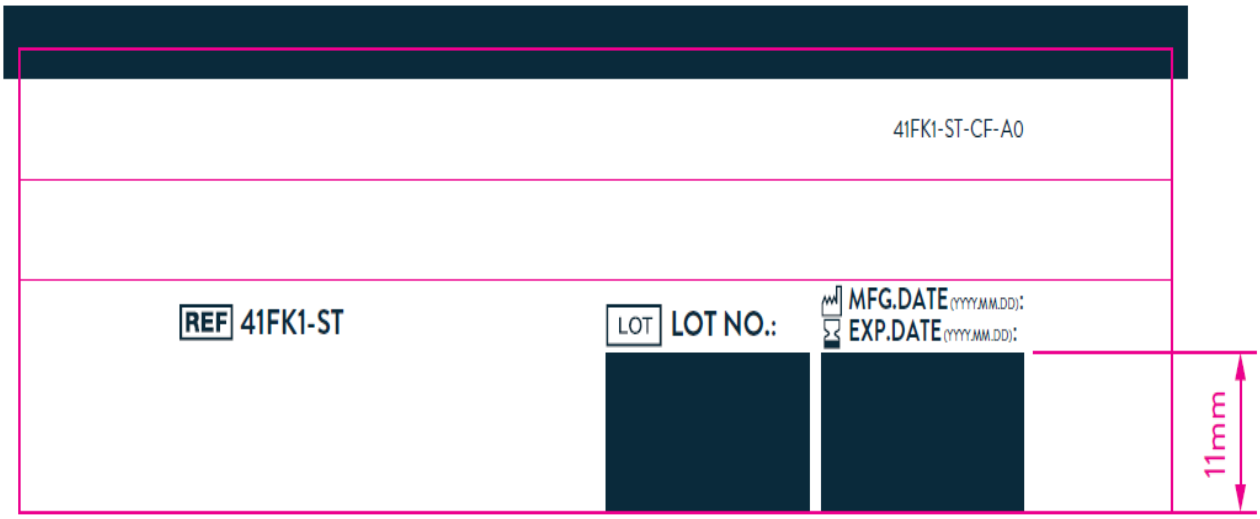
2.0 Instructions for Use (IFU)

[1] Available on the web page https://www.who.int/publications/i/item/guidance-for-post-market-surveillance-and-market-surveillance-of-medical-devices-including-in-vitro-diagnostics.

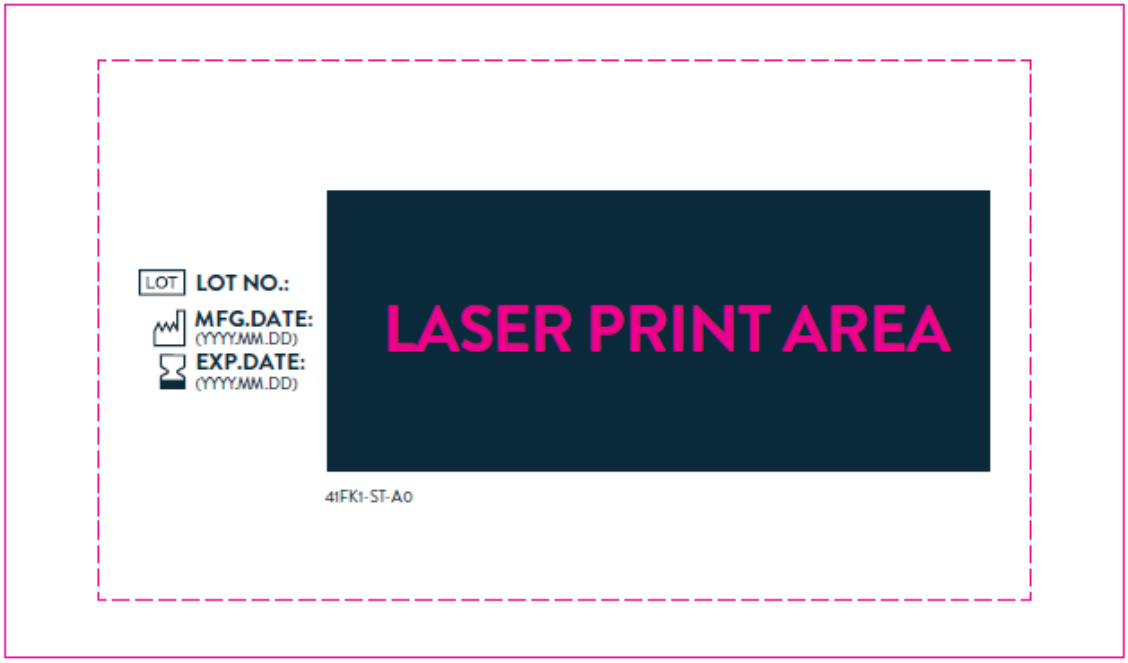
1.0 Product labels

Test device big pouch (front and back side)

