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

Product: Panbio COVID-19 Ag Rapid Test Device (NASAL)

Manufacturer: Abbott Rapid Diagnostics Jena GmbH

EUL Number: EUL-0587-032-00

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 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: desk-top 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 Ag Rapid Test Device (NASAL), product codes 41FK11 and 41FK21, CE marked regulatory version, manufactured by Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, 07743 Jena, Germany, was listed on 19 November 2020[1].

Report amendments and/or product changes

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

Version	Summary of amendment	Date of report amendment
2.0	Addition of a new kit with reference number 41FK21 that contains test devices with a 2D barcode printed on the test device, which encodes traceability information for the product, and changes to the labelling.	20-Jan-2021
3.0	1. Validation and implementation of additional nasal swabs from a different supplier to Panbio COVID-19 Ag Rapid Test Device (Nasal).	04-May-2021

[1] EUL renewal assessment is ongoing.

	2. Amendments to the IFUs to include data from a study on asymptomatic individuals. 3. Amendments to the nasal product IFU to add the results of a study of supervised self-collection of nasal swab specimens[2].	
4.0	Extension of shelf life to 24 months based on accelerated stability data. Real time studies are ongoing.	9-Nov-2021

Intended use:

According to the claim of intended use from Abbott Rapid Diagnostics Jena GmbH, "*Panbio COVID-19 Ag Rapid Test Device is an in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation. The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.*"

Specimen type that was validated:

Nasal swab specimens.

[2] The WHO EUL assessment was abridged based on reliance on the product authorization under the USFDA Emergency Use Authorization. WHO does not recommend the use of health care provider instructed/observed self-collected nasal, nasopharyngeal or oropharyngeal swab specimens. Please refer to the WHO guidance on Diagnostic testing for SARS-CoV-2 at the following link.

https://apps.who.int/iris/discover?query=Diagnostic+testing+for+SARS-CoV-2%3A+Interim+guidance

Test kit contents:

Component	25 tests (product code 41FK11)	25 tests (product code 41FK21)
Test device (individually in a foil pouch with desiccant)	25	25 with a 2D barcode printed on the test device.
Buffer	1 x 9ml bottle	1 x 9ml bottle
Extraction tubes	25	25
Extraction tube caps	25	25
Positive control swab	1	1
Negative control swab	1	1
Sterilized nasal swabs for sample collection	25	25
Tube rack	1	1
Quick reference guide	1	1
Instructions for use	1	1

Items required but not provided

- Personal Protective Equipment per local recommendations (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves)
- Timer
- Biohazard container

Storage:

2-30°C.

Shelf-life upon manufacture:

24 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 change notification for their EUL listed product, Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal) to introduce nasal swab specimen as an additional claimed specimen type. The new configuration was adapted from the corresponding accepted EUL product (Panbio COVID-19 Ag Rapid Test Device

(Nasopharyngeal)) for which a WHO EUL assessment had already been conducted and accepted. Additional data was generated to meet particular requirements for EUL as set out in the "*Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid and rapid diagnostics tests detecting SARS-CoV-2 antigens (PQDx_0347)"*. The information (data and documentation) submitted in the change notification was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

Post listing Commitments for EUL:

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

1. Provide additional microbial interference study report by 31 December 2020. Submitted evidence is under review.
2. Provide accelerated stability data by 31 January 2021, 31 March 2021, and 31 July 2021. This commitment was fulfilled, issue closed.
3. Provide interim and final real time stability reports as agreed (31 October,2021, 31 January, 30 April, 31 July, and 31 October 2022) and in use stability study final report by 31 October 2022.
4. Provide additional clinical study information by 31 March 2021. This commitment was fulfilled, issue closed.

Risk benefit assessment conclusion: acceptable.

Quality Management Systems Review

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

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

Quality management documentation assessment conclusion: 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. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensure that post-emergency use listing safety, quality and performance monitoring activities are in place which 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).[3]

Scope and duration of procurement eligibility

Panbio COVID-19 Ag Rapid Test Device (NASAL), product codes 41FK11 and 41FK21, manufactured by Abbott Rapid Diagnostics Jena GmbH is considered to be eligible for WHO procurement for 12 months from the day of listing[4]. The assay may be used for the detection of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigens. 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 on-going 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, performance during post-market surveillance activities, and if new data becomes available to WHO that changes the risk benefit balance.

[3] 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.
[4] EUL renewal assessment is ongoing.

Labelling

1.0 Labels

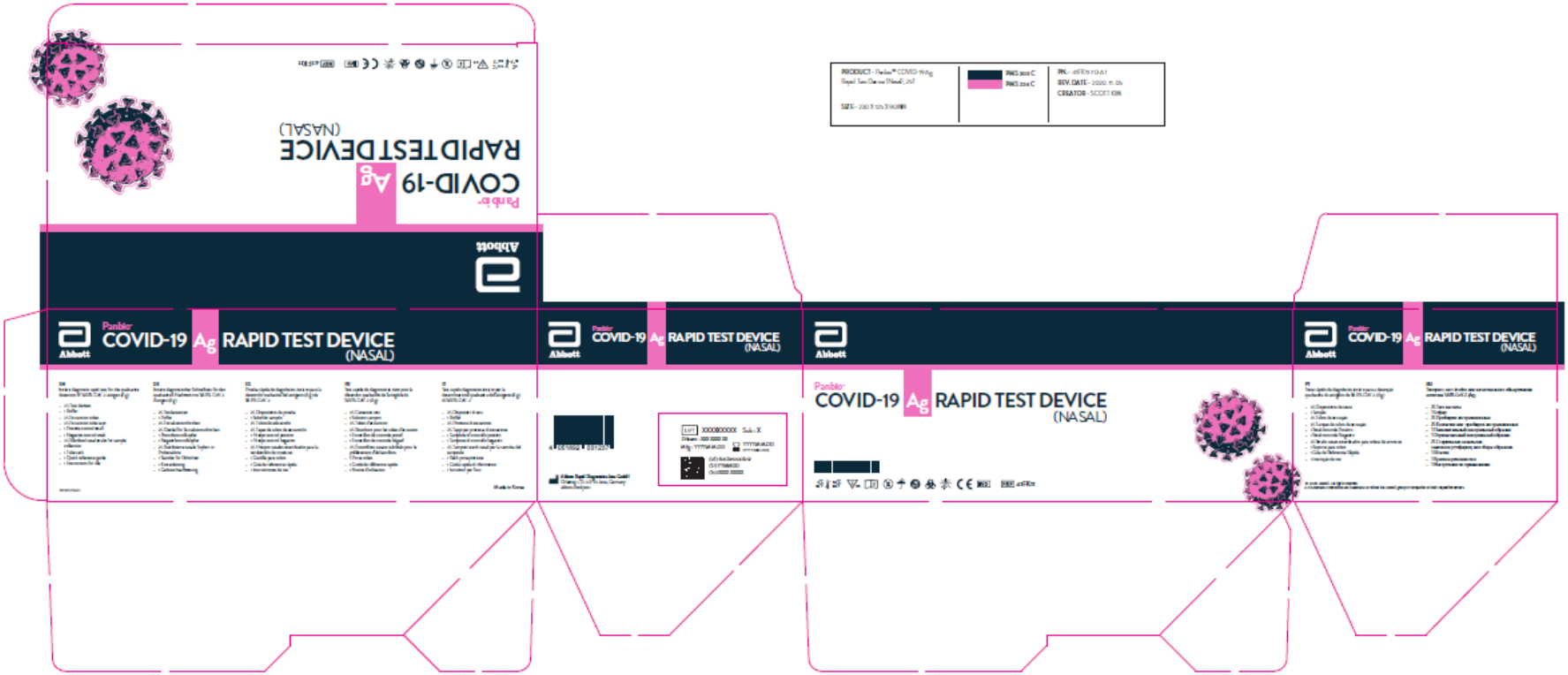
2.0 Instructions for Use (IFU)

