


Abbott

Scale Up COVID-19 Antigen Testing

Panbio™ COVID-19 Ag Rapid Test Device

FOR EXTERNAL USE. Proprietary and confidential — do not distribute.



Contents

- Introduction
- The role of Antigens in COVID-19 testing
- Panbio™ COVID-19 Ag Rapid Test Device

Introduction

COVID-19

COVID-19: Coronavirus Infectious Disease-2019

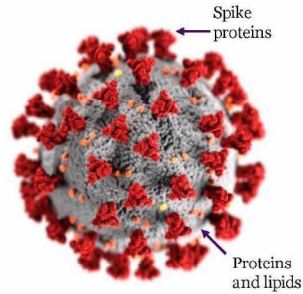
- Caused by SARS-CoV-2
- Declared a pandemic by the WHO on 11-Mar-2020

Six other types of Coronavirus are known to infect humans¹

- Some cause common cold
- Two caused previous outbreaks: SARS and MERS

Attributes:

- Named after the crownlike spikes on the surface¹
- Virus is enveloped in bubble of oily lipid molecules
- Oily membrane falls apart on contact with soap²



¹ [CDC Human Coronavirus Types, 2020](https://www.cdc.gov/coronavirus/types.html) <https://www.cdc.gov/coronavirus/types.html>

² <https://www.nytimes.com/interactive/2020/03/11/science/how-coronavirus-is-killed.html?>

Photo credit: CDC Public Domain <https://hhl.cdc.gov/Details.aspx?id=23312>

Transmission and Infection

Respiratory droplets enter the body through the nose, mouth or eyes¹

Attaches to cells in airway that express the ACE2 receptor protein

- Virus infects a cell by fusing its oily membrane
- Hijacks the cell, assembles new copies of the virus and releases millions of copies

Clinical Presentation (& rate of occurrence)²

- *Mild to Moderate cases* (81%)
 - mild symptoms up to mild pneumonia
- *Severe cases* (14%)
 - Dyspnea, hypoxia, or >50% lung involvement on imaging)
- *Critical cases* (5%)
 - respiratory failure, shock, or multiorgan system dysfunction

High Risk Patient Population²

- Elderly, Cardiovascular Disease, Diabetes, Hypertension

1. CDC How COVID-19 Spreads 2020. <https://www.cdc.gov/coronavirus/2019-nCoV/research/transmission.html>

2. CDC Management of Patients with Confirmed 2019-nCoV June 2020. <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-guidance-management-patients.html>

The role of Antigens in COVID-19 testing

Suggested Use Cases for Ag (FIND)¹

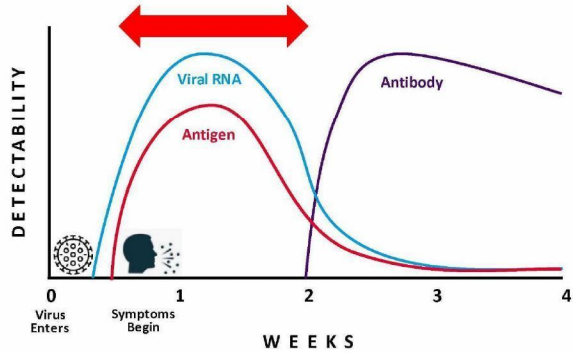
- Ag tests are useful for detection of COVID-19 active infection.
- Ag RDTs should be prioritized for case management to enable decentralized testing, especially when access to PCR testing is limited.

Use Cases:

- Triage suspect cases
- Confirm active infection
- Contact tracing

1. FIND Rapid Diagnostic Tests for COVID-19, 18 May 2020. https://www.finddx.org/wp-content/uploads/2020/05/FIND_COVID-19_RDTs_18.05.2020.pdf

When to Test for Antigen^{1,2,3}



1. Sethuraman, N., Jeremiah, S.S., Ryo, A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. 6 May 2020. doi: 10.1001/jama.2020.8259
2. Theel ES, The role of antibody testing for SARS-CoV-2: is there one? J Clin Microbiol. 58:e00797-20. 2020. <https://doi.org/10.1128/JCM.00797-20>.
3. CDC Symptom-Based Strategy to Discontinue Isolation for Persons with COVID-19. Decision Memo. May 3, 2020

COVID-19 Antigen Test

- **How does it work?**

- Directly detects the presence of the virus, indicating **active infection** (i.e. replication of the virus)

- **Where and who performs?**

- Trained healthcare workers, wearing appropriate personal protective equipment (PPE) at decentralized points of need

- **Benefits**

- Enables fast, **decentralized access to direct testing** for the virus, relieving the burden on the laboratory testing system
- If used for contact tracing, provides an **objective marker to define chains of transmission**

Introducing the Panbio™ COVID-19 Rapid Test Device

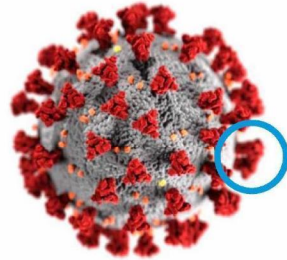


Panbio™ COVID-19 Ag Rapid Test Device

- Abbott's Panbio COVID-19 Ag Rapid Test Device is intended for the detection of the SARS-CoV-2 virus in people suspected of having COVID-19
- Requires no instrumentation and provides results in 15-20 minutes, making it a valuable tool for mass testing in decentralized settings
- Designed to offer an accessible, portable, and scalable option for COVID-19 testing
- May also be a very useful tool for supporting public health strategies, such as contact tracing and large-scale testing of people suspected of having an active infection

Panbio™ COVID-19 Ag Rapid Test Device

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



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 nasopharyngeal 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.