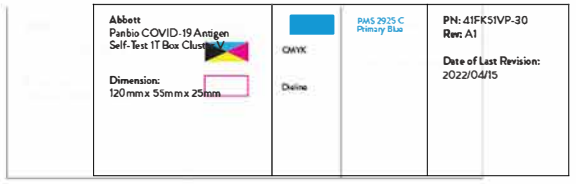


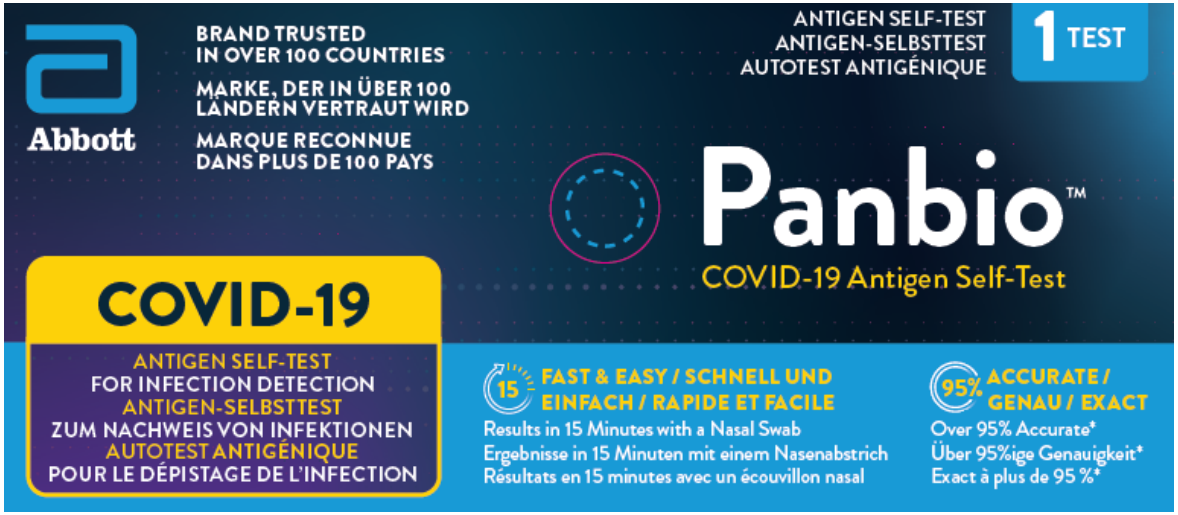


Test device small pouch labels (front and back side)



Overview Complete Kit Packaging for Panbio™ COVID-19 Antigen Self-Test Ref. 41FK51

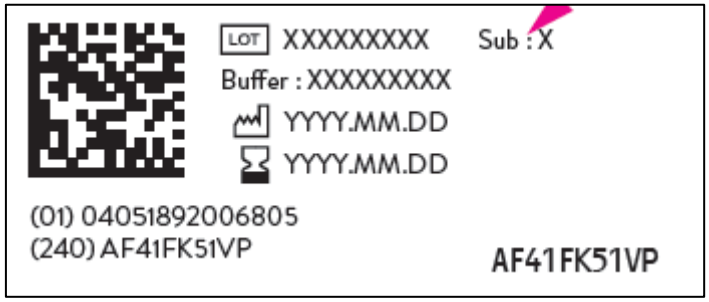




Kit Packaging for Panbio™ COVID-19 Antigen Self-Test Ref. 41FK51 incl. printed information.

Panbio™ COVID-19 Antigen Self-Test Ref. 41FK51 specific label information: Kit contents and test accuracy information (in EN, DE, and FR).

