



Evolution of COVID-19 Rapid Antigen Testing

Panbio™ COVID-19 Ag Rapid Test Device

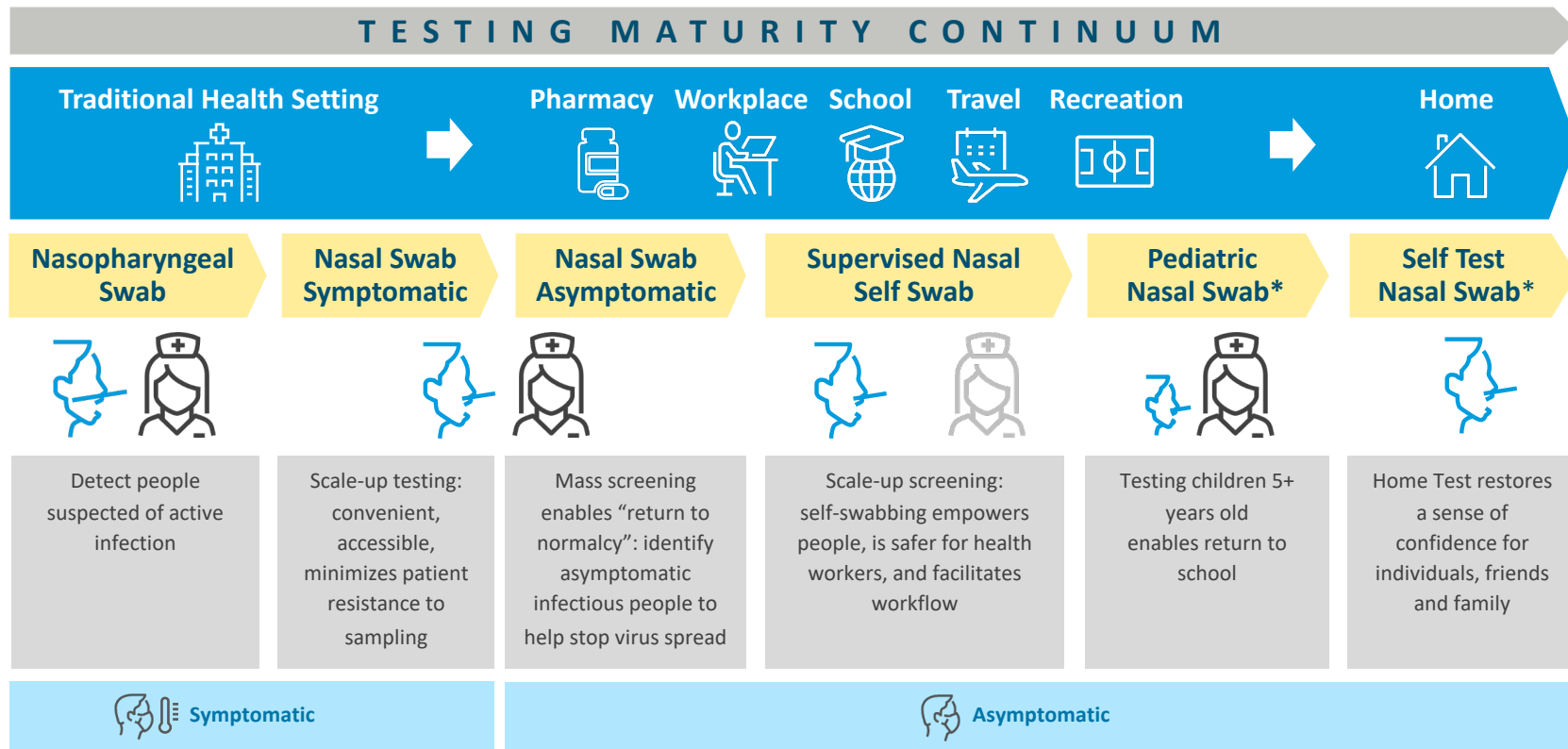


FOR EXTERNAL USE

Product not available in all countries. Not approved for sale in the USA.