3.0 Quick reference guide

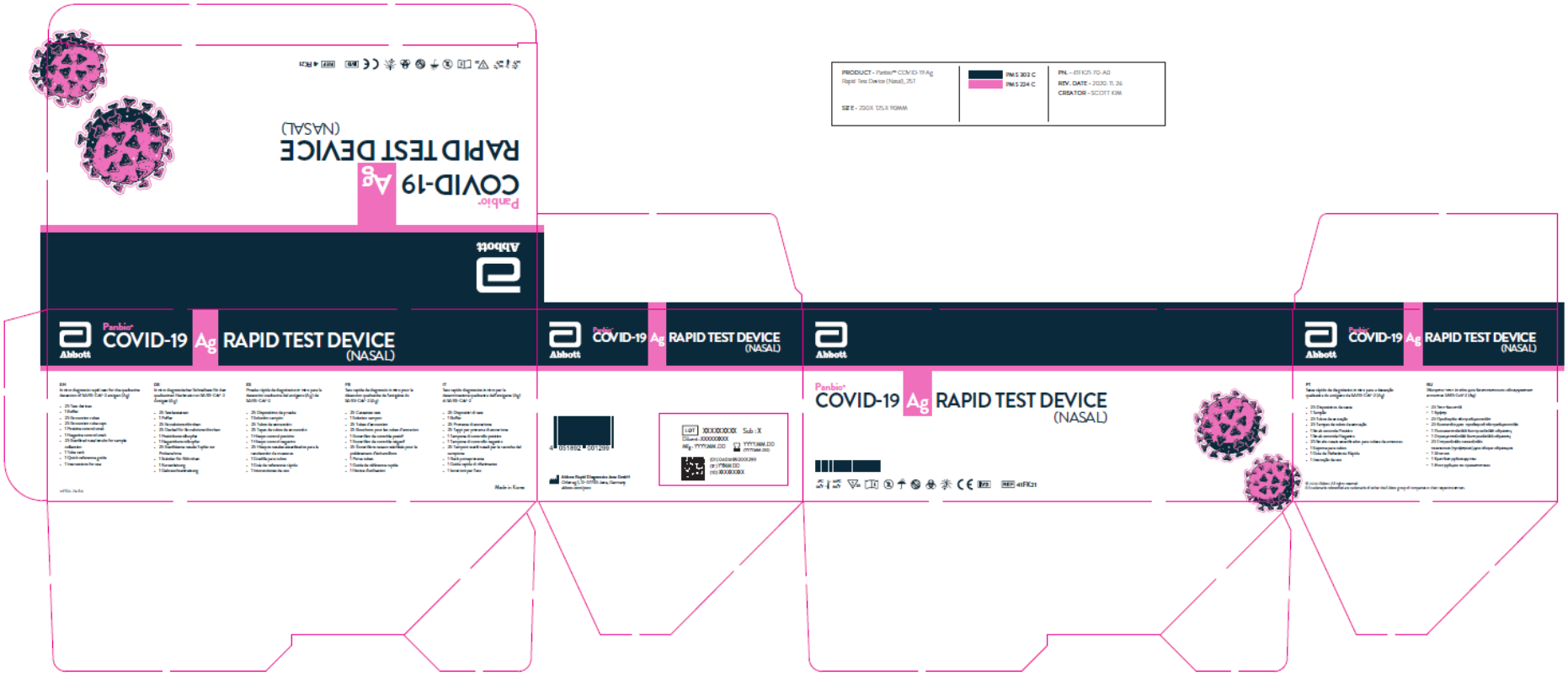
1.0 Product labels

1.1 Outside box label

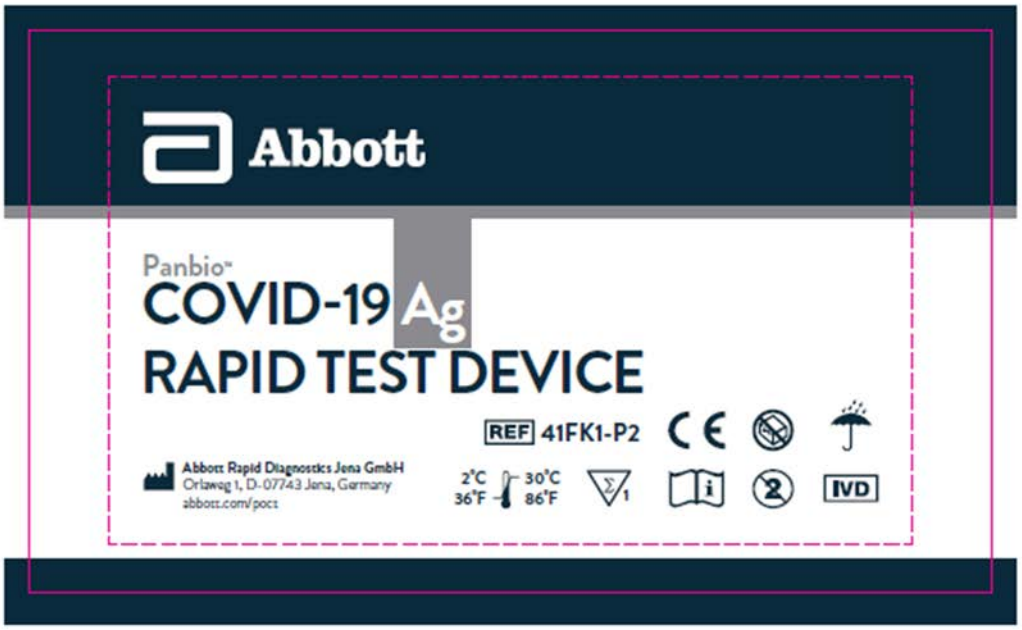
1.1.1 Product code 41FK11



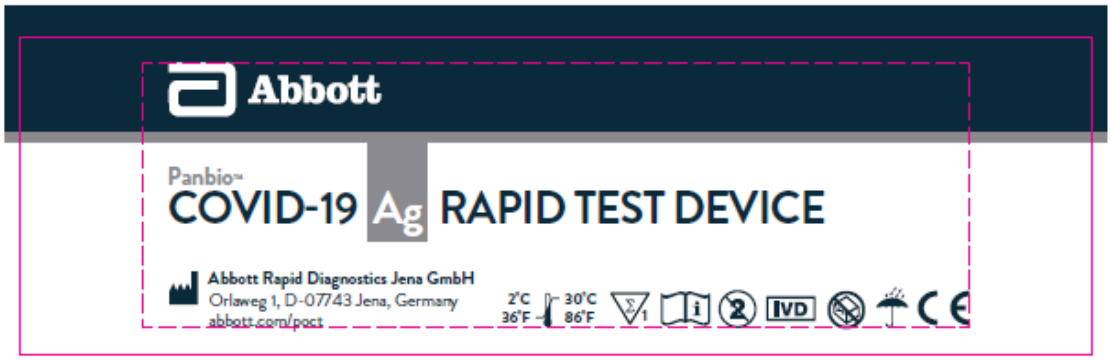
1.1.2 Product code 41FK21



1.2 Test device labels (front and back side) Big Pouch

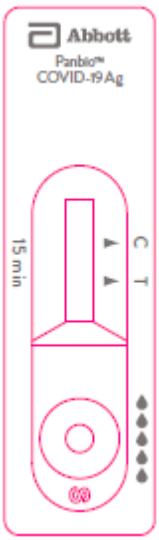


1.3 Test device labels (front and back side) Small Pouch

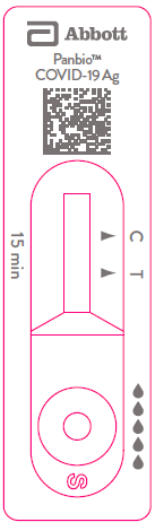