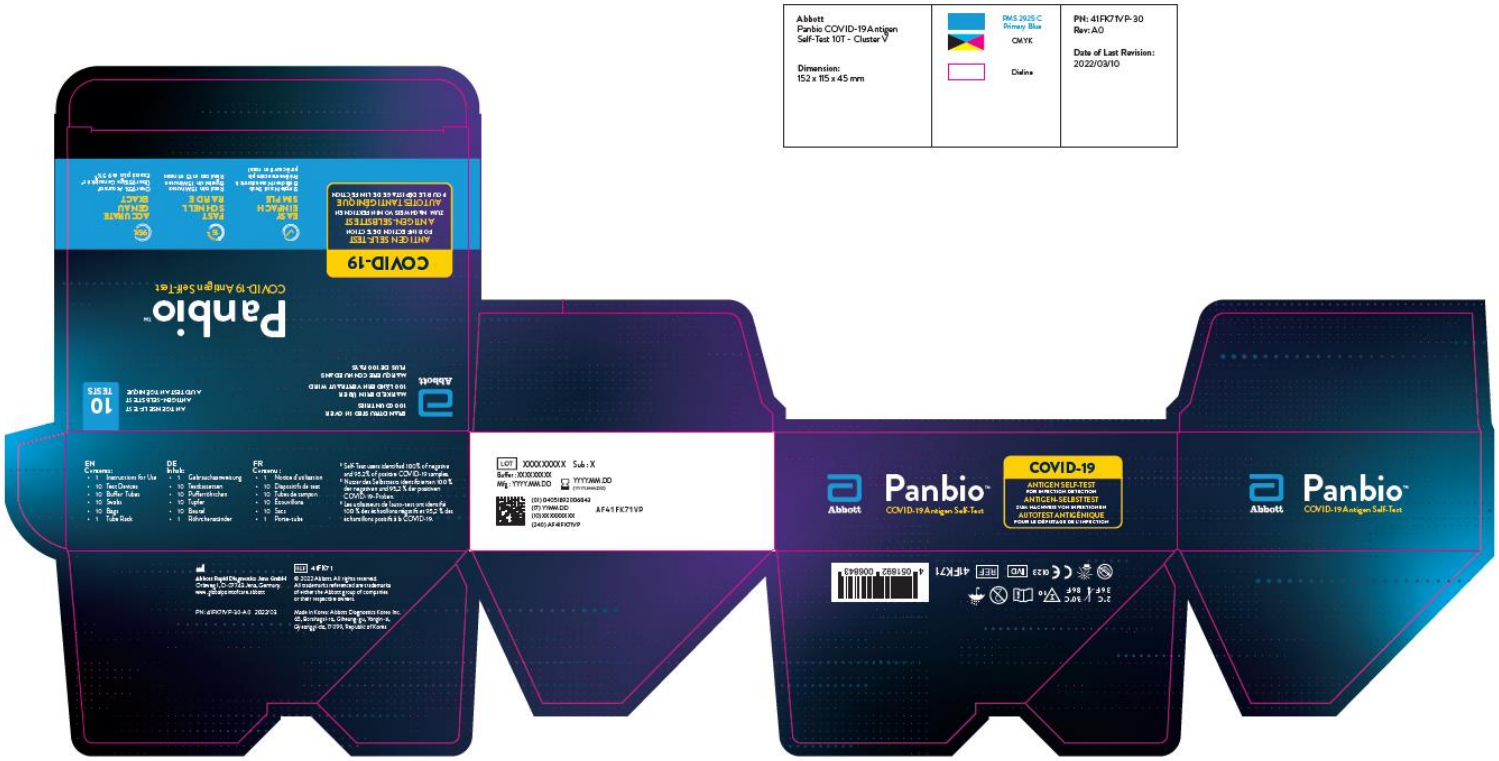
Panbio™ COVID-19 Antigen Self-Test Ref. 41FK51 specific label information



Panbio™ COVID-19 Antigen Self-Test Ref. 41FK51 specific label information (Lot number, expiry and manufacturing dates, UDI information).

Panbio™ COVID-19 Antigen Self-Test – Product name and intended use.