Specifications

Performance

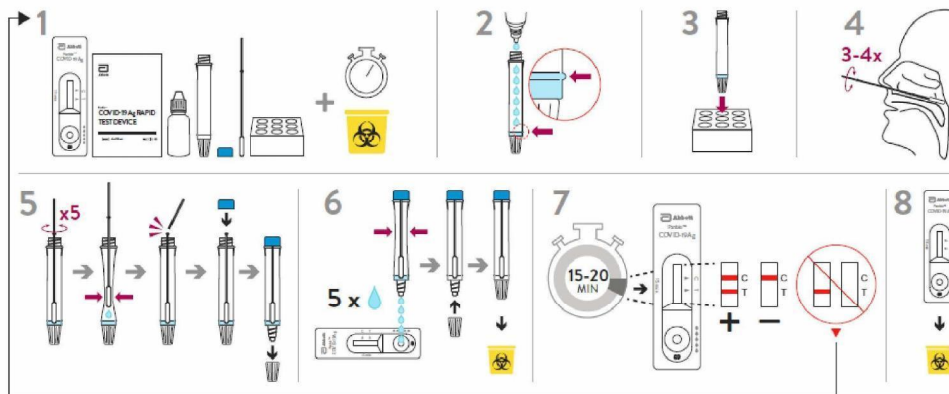
- Sensitivity: 93.3% (98.2% for samples with Ct values ≤ 33)
- Specificity: 99.4%

Specifications

- Test time: 15–20 minutes
- Storage: 2°C–30°C
- CE Mark
- Sample Type: Nasopharyngeal swab



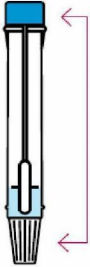
Test Procedure



Biohazard Containment Features Help Protect Staff

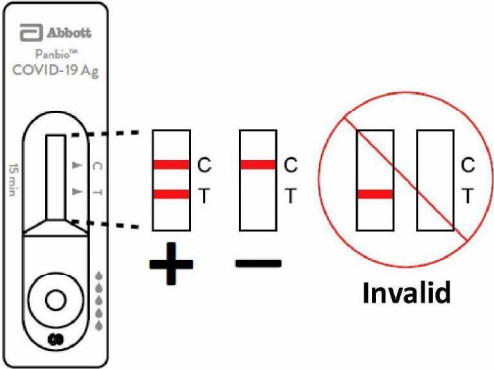


Special “break off” swab stays contained in tube, minimizing staff exposure



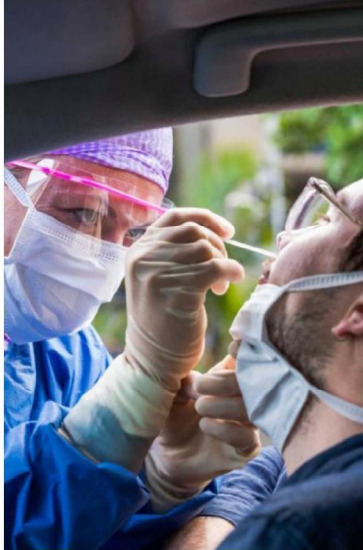
Safely dispose the fully enclosed extraction tube

Simple Results Interpretation



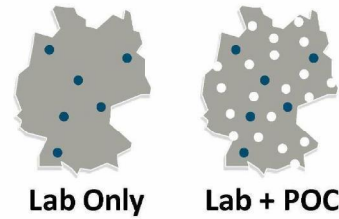
Deploy at Point of Care

- Portable format allows fast setup of decentralized testing sites
- Deploy in lab and non-lab decentralized locations
- Samples are taken and directly applied to test at point of care
- No requirement to ship samples



Extend Capacity of Lab Testing

- Relieve burden on busy labs
- Mass testing becomes achievable
- Extend geographic coverage
- Test can be run outside lab setting
- Deploy where lab PCR is unavailable/inconvenient



Faster Answers for Patients

- Test is run at point of care
- Answers in 15-20 minutes, while patients wait
- Fewer follow up calls to patients
- Fast alternative if lab PCR unavailable
- Fewer bottlenecks on throughput
- Help reduce overall community transmission



Accessible Solution

- Less costly than molecular
- No capital equipment required
- No pre-installed instrumentation required
- Fewer infrastructure needs
- Simplified training



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
- 1 Positive control swab
- 1 Negative control swab
- 25 Sterilized nasopharyngeal swabs for sample collection
- 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

Ordering Information

- Cat No: 41FK10
- 25 Tests per Kit Box

Languages

- English
- German
- Spanish
- French
- Italian
- Portuguese
- Russian



532268