1.4. Testing device printing

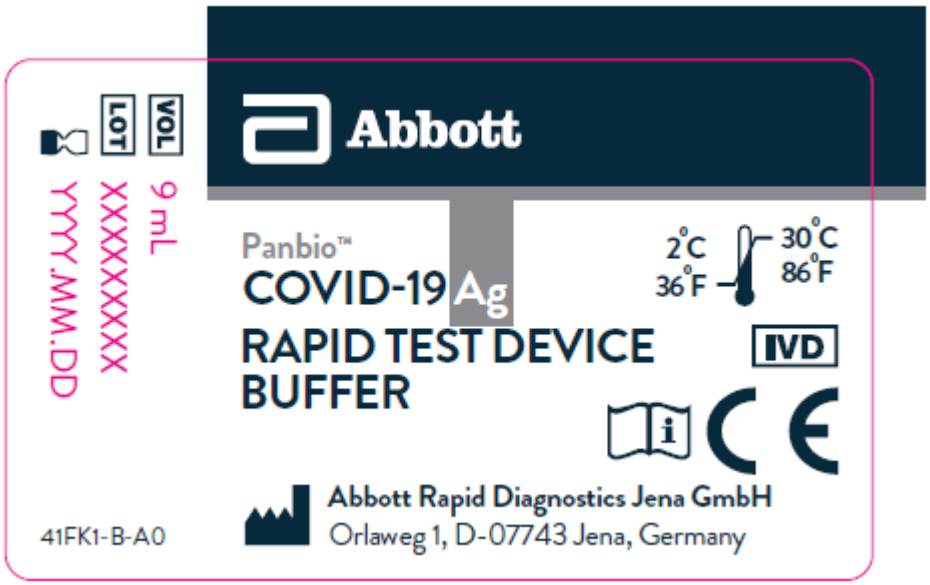
1.4.1 Product code 41FK11



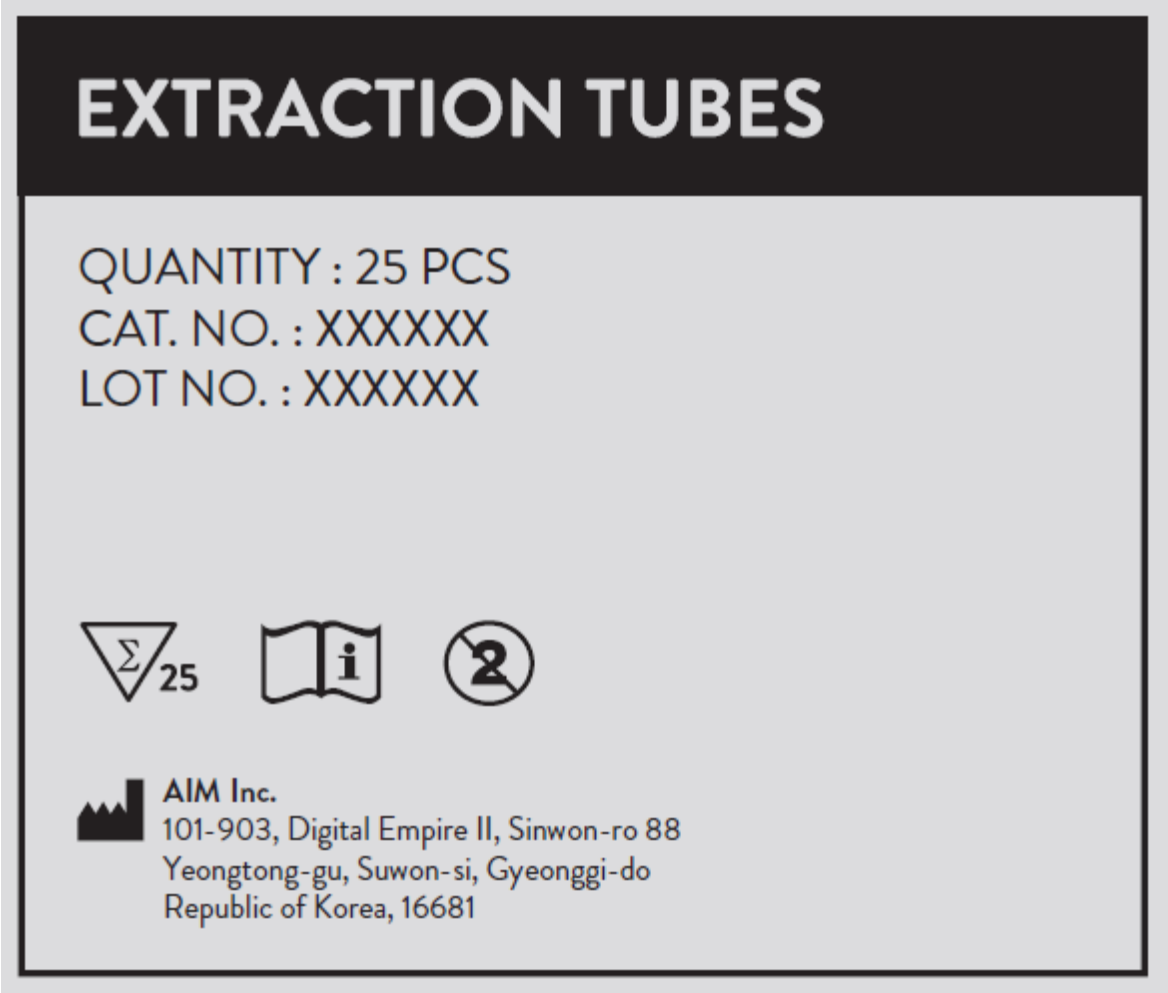
1.4.2 Product code 41FK21



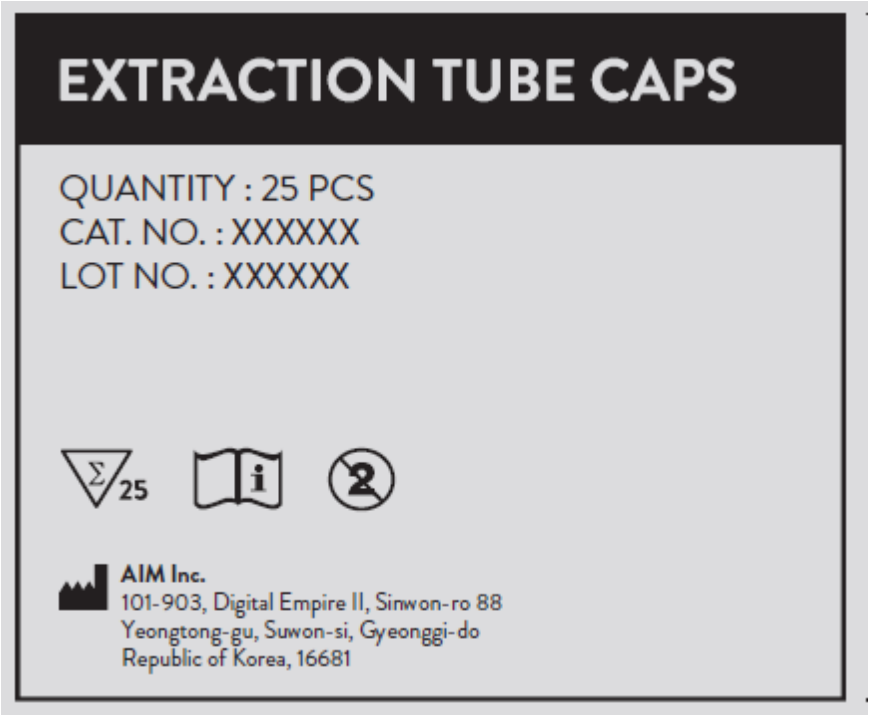
1.5 Buffer


LOT
VOL
9 mL
YYYY.MM.DD
XXXXXXXX
Abbott
Panbio™
COVID-19 Ag
RAPID TEST DEVICE
BUFFER
2°C
36°F
30°C
86°F
IVD
Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1, D-07743 Jena, Germany
41FK1-B-A0