Panbio™ COVID-19 Antigen Self-Test Ref. 41FK51 barcode and specific label information

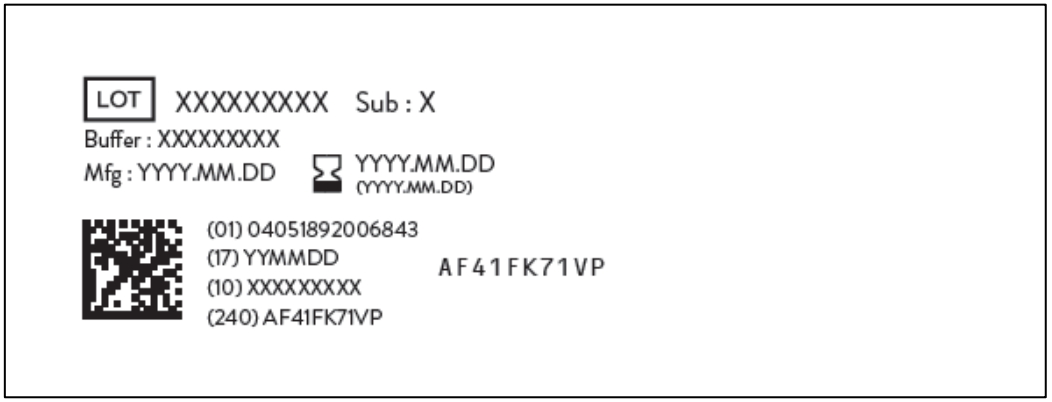


Overview: Complete Kit Packaging for Panbio™ COVID-19 Antigen Self-Test Ref. 41FK71 (English, German, French)

Kit Packaging for Panbio™ COVID-19 Antigen Self-Test Ref. 41FK71 incl. printed information.

Panbio™ COVID-19 Antigen Self-Test Ref. 41FK71 specific label information: Kit contents and test accuracy information (in EN, DE, and FR).

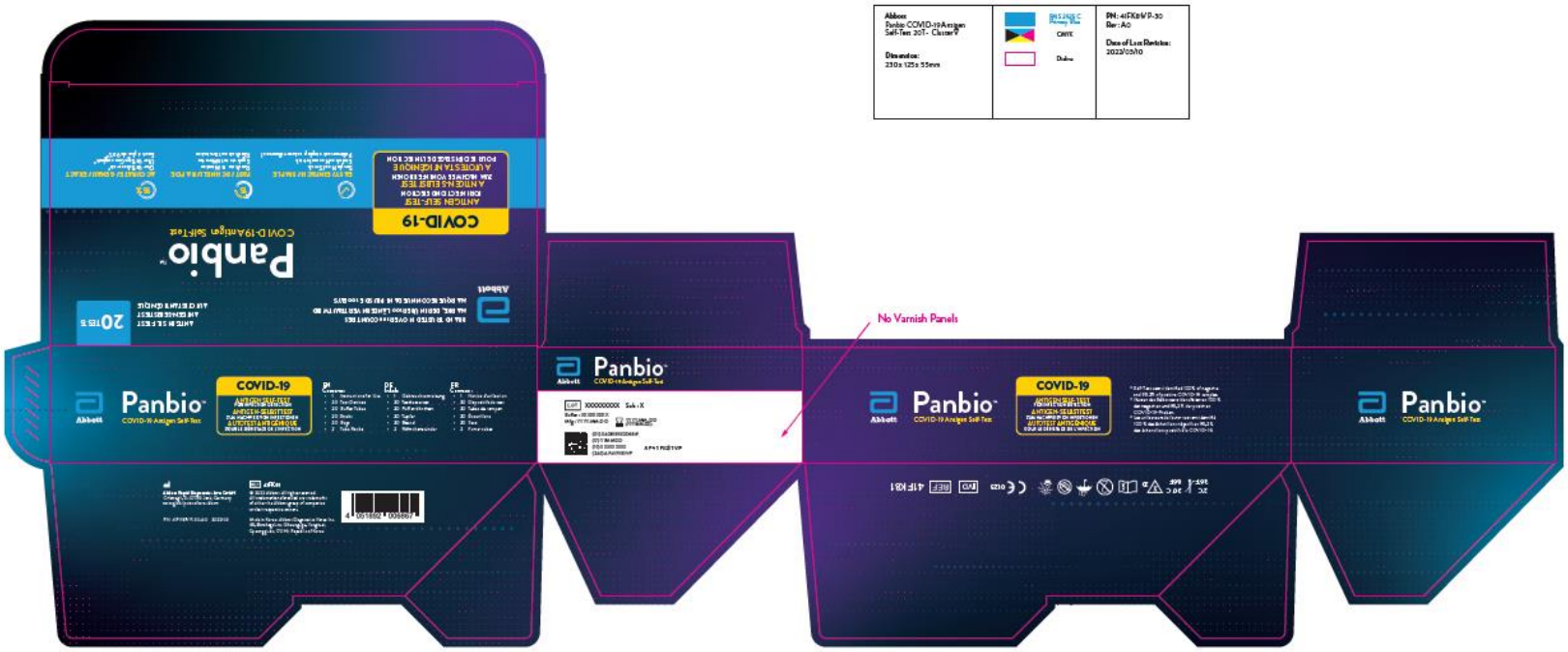
Panbio™ COVID-19 Antigen Self-Test Ref. 41FK71 specific label information