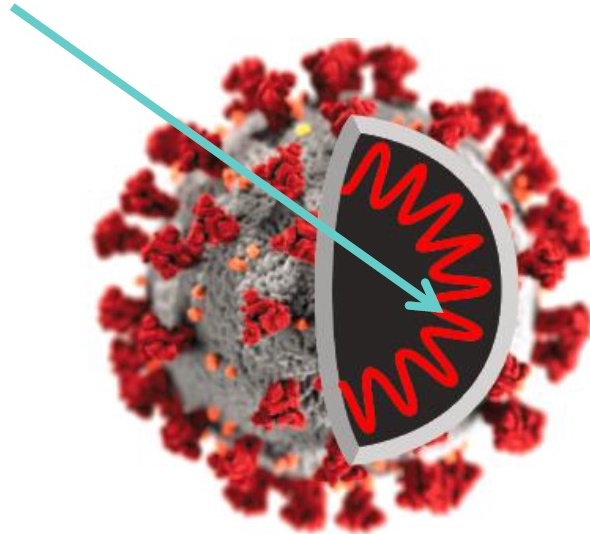
Abbott is making COVID-19 rapid testing easier to use so more people can be tested to help life return to normal

TESTING MATURITY CONTINUUM

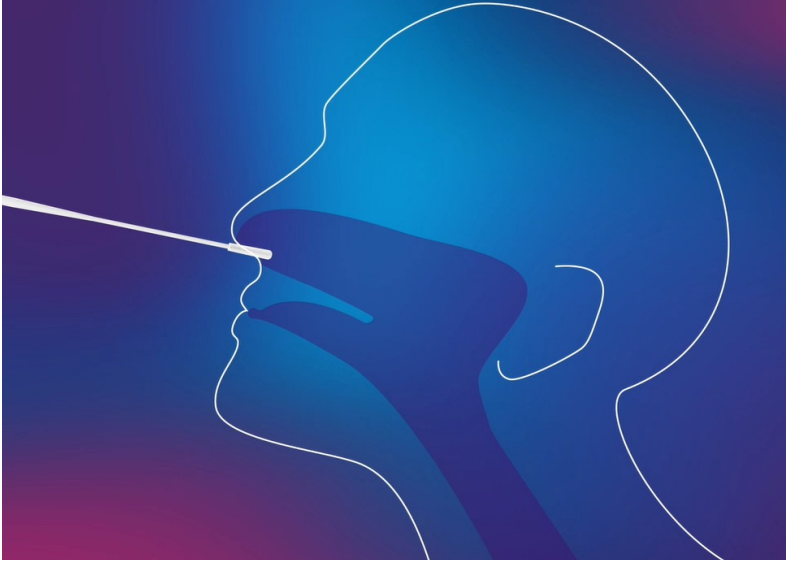


Panbio™ COVID-19 Ag Rapid Test Device

- *In vitro* diagnostic rapid test for qualitative detection of SARS-CoV-2 antigen (Ag)
- Detects nucleocapsid protein inside the SARS-CoV-2 virus



Nasopharyngeal Swab



- Before COVID-19, Nasopharyngeal sample collection was considered the standard of care due to its high performance, especially on PCR tests.
- Healthcare professional inserts the swab deep into the nasal cavity, which can be inconvenient and uncomfortable for people.

Nasal Swab

Less invasive procedure minimizes patient resistance to testing



- Clinical Studies with Panbio™ COVID-19 Ag Rapid Test Device demonstrate equivalent performance between Nasal and Nasopharyngeal sample collection¹
- Nasal procedure introduces swab only 2cm into nose
- Enables faster throughput and efficient workflow
- Patients can self-swab with the Panbio™ COVID-19 Ag Rapid Test Device
- Health worker can keep distance while patient self-swabs
- Nasal swabbing is now the preferred sample collection method in several countries because it is more convenient for health care workers and minimizes patient resistance to testing.

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.