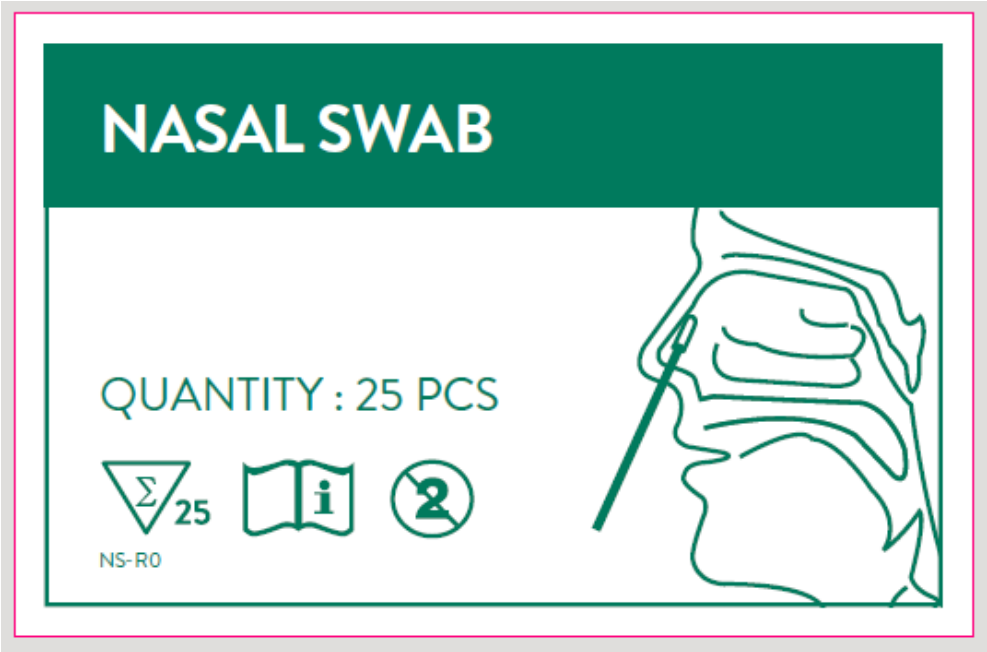
1.6 Extraction tubes (bag label)

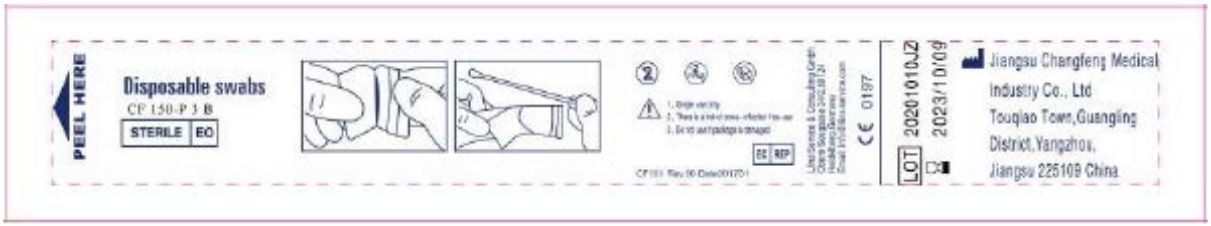


1.7 Extraction tube caps (bag label)



1.8 Sterilized swabs





1.9 Control swabs

1.9.1 Negative control

1.9.2 Positive control

2.0 Instructions for use[5]

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

Abbott

REF 41FK11/41FK21

CE

Panbio™

COVID-19 Ag Rapid Test Device

(NASAL)

***In vitro* diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen (Ag)**

About the Test

EN

Introduction

The Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[1]. The SARS-CoV-2 is a β-coronavirus, which is an enveloped non-segmented positive-sense RNA virus[2]. It is spread by human-to-human transmission via droplets or direct contact, and infection has been estimated to have a mean incubation period of 6.4 days and a basic reproduction number of 2.24-3.58. Among patients with pneumonia caused by SARS-CoV-2, fever was the most common symptom, followed by cough[3]. The main IVD assays used for COVID-19 employ real-time reverse transcriptase-polymerase chain reaction (RT-PCR) that takes a few hours[4]. The availability of a cost-effective, rapid point-of-care diagnostic test is critical to enable healthcare professionals to aid in the diagnosis of patients and prevent further spread of the virus[5]. Antigen tests will play a critical role in the fight against COVID-19[6].

Test Principle

Panbio™ COVID-19 Ag Rapid Test Device contains a membrane strip, which is pre-coated with immobilized anti-SARS-CoV-2 antibody on the test line and mouse monoclonal anti-chicken IgY on the control line. Two types of conjugates (human IgG specific to SARS-CoV-2 Ag gold conjugate (binds to the nucleocapsid protein) and chicken IgY gold conjugate) move upward on the membrane chromatographically and react with anti-SARS-CoV-2 antibody and pre-coated mouse monoclonal anti-chicken IgY respectively. For a positive result, human IgG specific to SARS-CoV-2 Ag gold conjugate and anti-SARS-CoV-2 antibody will form a test line in the result window. Neither the test line nor the control line are visible in the result window prior to applying the patient specimen. A visible control line is required to indicate a test result is valid.

Intended Use

Panbio™ COVID-19 Ag Rapid Test Device is an *in vitro* diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation. The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.

Kit Variants

- **41FK11** No 2D barcode printed on the contained test devices
- **41FK21** Contains test devices with a 2D barcode printed on the test device, which encodes traceability information for the product

Materials Provided

- 25 Test devices with desiccant in individual foil pouch
- Buffer (1 x 9 ml/bottle)
- 25 Extraction tubes
- 25 Extraction tube caps
- 1 Positive control swab
- 1 Negative control swab
- 25 Sterilized nasal swabs for sample collection
- 1 Tube rack
- 1 Quick Reference Guide (Nasal)
- 1 Instructions for use

Materials Required but not Provided

- Personal Protective Equipment per local recommendations (i.e. gown/ lab coat, face mask, face shield/eye goggles and gloves), Timer, Biohazard container

Active Ingredients of Main Components

- **1 Test device** Gold conjugate: Human IgG specific to SARS-CoV-2 Ag gold colloid and Chicken IgY - gold colloid, Test line: Mouse monoclonal anti-SARS-CoV-2, Control line: Mouse monoclonal anti-Chicken IgY
- **Buffer** Tricine, Sodium Chloride, Tween 20, Sodium Azide (<0.1%), Proclin 300

Storage and Stability

1. The test kit should be stored at a temperature between 2-30 °C. Do not freeze the kit or its components.
   Note: When stored in a refrigerator, all kit components must be brought to room temperature (15-30 °C) for a minimum of 30 minutes prior to performing the test. Do not open the pouch while components come to room temperature.
2. The Buffer bottle may be opened and resealed for each assay. The Buffer cap should be firmly sealed between each use. The Buffer is stable until expiration date if kept at 2-30 °C.
3. Perform the test immediately after removing the test device from the foil pouch.
4. Do not use the test kit beyond its expiration date.

5. The shelf life of the kit is as indicated on the outer package.
6. Do not use the test kit if the pouch is damaged or the seal is broken.
7. Direct swab specimens should be tested immediately after collection. If immediate testing is not possible, the swab specimen can be kept in an extraction tube filled with extraction buffer (300 µl) at room temperature (15-30 °C) for up to two hours prior to testing.

Warnings

1. For *in vitro* diagnostic use only. Do not reuse the test device and kit components.
2. These instructions must be strictly followed by a trained healthcare professional to achieve accurate results. All users have to read the instruction prior to performing a test.
3. Do not eat or smoke while handling specimens.
4. Wear protective gloves while handling specimens and wash hands thoroughly afterwards.
5. Avoid splashing or aerosol formation of specimen and buffer.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials (i.e. swab, extraction tube, test device) in a biohazard container as if they were infectious waste and dispose according to applicable local regulations.
8. Do not mix or interchange different specimens.
9. Do not mix reagent of different lots or those for other products.
10. Do not store the test kit in direct sunlight.
11. To avoid contamination, do not touch the head of provided swab when opening the swab pouch.
12. The sterilized swabs should be used only for nasal specimen collection.
13. To avoid cross-contamination, do not reuse the sterilized swabs for specimen collection.
14. Do not dilute the collected swab with any solution except for the provided extraction buffer.
15. The buffer contains <0.1% sodium azide as a preservative which may be toxic if ingested. When disposed of through a sink, flush with a large volume of water.[7]
16. Do not use the positive or negative control swab for specimen collection.