Panbio™ COVID-19 Antigen Self-Test Ref. 41FK71 specific label information (Lot number, Buffer code, expiry and manufacturing dates, UDI information).

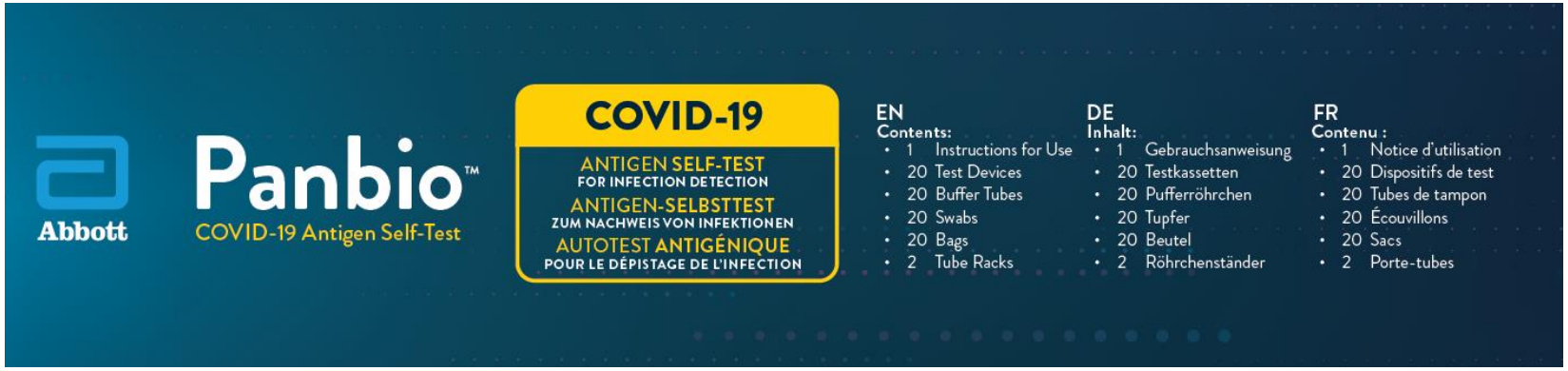
Panbio™ COVID-19 Antigen Self-Test – Product name and intended use.

Panbio™ COVID-19 Antigen Self-Test Ref. 41FK71 barcode and specific label information: Reference number, symbols (incl. storage conditions, warnings and precautions, IVD).



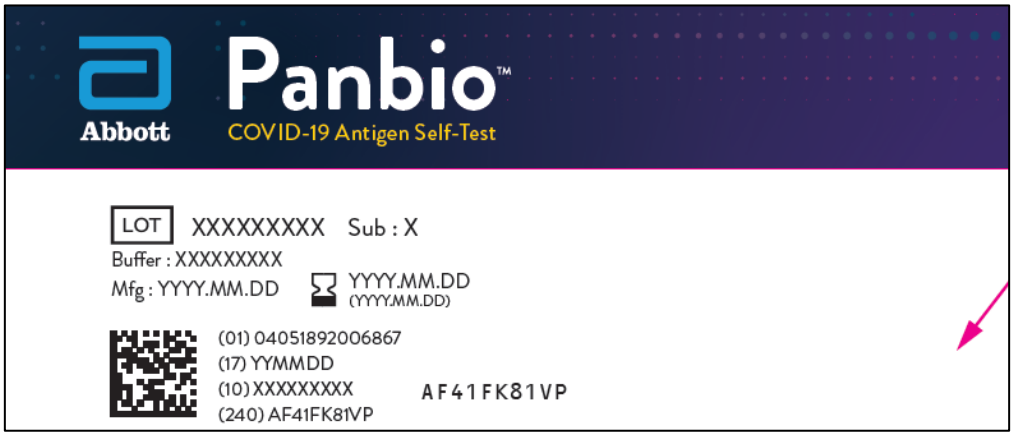
Overview: Complete Kit Packaging for Panbio™ COVID-19 Antigen Self-Test Ref. 41FK81 (English, German, French)

Kit Packaging for Panbio™ COVID-19 Antigen Self-Test Ref. 41FK81 incl. printed information.



