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:


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.

Intended use:

According to the claim of intended use from Abbott Rapid Diagnostics Jena GmbH, “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:

<table>
<thead>
<tr>
<th>Component</th>
<th>1 Test(T) (41FK51)</th>
<th>10 T (41FK71)</th>
<th>20 T (41FK81)</th>
<th>4 T (41FK91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions for use</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Test device</td>
<td>1</td>
<td>10</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>Buffer tube</td>
<td>1</td>
<td>10</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>Swab</td>
<td>1</td>
<td>10</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>Bag</td>
<td>1</td>
<td>10</td>
<td>20</td>
<td>4</td>
</tr>
<tr>
<td>Tube rack</td>
<td></td>
<td>1</td>
<td>2</td>
<td>\</td>
</tr>
</tbody>
</table>

Items required but not provided

Timing device

Storage

2-30°C.

Shelf-life upon manufacture

12 months (real-time stability studies are ongoing).

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

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).  

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)
1.0 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

No Varnish Panels
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 (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.
<table>
<thead>
<tr>
<th>EN</th>
<th>DE</th>
<th>FR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contents: 1 Instructions for Use, 10 Test Devices, 10 Buffer Tubes, 10 Swabs, 10 Bags, 1 Tube Rack</td>
<td>Inhalte: 1 Gebrauchsanweisung, 10 Testkassetten, 10 Pufferröhrchen, 10 Tupfer, 10 Beutel, 1 Rohrenständer</td>
<td>Contenu: 1 Notice d'utilisation, 10 Dispositifs de test, 10 Tubes de tampon, 10 Écouvillons, 10 Sacs, 1 Porte-tube</td>
</tr>
</tbody>
</table>

* Self-Test users identified 100% of negative and 95.2% of positive COVID-19 samples. * Nutzer des Selbsttests identifizierten 100% der negativen und 95.2% der positiven COVID-19-Proben. * Les utilisateurs de l'auto-test ont identifié 100% des échantillons négatifs et 95.2% des échantillons positifs à la COVID-19.

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 (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).
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).

EN Contents:
- 1 Instructions for Use
- 4 Test Devices
- 4 Buffer Tubes
- 4 Swabs
- 4 Bags

DE Inhalts:
- 1 Gebrauchsanweisung
- 4 Testgeräte
- 4 Testtuben
- 4 Stäbchen
- 4 Test

FR Contenu:
- 1 Notice d'utilisation
- 4 Dispositifs de test
- 4 Tubes tampons
- 4 Équilibres
- 4 Sacs
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)
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 use²

² English version of the IFU was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
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 nucleic acid test (NAT)-positive 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 at the diagnosis of an active SARS-CoV-2 infection. Children under 14 years should be supported by an adult.

### INTENDED USE

The Panbio™ COVID-19 Antigen Self-Test is a rapid immunoassay that uses a human nasal swab specimen for the qualitative detection of SARS-CoV-2 antigen (Ag). It is intended for use by a lay individual to self-administer and self-test in a private setting.

### TEST PRINCIPLE

The Panbio™ COVID-19 Antigen Self-Test is a lateral flow test that detects the nucleic acid antigen of the Coronavirus SARS-CoV-2-19 virus from a mid-turbinate nasal sample. The test includes test device, control device, buffer tube, and swab.

### TECHNICAL SUPPORT

**Abbott Global Point of Care**

**Europe Middle East**
+44 61 483 9032
EMEHealthSupport@abbott.com

**Asia Pacific**
41 61 483 9030
TechService DA@abbott.com

**Canada**
+60 818 8335
Ccaproductsupport@abbott.com

**Africa**
+27 10 500 9700
arcticsupport@abbott.com

**Glossary of Symbols**

- **Do not reuse**
- **Batch code**
- **Consult instructions for use**
- **Use by date**
- **Manufacturer**
- **Contains sufficient for one test**
- **Cautions**
- **Do not use if package is damaged**
- **Medical device**

**Abbott Royal Diagnosis Jews GmbH**

Charing 1, D-76380 Kusel, Germany
www.globalpointofcare.abbott

**Neustar Medicals**

Anshing Changfing Medical Industry Co., Ltd.