Test Procedure (Refer to Figure)

Nasal swab Specimens

Note: Healthcare professionals should comply with personal safety guidelines including the use of personal protective equipment.

Test Preparation

1. Allow all kit components to reach a temperature between 15-30 °C prior to testing for 30 minutes.
2. Remove the test device from the foil pouch prior to use. Place on a flat, horizontal and clean surface.
3. Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300 µl).
   ⚠ **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.
4. Place the extraction tube in the tube rack.

Nasal Mid-Turbinate (NMT) Specimen Collection & Extraction

Specimens are collected by the professional user as described below. Alternatively, nasal specimen collection steps 1-3 can be completed by the patient according to oral instructions and under supervision of the professional user. For supervised patient self-collection, the swab is handed to the patient by the professional user and after sampling, the patient hands the swab back to the professional user to complete the remaining steps of the procedure.

1. Tilt the patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at the turbinates).
   ⚠ **Caution:** Ensure that the patient's head is kept still during nasal specimen collection, as sudden movements may cause swab stick breakage.
2. Rotate the swab five times against the nasal wall then slowly remove from the nostril.
3. Using the same swab repeat the collection procedure with the second nostril.
   Note: Ensure a minimum waiting period of 24 hours before performing a new nasal sampling from both nostrils (e.g. for a repeat test).
   ⚠ **Caution:** If the nasal swab stick breaks prior to obtaining a nasal specimen, repeat specimen collection with a new swab. If the nasal swab breaks during sampling, consultation with a medical healthcare professional is recommended to determine and initiate necessary treatment and monitoring.
4. Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.
5. Break the swab at the breakpoint and close the cap of extraction tube.

Reaction with Test Device

1. Open the dropping nozzle cap at the bottom of the extraction tube.
2. Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.
   ⚠ **Caution:** Bubbles that occur in the extraction tube can lead to inaccurate

results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.

3. Close the nozzle and dispose of the extraction tube containing the used swab according to your local regulations and biohazard waste disposal protocol.
4. Start timer. Read result at 15 minutes. Do not read results after 20 minutes.
5. Dispose of the used device according to your local regulations and biohazard waste disposal protocol.

Positive / Negative Control Swab

⚠ **Caution:** Control use only. Do not use the positive or negative control swab for specimen collection.

Note: Please refer to the External Quality Control section of this Instructions for use for the frequency of testing external quality control swabs.

1. Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300 µl).
   ⚠ **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.
2. Place the extraction tube in the tube rack.
3. Insert the positive or negative control swab in the buffer fluid inside of the extraction tube and soak the swab for 1 minute. Swirl the control swab tip in the buffer fluid inside of the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.
4. Dispose of the used control swab in accordance with your biohazard waste disposal protocol.
5. Close the cap of the extraction tube.
6. Follow the above test procedure [Reaction with Test Device].

Test Interpretation (Refer to Figure)

1. **Negative result:** The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.
2. **Positive result:** The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a positive result.
   ⚠ **Caution:** The presence of any test line (T), no matter how faint, indicates a positive result.
3. **Invalid result:** If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.

Test Limitations

1. The contents of this kit are to be used for the professional and qualitative detection of SARS-CoV-2 antigen from nasal swab. Other specimen types may lead to incorrect results and must not be used.
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 negative test result may occur if the specimen was collected, extracted or transported improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by viral culture or a molecular assay.
4. Positive test results do not rule out co-infections with other pathogens.
5. Test results must be evaluated in conjunction with other clinical data available to the physician.
6. Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.
7. Panbio™ COVID-19 Ag Rapid Test Device 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]
8. Positive results may occur in cases of infection with SARS-CoV.

Quality Control

1. **Internal Quality Control:**
   The test device has a test line (T) and a control line (C) on the surface of the test device. Neither the test line nor the control line are visible in the result window before applying a specimen. The control line is used for procedural control and should always appear if the test procedure is performed properly and the test reagents of the control line are working.
2. **External Quality Control:**
   The controls are specifically formulated and manufactured to ensure performance of the Panbio™ COVID-19 Ag Rapid Test Device and are used to verify the user's ability to properly perform the test and interpret the results. The Positive Control contains recombinant SARS-CoV-2 nucleocapsid protein, which is not contagious. The Positive Control will produce a positive test result and has been manufactured to produce a visible test line (T). The Negative Control will produce a negative test result. Control swabs are not specific for a particular Panbio™ COVID-19 Ag Rapid Test Device lot and may be used between test device lots until the swabs' expiry dates.
   Good laboratory practice suggests the use of positive and negative controls to ensure that:

- Test reagents are working, and
- The test is correctly performed.

The external controls can be run under any of the following circumstances:

- By a new operator prior to performing testing on patient specimens,
- When receiving a new test shipment,
- At periodic intervals as dictated by local requirements, and/or by the user's Quality Control procedures.

Performance Characteristics

1. **External evaluation of Panbio™ COVID-19 Ag Rapid Test Device (Symptomatic)**
   Clinical performance of Panbio™ COVID-19 Ag Rapid Test Device was determined by testing 104 positive nasal swab specimens and 404 negative specimens for SARS-CoV-2 antigen (Ag) to have a sensitivity of 98.1% (95% CI: 93.2-99.8%) and a specificity of 99.8% (95% CI: 98.6-100.0%). Clinical specimens were determined to be positive or negative using an FDA EUA RT-PCR reference method. The individuals on which the reported sensitivity and specificity are based also had a nasopharyngeal swab taken, which was tested in the FDA EUA approved RT-PCR.

Panbio™ COVID-19 Ag Rapid Test Device Results

		Nasal PCR Test Result		
		Positive	**Negative**	**Total**
Panbio™ COVID-19 Ag Rapid Test Device Result (nasal swab specimens)	**Positive**	102	1	103
	Negative	2	403	405
	Total	104	404	508
		Sensitivity	**Specificity**	**Overall Percent Agreement**
		98.1% [93.2%; 99.8%]	**99.8%** [98.6%; 100.0%]	**99.4%** [98.3%; 99.9%]

- Performance data was calculated from a study of individuals suspected of exposure to COVID-19 or who have presented with symptoms in the last 7 days.
- Stratification of the positive specimens post onset of symptoms or suspected exposure between 0-3 days has a sensitivity of 100.0% (95% CI: 92.3-100.0%; n=46) and 4-7 days has a sensitivity of 96.6% (95% CI: 88.1-99.6%; n=58).
- Positive agreement of the Panbio™ COVID-19 Ag Rapid Test Device is higher with samples of Ct values ≤30 with a sensitivity of 100.0% (95% CI: 96.0-100.0%) and Ct values ≤33 with a sensitivity of 99.0% (95% CI: 94.5-100.0%). As indicated in References 8-10, patients with Ct value >30 are no longer contagious. [8, 9, 10]
- The clinical performance data was also calculated vs nasopharyngeal swab specimens using an FDA EUA RT-PCR reference and has a sensitivity of 91.1% (95% CI: 84.2-95.6%) and specificity of 99.7% (95% CI: 98.6-100.0%).

2. External evaluation of Panbio™ COVID-19 Ag Rapid Test Device (Asymptomatic)

Clinical performance of Panbio™ COVID-19 Ag Rapid Test Device was determined by testing 483 asymptomatic subjects for SARS-CoV-2 antigen (Ag). Clinical specimens were determined to be positive or negative using an FDA EUA RT-PCR reference method.

The positive results (n=50) were stratified by the comparator method cycle threshold (Ct) counts and assessed to better understand the correlation of product performance, as a surrogate for the amount of virus present in the clinical sample. A lower Ct value corresponds to a higher virus concentration. As presented in the table below, the positive agreement increases with lower Ct values.