Panbio™ COVID-19 Antigen Self-Test Ref. 41FK81 specific label information: Kit contents (in EN, DE, and FR).

Panbio™ COVID-19 Antigen Self-Test Ref. 41FK81 specific label information.



Panbio™ COVID-19 Antigen Self-Test Ref. 41FK81 specific label information (Lot number, Buffer code, expiry and manufacturing dates, UDI information).

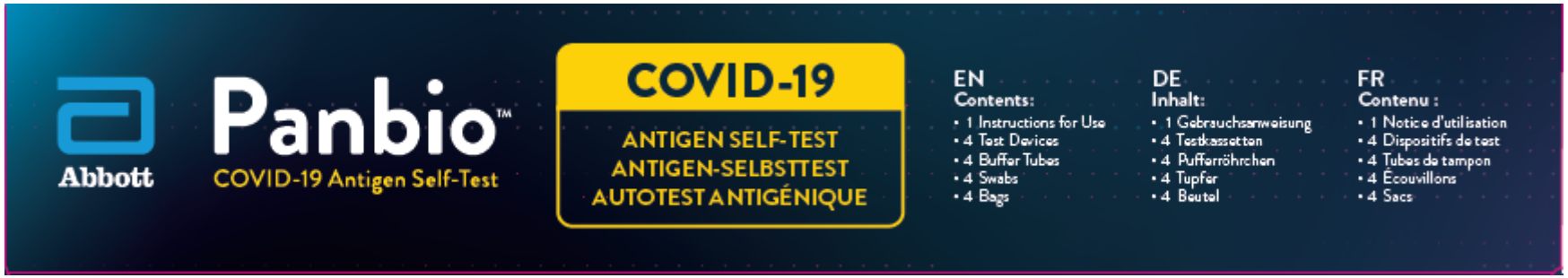
Panbio™ COVID-19 Antigen Self-Test – Product name and intended use

Panbio™ COVID-19 Antigen Self-Test Ref. 41FK81 specific label information: Reference number, symbols (incl. storage conditions, warnings and precautions, IVD).

Abbott Panbio COVID-19 Antigen Self-Test 4T Box Cluster V **Dimension:** 200mm x 61mm x 35mm	PMS 2925 C Primary Blue CMYK Dieline	**PN:** 41FK91VP-30 **Rev:** A.0 **Date of Last Revision:** 2022/02/21

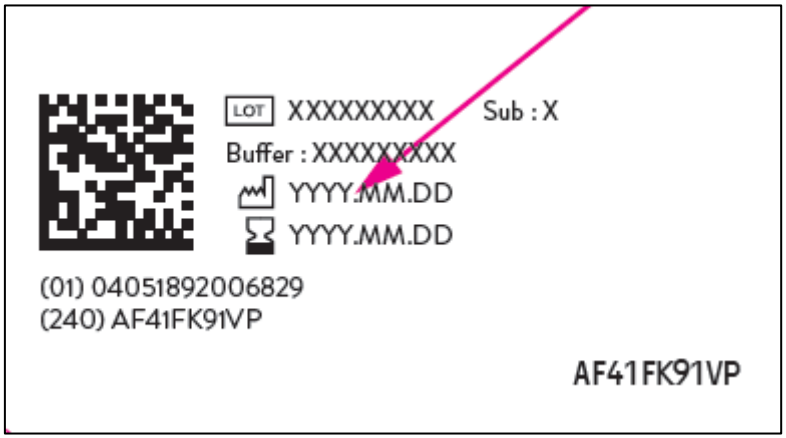
Overview: Complete Kit Packaging for Panbio™ COVID-19 Antigen Self-Test Ref. 41FK91 (English, German, French)

Kit Packaging for Panbio™ COVID-19 Antigen Self-Test Ref. 41FK91 incl. printed information



Panbio™ COVID-19 Antigen Self-Test Ref. 41FK91 specific label information: Kit contents (in EN, DE, and FR).