Tong Xin Road, West Section Tong Xin Road 202050
*** Hubei, China

**Línea Service & Consulting GmbH**

Calle Sierpes 342, 4842 Harburg, Germany

**INTENDED USE**

- **1 Instructions for Use, 1 Test Device, 1 Buffer Tube, 5 Swabs, 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
  - **8.1.1**

### STORED AND STABLE

- Store the test kit in cool, dry place (2-30°C). Do not freeze the kit or its components.
- Do not use the test kit beyond the expiration date as indicated on the outer package.
- Perform the test immediately after removing the Test Device from the protective packaging.
- 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 cut or stroke while handling specimen.
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., Swabs, Buffer Tubes, Test Device) in fog-proof providers.
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. For testing, only use the test kit in the area where the test device and the swab are located.
10. Do not substitute the swab buffer or other liquid before inserting the swab into the nose.
11. The provided Buffer Tube contains 0.15 mL sodium as a preservative which may be toxic if ingested. If you get buffer solution into your eye, rinse for at least 15 minutes under running water. If vision irritation, go to a doctor.
12. If you have stored the kit in the refrigerator, store the kit at room temperature (55-90°F) for 30 minutes before use.
13. Do not use the test kit if the pouch is damaged or the seal is broken.
14. Swab test device should be immediately collected after detection.

### TEST LIMITATIONS

1. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigen (Ag) from nasal swab. Other specimen types may lead to incorrect results and must not be used.
2. Antigen infections that are caused by microorganisms other than SARS-CoV-2 are not detected by this test.
3. 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 confirmed diagnostic should only be made by a health care professional after clinical and laboratory findings have been evaluated.
5. 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 coronovirus 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.
6. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.

### TECHNICAL SUPPORT

**Country**

**Phone**

**Australian Technical Support**
+61 7 3363 7711
TechSupport DA@abbott.com

**Canada**

+60 818 8335
Ccaproductsupport@abbott.com

**Africa**

+27 10 500 9700
arcticsupport@abbott.com

### WHAT DOES THIS TEST DO?

**The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigen (Ag) from nasal swab. Other specimen types may lead to incorrect results and must not be used.**

### 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.
- False positive test results may occur if symptoms continue, you should repeat the test after 1-2 days, as the coronovirus 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 healthcare persons, to correctly identify 99.6% (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 98.2% (802 out of 804) SARS-CoV-2 positive nasal samples with a confidence interval of 99.2% to 99.9% (known as test sensitivity).

In a clinical evaluation of 483 asymptomatic patients the Panbio™ COVID-19 Antigen Self-Test showed a sensitivity of 99.3% (confidence interval: 97.9% to 99.7%) of SARS-CoV-2 positive samples at lower Ct (cycle threshold) values of ≤30 which corresponds to higher virus concentration (≥25,000 genome copies per mL) within the test system. The specificity of the test was 99.9% (confidence interval: 99.7% to 100.0%);

### WHAT DOES IT MEAN IF I HAVE A POSITIVE RESULT?

• You can help limit the spread of COVID-19 by knowing your infection status and taking appropriate social distancing measures.
• The test may be negative before you develop symptoms.
• The test was not performed per the instructions.
• Specimen collection, extraction or transport was not performed correctly.

### WHAT DOES IT MEAN IF I HAVE A NEGATIVE RESULT?

A negative test result makes it unlikely that you have COVID-19 at the time of testing. The test does not detect any viruses in your nasal swab sample, but it is possible that your test gave a false negative result.

### 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 healthcare persons, to correctly identify 99.6% (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 98.2% (802 out of 804) SARS-CoV-2 positive nasal samples with a confidence interval of 99.2% to 99.9% (known as test sensitivity).
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

Note: Be careful not to spill the Tube contents.

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
1. 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.

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

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

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.

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

These are examples of positive tests:

Note: After 20 minutes the result might become inaccurate.

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

Invalid Result (test did not work)
Find the 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:

Note: 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:

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.
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.

NEGATIVE RESULT
Find result window and look for a single line in window.
Negative Result: If you only see 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.

17: PLACE COMPONENTS INTO BAG

18: SEAL BAG

19: DISPOSE