The specificity (n=433) was 100% with 95% CI [99.2%; 100.0%].

The results for sensitivity are summarized in the following table:

	All Nasal PCR Positive Samples (n=50)	**Ct values ≤ 33 (n=40)**	**Ct values ≤ 30 (n=32)**
Sensitivity [CI 95%]	66.0% [51.2%; 78.8%]	80.0% [64.4%; 90.9%]	93.8% [79.2%; 99.2%]

As indicated in References 8-10, patients with Ct value >30 are no longer contagious. [8,9,10]

3. External evaluation of Panbio™ COVID-19 Ag Rapid Test Device (Self-Collected Swab)

The clinical performance of Panbio™ COVID-19 Ag Rapid Test Device was assessed in 287 symptomatic subjects (≥16 years of age) who collected their swab specimen (self swabbing) under the direction and supervision of a trained professional. The swab was then handed to the trained professional who executed the remaining steps of the procedure. The trained professional also collected a nasopharyngeal swab from each subject to be used as a reference specimen. The reference specimen was tested on the Panbio™ COVID-19 Ag Rapid Test Device.

The results are summarized in the following table:

		Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)		
		Positive	**Negative**	**Total**
Panbio™ COVID-19 Ag Rapid Test Device (Nasal) – Self-collected Swab	**Positive**	110	0	110
	Negative	2	175	177
	Total	112	175	287
		Positive Agreement	**Negative Agreement**	**Overall Percent Agreement**
		98.2% [93.7%; 99.8%]	**100.0%** [97.9%; 100.0%]	**99.3%** [97.5%; 99.9%]

4. External evaluation of Panbio™ COVID-19 Ag Rapid Test Device (Pediatric)
Clinical performance of Panbio™ COVID-19 Ag Rapid Test Device was determined by testing a total of 93 positive nasal swab specimens and 318 negative specimen for SARS-CoV-2 antigen (Ag) from pediatric symptomatic and asymptomatic subjects between 0 and 15 years who were suspected of exposure to COVID-19 or who have presented with symptoms in the last 7 days, to have a sensitivity of 82.8% (95% CI: 73.6-89.8%) and a specificity of 100% (95% CI: 98.8-100%). Clinical specimens were determined to be positive or negative using a nasal swab specimen with an FDA EUA RT-PCR reference method. Lower Ct value corresponds to a higher virus concentration.

The specificity (n=318) was 100% with 95%CI [98.8-100%].

Overall results for sensitivity are summarized in the following table according to age:

		All Positive Samples	Ct values ≤ 33	Ct values ≤ 30
Sensitivity [CI 95%]	**Total**	**82.8% [73.6%; 89.8%] (n=93)**	**87.2% [73.5%; 89.8%] (n=86)**	**93.2% [84.7%; 97.7%] (n=73)**
	Age 0-5	79.4% [62.1%; 91.3%] (n=34)	87.1% [70.2%; 96.4%] (n=31)	91.3% [72.0%; 99.0%] (n=23)
	Age 6-10	84.8% [68.1%; 94.9%] (n=33)	87.0% [71.0%; 96.5%] (n=32)	93.3% [77.9%; 99.2%] (n=30)
	Age 11-15	84.6% [65.1%; 95.6%] (n=26)	87.0% [66.4%; 97.2%] (n=23)	95.0% [75.1%; 99.8%] (n=20)

The following table presents results for symptomatic and asymptomatic pediatric cohorts:

		All Nasal PCR Positive Samples	Ct values ≤ 33	Ct values ≤ 30
Sensitivity [CI 95%]	**Symptomatic**	87.0% [77.4%; 93.6%] (n=77)	91.5% [82.5%; 96.8%] (n=71)	95.1% [86.3%; 99.0%] (n=61)
	Asymptomatic	62.5% [35.4%; 84.8%] (n=16)	66.7% [38.4%; 88.2%] (n=15)	83.3% [51.6%; 97.9%] (n=12)

5. Detection Limit
Panbio™ COVID-19 Ag Rapid Test Device was confirmed to detect $2.5X10^{1.8}$ $TCID_{50}$/ml of SARS-CoV-2 which was isolated from a COVID-19 confirmed patient in Korea.

6. Hook Effect

There is no hook effect at $1.0x10^{5.8}$ $TCID_{50}$/ml of SARS-CoV-2 which was isolated from a COVID-19 confirmed patient in Korea.

7. Cross Reactivity

Cross-reactivity of Panbio™ COVID-19 Ag Rapid Test Device was evaluated by testing 46 viruses and 21 other microorganisms. The final test concentrations of viruses and other microorganisms are documented in the Table below. The following viruses and other microorganisms except the Human SARS-coronavirus Nucleoprotein have no effect on the test results of Panbio™ COVID-19 Ag Rapid Test Device.

Panbio™ COVID-19 Ag Rapid Test Device has cross-reactivity with Human-SARS-coronavirus Nucleoprotein at a concentration of 25 ng/ml or more because SARS-CoV has high homology (79.6%) to the SARS-CoV-2.

No.	Types of Specimen	Cross Reaction Substance	Final Test Concentration	Test Result
1	Virus	Adenovirus Type 1	$1.54 X 10^{7}$ PFU/ml	No cross reaction
2		Adenovirus Type 5	$4.0 X 10^{8}$ PFU/ml	No cross reaction
3		Adenovirus Type 7	$2.0 X 10^{9}$ PFU/ml	No cross reaction
4		Enterovirus (EV68)	$2.0 X 10^{7}$ PFU/ml	No cross reaction
5		Echovirus2	$7.0 X 10^{5.5}$ PFU/ml	No cross reaction
6		Echovirus11	$3.5 X 10^{6.25}$ PFU/ml	No cross reaction
7		Enterovirus D68	$2.0 X 10^{7}$ PFU/ml	No cross reaction
8		Human herpesvirus (HSV) 1	$3.5 X 10^{7.5}$ PFU/ml	No cross reaction
9		Human herpesvirus (HSV) 2	$3.5 X 10^{5.75}$ PFU/ml	No cross reaction
10		Mumps Virus Ag	$1.1 X 10^{5}$ PFU/ml	No cross reaction
11		Influenza virus A (H1N1) Strain (A/Virginia/ATCC1/2009)	$2.6 X 10^{5}$ PFU/ml	No cross reaction
12		Influenza virus A (H1N1) Strain (A/WS/33)	$3.5 X 10^{7.25}$ PFU/ml	No cross reaction

No.	Types of Specimen	Cross Reaction Substance	Final Test Concentration	Test Result
13		Influenza virus A (H1N1) Strain (A/California/08/2009/pdm09)	1.1×10^8 PFU/ml	No cross reaction
14		Influenza virus B Strain (B/Lee/40)	$3.5 \times 10^{6.25}$ PFU/ml	No cross reaction
15		Parainfluenza Type 1	2.1×10^8 PFU/ml	No cross reaction
16		Parainfluenza Type 2	3.5×10^5 PFU/ml	No cross reaction
17		Parainfluenza Type 3	4.6×10^7 PFU/ml	No cross reaction
18		Parainfluenza Type 4A	2.0×10^7 PFU/ml	No cross reaction
19		Respiratory syncytial virus (RSV) type A	3.0×10^5 PFU/ml	No cross reaction
20		Respiratory syncytial virus (RSV) type B	3.9×10^5 PFU/ml	No cross reaction
21		Rhinovirus A16	8.8×10^5 PFU/ml	No cross reaction
22	Virus	HCoV-HKU1	1.5mg/ml	No cross reaction
23		HCoV-NL63	1.2×10^5 PFU/ml	No cross reaction
24		HCoV-OC43	6.2×10^5 PFU/ml	No cross reaction
25		HCoV-229E	1.1×10^6 PFU/ml	No cross reaction
26		Human SARS-coronavirus Nucleoprotein	25 ng/ml	Cross Reaction
27		MERS-CoV Nucleoprotein	0.25 mg/ml	No cross reaction
28		Human Metapneumovirus (hMPV) 16 Type A1	1.1×10^6 PFU/ml	No cross reaction
29		Adenovirus Type 2	1.96×10^7 PFU/ml	No cross reaction
30		Adenovirus Type 3	$1.4 \times 10^{6.5}$ PFU/ml	No cross reaction
31		Adenovirus Type 4	$3.5 \times 10^{6.5}$ PFU/ml	No cross reaction