Product Information

Cat No/REF:	41FK11 (CE, WHO EUL)	
Sample Type:	Nasal swab	
Quantity:	25 tests/kit	
Storage:	2-30°C	
Shelf Life:	12 months	
Test Time:	15 minutes Do not read results after 20 minutes	
Multiple Language IFU:	English German Spanish French	Italian Portuguese Russian



Kit Contents: Everything Needed to Run a Test

MATERIALS PROVIDED

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

REQUIRED BUT NOT PROVIDED

- Personal protective equipment (PPE)
- Protective gloves
- Timer
- Biohazard container

Specifications

PERFORMANCE*

- **Sensitivity: 98.1%** [95% CI: 93.2% -99.8%]
- **Specificity: 99.8%** [95% CI: 98.6% - 100.0%]

*Performance determined from 104 positive samples confirmed with nasal PCR using FDA EUA RT-PCR method

*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%).

SPECIFICATIONS

- Test time: 15 minutes
- Storage: 2°C–30°C
- Sample Type: Nasal swab
- CE Mark, WHO EUL



Nasal Swab for Asymptomatic People

At Least 50% Of New Infections Originate From Exposure to Asymptomatic Individuals¹

- Mass screening of populations including asymptomatic individuals can quickly filter out potentially contagious people and rebuild a sense of safer workplaces, schools, airports and recreational gatherings.²
- Frequent ongoing screening in congregate settings reduces the risk of infection and informs control measures.³
- Clinical data demonstrate that testing with the Panbio™ COVID-19 Ag Rapid Test Device can effectively identify both symptomatic and asymptomatic individuals who are contagious.⁴

1. Johansson et al. SARS-CoV-2 Transmission From People Without COVID-19 Symptoms. JAMA Netw Open. 2021;4(1):e2035057.

2. CDC SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces Oct 2020. <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html#print>

3. CDC Interim Guidance for Antigen Testing for SARS-CoV-2 2020. <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>

4. Panbio COVID-19 Ag Rapid Test Device Instructions for Use



Supervised Nasal Self Swabbing

Patient-friendly, Self-collected Nasal Swab Minimizes Health Worker Exposure



Dr. Amilcar Tanuri

Full Professor & Head of Molecular Virology Laboratory
The Federal University of Rio de Janeiro, Brazil

- Patients can perform nasal swab self-collection, supervised by a trained professional.
- Health workers can maintain distance during the sample collection procedure, which minimizes their personal exposure.
- Self-collection offers a more comfortable patient experience and feeling of control during the sampling procedure.

Self Test Nasal Swab for Consumers*

- Restore a sense of confidence for children, adults, friends and family
- Allow testing in the comfort and convenience of home
- Additional tool to fight the pandemic



*Product under development, not available for sale

Evidence

- Several clinical studies¹ and independently conducted product evaluations² have consistently demonstrated the solid performance of Panbio™ COVID-19 Ag Rapid Test Device:
 - In both **symptomatic** and **asymptomatic** populations
 - Using nasopharyngeal or nasal sample collection, including supervised self collection
- **Panbio™ COVID-19 Ag Rapid Test Device is currently the only Antigen test granted WHO EUL for use in Asymptomatic patients and for Nasal Self-swabbing**

1. Panbio COVID-19 Ag Rapid Test Device Instructions for Use

2. FIND Evaluation of Abbott Panbio COVID-19 Ag Rapid Test Device External Reports <https://www.finddx.org/sarscov2-eval-antigen/>

Summary

- Abbott is leading the way in COVID-19 testing innovation, developing and bringing to market a broad set of testing solutions
- Panbio™ COVID-19 Ag Rapid Test Device is a rapid, accessible and easy to use testing solution for detecting COVID-19 active infection
- We continue to advance COVID-19 diagnostics and anticipate the launch of another innovation: Panbio™ COVID-19 Antigen Self-Test
- Our goal is to collaborate with the global community and provide testing solutions that address unmet needs so we can all return to normal



Abbott