Panbio™ COVID-19 Antigen Self-Test Ref. 41FK91 specific label information



Panbio™ COVID-19 Antigen Self-Test Ref. 41FK91 specific label information (Lot number, Buffer code, expiry and manufacturing dates, UDI information)

Panbio™ COVID-19 Antigen Self-Test – Product name, intended use and information about test accuracy.

Panbio™ COVID-19 Antigen Self-Test Ref. 41FK91 specific label information: Reference number, symbols (incl. storage conditions, warnings and precautions, IVD)

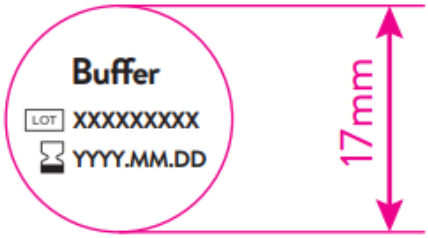
Accessory Labelling

Sterilized Swab

Sterilized nasal swab label from supplier Jiangsu Changfeng Medical.

Sterilized nasal swab label from supplier HLB Co. LTD Healthcare.

Buffer tube



Buffer tube label.

2.0 Instructions for use[2]

[2] English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

REF 41FK51/41FK71
41FK81/41FK91

EN

ENGLISH

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 or additional technical support contacts.

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 tube with buffer solution and a nasal swab.

To use the test, a human nasal specimen is collected using the swab provided in the kit. After sample collection, the nasal swab is transferred to the buffer 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 Buffer Tube, 1 Swab, 1 Bag
4 Tests	1 Instructions for Use, 4 Test Devices, 4 Buffer Tubes, 4 Swabs, 4 Bags
10 Tests	1 Instructions for Use, 10 Test Devices, 10 Buffer Tubes, 10 Swabs, 10 Bags, 1 Tube Rack
20 Tests	1 Instructions for Use, 20 Test Devices, 20 Buffer Tubes, 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, Buffer Tube, Test Device) in bag provided.
7. Use only the liquid from the Buffer Tube 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 Buffer Tube.
10. The provided Swab should be used only for nasal (mid-turbinate) specimen collection.
11. Each single Test Device, Swab, Buffer Tube 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 Tube 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.

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 possible cross-reactions 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 possible 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 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.

TECHNICAL SUPPORT

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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: 2022.04
41FK-CP-01-EN-A1

Nasal Swab Manufacturers

Jiangsu Changfeng Medical Industry Co., Ltd.
Touqiao Town, Guangling District Yangzhou 225109
Jiangsu, P.R. China
CE 0197 MD

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

HLB Co., LTD. Healthcare
10-5, Myeonghaksandanseoro, Yeondong-myeon,
Sejong-si, 30068, Korea
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

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

A. PREPARE FOR THE TEST

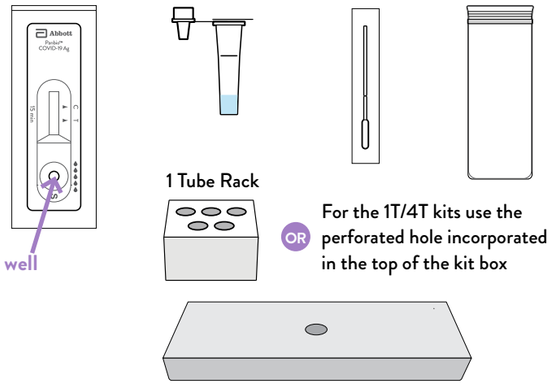
1. Check the expiration date on the box. Do not use if the kit is expired.

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

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

Do not open individual components until instructed.

1 Test Device | 1 Buffer Tube | 1 Swab | 1 Bag

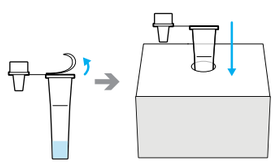


1 Tube Rack

OR For the 1T/4T kits use the perforated hole incorporated in the top of the kit box

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

3. Keep Buffer Tube upright and remove foil. Place the Buffer Tube in the tube rack before proceeding to the next step.



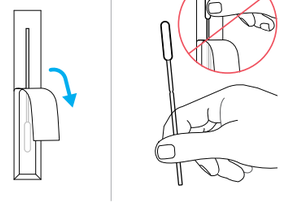
Note: Be careful not to spill the Tube contents.

B. COLLECT THE NASAL SAMPLE

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

4. Open Swab protective package at stick end.

Take Swab out.