No.	Types of Specimen	Cross Reaction Substance	Final Test Concentration	Test Result
32	Virus	Enterovirus C	6.0×10^7 PFU/ml	No cross reaction
33		Influenza virus A (H3N2) Strain (A/Hong Kong/8/68)	$3.5 \times 10^{5.5}$ PFU/ml	No cross reaction
34		Influenza virus A (H5N1)	1.5 mg/ml	No cross reaction
35		Influenza virus B Strain (Victoria)	5.46×10^6 PFU/ml	No cross reaction
36		Rhinovirus 14	1.6×10^8 PFU/ml	No cross reaction
37		Human cytomegalovirus	7.0×10^5 PFU/ml	No cross reaction
38		Norovirus	7.14×10^7 PFU/ml	No cross reaction
39		Varicella-zoster virus	1.96×10^4 PFU/ml	No cross reaction
40		Measles virus	6.1×10^5 PFU/ml	No cross reaction
41		EB virus	5.6×10^8 copies/ml	No cross reaction
42		Influenza virus (H7N9)	1.5mg/ml	No cross reaction
43		Influenza virus B Strain (Yamagata)	2.73×10^{10} PFU/ml	No cross reaction
44		Rhinovirus 54	$3.5 \times 10^{5.67}$ PFU/ml	No cross reaction
45		Rotavirus	1.12×10^7 PFU/ml	No cross reaction
46		Adenovirus type 11	3.0×10^6 PFU/ml	No cross reaction

No.	Types of Specimen	Cross Reaction Substance	Final Test Concentration	Test Result
1	Other Microorganism	*Staphylococcus saprophyticus*	7.9×10^7 CFU/ml	No cross reaction
2		*Neisseria sp. (Neisseria lactamica)*	6.8×10^8 CFU/ml	No cross reaction
3		*Staphylococcus haemolyticus*	1.4×10^{10} CFU/ml	No cross reaction
4		*Streptococcus salivarius*	7.84×10^7 CFU/ml	No cross reaction
5		*Hemophilus parahaemolyticus*	8.8×10^8 CFU/ml	No cross reaction
6		*Proteus vulgaris*	2.9×10^7 CFU/ml	No cross reaction
7		*Moraxella catarrhalis*	1.9×10^8 CFU/ml	No cross reaction
8		*Klebsiella pneumoniae*	2.0×10^7 CFU/ml	No cross reaction
9		*Fusobacterium necrophorum*	7.0×10^8 CFU/ml	No cross reaction
10		*Mycobacterium tuberculosis*	10mg/ml	No cross reaction
11		Pooled human nasal wash	N/A	No cross reaction
12		*Streptococcus pyogenes*	3.6×10^7 CFU/ml	No cross reaction
13		*Mycoplasma pneumoniae*	4.0×10^8 CFU/ml	No cross reaction
14		*Staphylococcus aureus*	1.3×10^8 CFU/ml	No cross reaction
15		*Escherichia coli*	6.8×10^6 CFU/ml	No cross reaction
16		*Chlamydia pneumoniae*	9.1×10^7 IFU/ml	No cross reaction
17		*Haemophilus influenzae*	3.4×10^8 CFU/ml	No cross reaction
18		*Legionella pneumophila*	1.2×10^6 CFU/ml	No cross reaction

No.	Types of Specimen	Cross Reaction Substance	Final Test Concentration	Test Result
19	Other Microorganism	*Streptococcus pneumoniae*	1.3×10^6 CFU/ml	No cross reaction
20		*Bordetella pertussis*	4.4×10^9 CFU/ml	No cross reaction
21		*Pneumocytis jirovecci (PJP)*	1.0×10^8 nuclei/ml	No cross reaction

** No concentration provided by supplier. Undiluted stock solution was tested.*

8. Interfering Substances

The following 43 potentially interfering substances have no impact on Panbio™ COVID-19 Ag Rapid Test Device. The final test concentrations of the interfering substances are documented in the Table below.

No.	Types of Specimen	Interfering Substances	Final Test Concentration	Test Result
1	Endogenous Substance	Mucin	0.5%	No Interference
2		Hemoglobin	100 mg/L	No Interference
3		Triglycerides	1.5 mg/L	No Interference
4		Icteric (Bilirubin)	40 mg/dL	No Interference
5		Rheumatoid factor	200 IU/ml	No Interference
6		Anti-nuclear antibody	>1:40	No Interference
7		Pregnant	10-fold dilution	No Interference
8	Exogenous Substance	Guaiacol glyceryl ether	1 µg/ml	No Interference
9		Albuterol	0.005 mg/dL	No Interference
10		Ephedrine	0.1 mg/ml	No Interference
11		Chlorpheniramine	0.08 mg/dL	No Interference
12		Diphenhydramine	0.08 mg/dL	No Interference
13		Ribavirin	26.7 µg /ml	No Interference
14		Oseltamivir	0.04 mg/dL	No Interference
15		Zanamivir	17.3 µg /ml	No Interference
16		Phenylephrine hydrochloride	15% v/v	No Interference
17		Oxymetazolin hydrochloride	15% v/v	No Interference
18		Amoxicillin	5.4 mg/dL	No Interference
19		Acetylsalicylic acid	3 mg/dL	No Interference
20		Ibuprofen	21.9 mg/dL	No Interference
21		Chlorothiazide	2.7 mg/dL	No Interference

No.	Types of Specimen	Interfering Substances	Final Test Concentration	Test Result
22	Exogenous Substance	Indapamide	140 ng/ml	No Interference
23		Glimepiride (Sulfonylureas)	0.164 mg/dL	No Interference
24		Acarbose	0.03 mg/dL	No Interference
25		Ivermectin	4.4 mg/L	No Interference
26		Lopinavir	16.4 µg/L	No Interference
27		Ritonavir	16.4 µg/L	No Interference
28		Chloroquine phosphate	0.99 mg/L	No Interference
29		Sodium chloride with preservatives	4.44 mg/ml	No Interference
30		Beclomethasone	4.79 ng/ml	No Interference
31		Dexamethasone	0.6 µg/ml	No Interference
32		Flunisolide	0.61 µg/ml	No Interference
33		Triamcinolone	1.18 ng/ml	No Interference
34		Budesonide	2.76 ng/ml	No Interference
35		Mometasone	1.28 ng/ml	No Interference
36		Fluticasone	2.31 ng/ml	No Interference
37		Sulfur	9.23 µg/ml	No Interference
38		Benzocaine	0.13 mg/ml	No Interference
39		Menthol	0.15 mg/ml	No Interference
40		Mupirocin	10 µg/ml	No Interference
41		Tobramycin	24.03 µg/ml	No Interference
42		Biotin	1.2 µg/ml	No Interference
43		HAMA	63.0 ng/ml	No Interference

9. Repeatability & Reproducibility

Repeatability & Reproducibility of Panbio™ COVID-19 Ag Rapid Test Device was established using in-house reference panels containing negative specimens and a range of positive specimens. There were no differences observed within-run, between-run, between-lots, between-sites, and between-days.

PREPARATION

1 Allow all kit components to reach a temperature between 15-30°C prior to testing for 30 minutes.
Note: Healthcare professionals should comply with personal safety guidelines including the use of personal protective equipment.