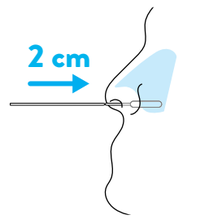


5. Swab both nostrils.

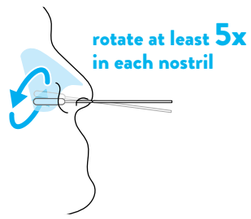
Insert the soft end of the Swab straight back into your nostril until resistance is felt (about 2 cm).

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

Remove Swab from nostril.



6. Using the same Swab, repeat step 5 in your other nostril.

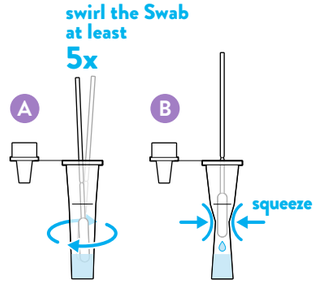


STOP **Check: Did you swab BOTH nostrils?**

7. Insert the Swab into the Buffer Tube.

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

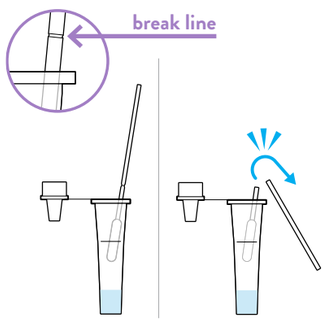
Squeeze the tube around the Swab tip to remove any remaining fluid.



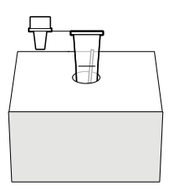
8. Hold the Buffer Tube firmly with one hand. Lift the Swab inside the Tube and locate the break line.

Snap the Swab handle at the break line.

Leave the Swab in the Tube and discard stick.

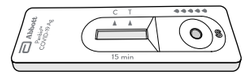


9. Return the Buffer Tube to the Tube Rack before proceeding to the next step.

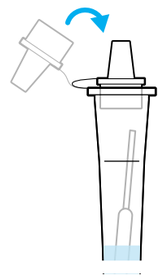


C. PERFORM THE TEST

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



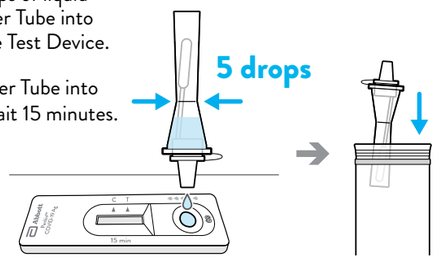
11. Press the nozzle cap tightly onto the Buffer Tube.



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

12. Squeeze 5 drops of liquid from the Buffer Tube into the well on the Test Device.

Place the Buffer Tube into the Bag and wait 15 minutes.



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

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

13. 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.

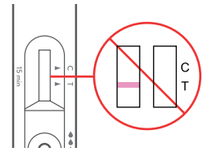
Note: After 20 minutes the result might become inaccurate.

D. READ TEST RESULT

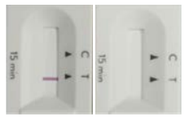
INVALID RESULT (test did not work)

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.



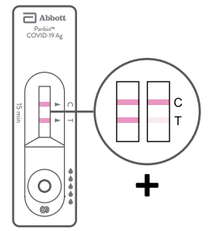
These are examples of invalid tests:



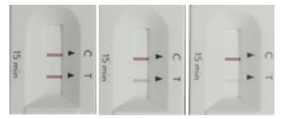
POSITIVE RESULT

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:



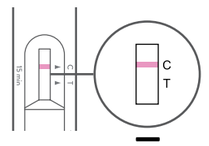
Look closely! The presence of any Test (T) line, no matter how faint is a positive result.

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.**

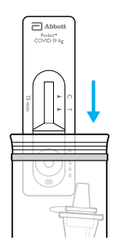


This is an example of a negative test:

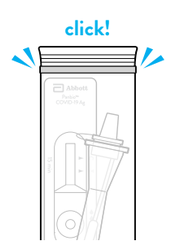
If symptoms continue, you should repeat the test after 1-2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-isolation and consult your doctor.

E. DISPOSE THE TEST KIT

14. Place the Test Device into the Bag.



15. Seal the Bag tightly.



16. Throw away the Bag in waste bin.