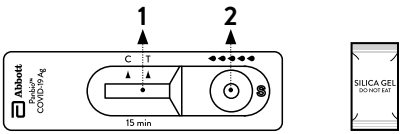
2 **Open the package and look for the following:**
1. Test device with desiccant in individual foil pouch
2. Buffer
3. Extraction tube
4. Extraction tube cap
5. Positive control swab
6. Negative control swab
7. Sterilized nasal swabs for sample collection
8. Tube rack
9. Quick reference guide (Nasal)
10. Instructions for use

3 Carefully read these instructions prior to using Panbio™ COVID-19 Ag Rapid Test Device kit.

4 Look at the expiration date of the kit box. If the expiration date has passed, use another kit.

5 **Open the foil pouch and look for the following:**
1. Result window
2. Specimen well

Then, label the device with the patient identifier.



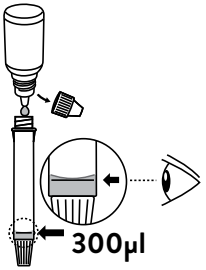
◆◆◆◆◆: 5 drops of the extracted specimen

ENGLISH

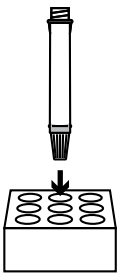
TEST PROCEDURE

1 Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300µl).

⚠ **Caution:** If the amount of buffer is excessive or insufficient, an improper test result may occur.

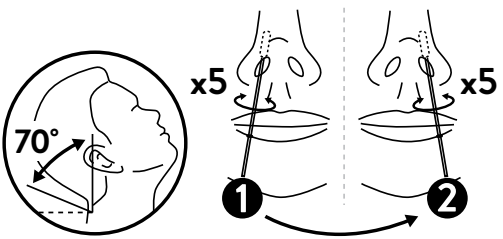


2 Place the extraction tube in the tube rack.



3 Tilt the patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at the turbinates). Rotate the swab five times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril. Slowly remove swab from the nostril.

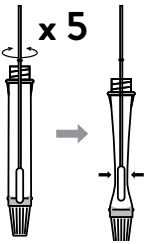
⚠ **Caution:** If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.



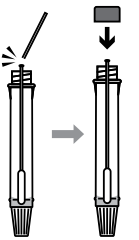
ENGLISH

TEST PROCEDURE

4 Insert the swab specimen in the extraction tube. Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.



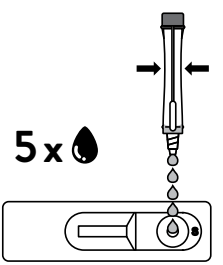
5 Break the swab at the breakpoint and close the cap of extraction tube.



6 Open the dropping nozzle cap at the bottom of the extraction tube.

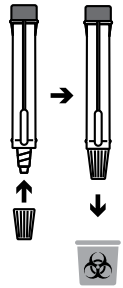
7 Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.

⚠ **Caution:** Bubbles that occur in the extraction tube can lead to inaccurate results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.



TEST PROCEDURE

8 Close the nozzle and dispose of the extraction tube containing the used swab according to your local regulations and biohazard waste disposal protocol.



9 Start timer. Read result at 15 minutes. Do not read results after 20 minutes.

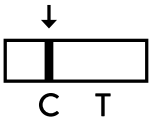
10 Dispose of the used device according to your local regulations and biohazard waste disposal protocol.

ENGLISH

TEST INTERPRETATION

NEGATIVE

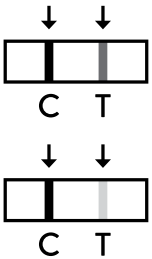
The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.



POSITIVE

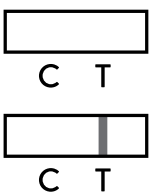
The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a positive result.

⚠ **Caution**: The presence of any test line (T), no matter how faint, indicates a positive result.



INVALID

If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly. It is recommended to read the IFU again before re-testing the specimen with a new test device.



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GLOSSARY OF SYMBOLS

	Temperature limitation
IVD	For *in vitro* diagnostic use only
	Do not reuse
	Do not use if package is damaged

LOT	Lot Number
REF	Catalog Number
	Consult instructions for use
	Keep dry
	Biological Risks
	Use By

	Manufacturer
	Date of manufacture
	Keep away from sunlight
	CE mark
	Contains sufficient for X tests
	Caution

STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
	Do not re-sterilize
CONTROL -	Negative control
CONTROL +	Positive control

TECHNICAL SUPPORT	
Europe & Middle East	+44 161 483 9032 EME.techsupport@abbott.com
Africa	+27 10 500 9700 ARCIS.techsupport@abbott.com
Russia & CIS	+44 161 483 9032 ARCIS.techsupport@abbott.com
Asia Pacific	+61 7 3363 7100 AP.techsupport@abbott.com
Latin America	+57 1 482 4033 LA.techsupport@abbott.com
Canada	+1 800 818 8335 Canproductsupport@abbott.com

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1, D-07743 Jena, Germany
abbott.com/poct

Date Issued : 2021.07
41FK11/41FK21-01-EN-A5

3.0 Quick reference guide

Panbio™

COVID-19 Ag RAPID TEST DEVICE

(NASAL)

QUICK REFERENCE GUIDE

REF 41FK11/41FK21

DE
Kurzanleitung (NASAL)
Technischer Support:
Abbott.com/POCT

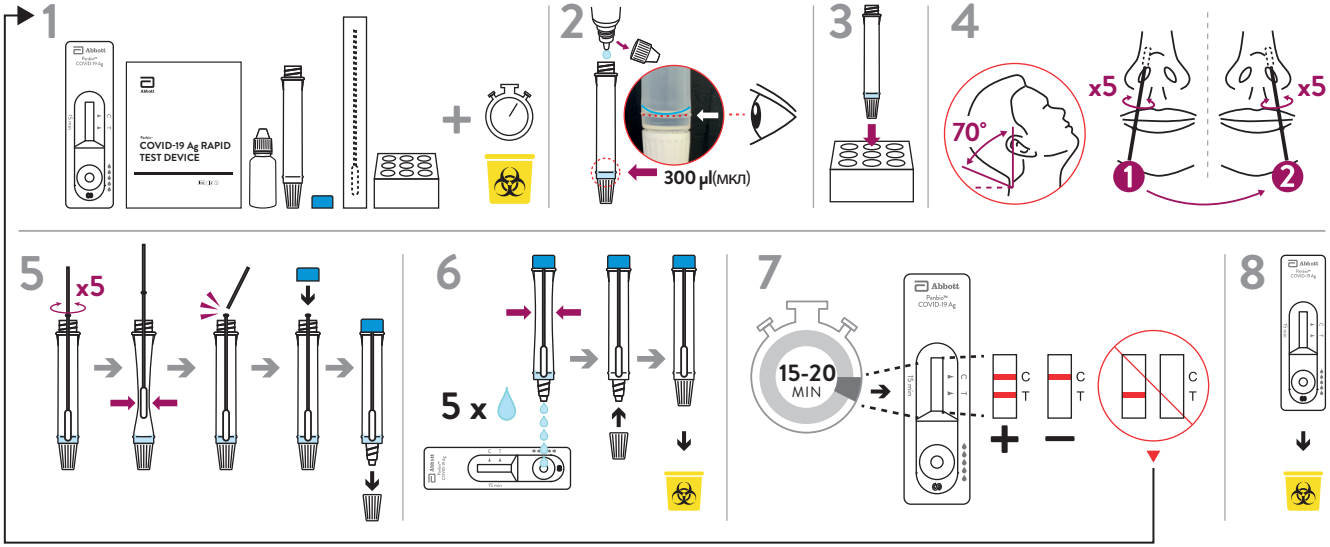
ES
Guía de referencia rápida (NASAL)
Asistencia técnica:
Abbott.com/POCT

FR
Guide de référence rapide (Prélèvement Nasal)
Support Technique ;
Abbott.com/POCT

IT
Guida Rapida di Riferimento (NASALE)
Supporto Tecnico
Abbott.com/POCT

PT
Guia de referência rápida (NASAL)
Suporte técnico:
Abbott.com/POCT

RU
Краткое руководство (назальный тампон)
Техническая поддержка:
Abbott.com/POCT



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