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Abbott

Scale Up COVID-19 Antigen Testing

Panbio™ COVID-19 Ag Rapid Test Device

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Introduction

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COVID-19

COVID-19: Coronavirus Infectious Disease-2019

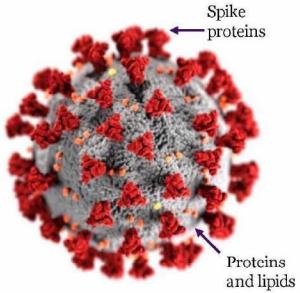
- Caused by SARS-CoV-2
- Declared a pandemic by the WHO on 11-Mar-2020

Six other types of Coronavirus are known to infect humans[1]

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

Attributes:

- Named after the crownlike spikes on the surface[1]
- Virus is enveloped in bubble of oily lipid molecules
- Oily membrane falls apart on contact with soap[2]



1. CDC Human Coronavirus Types 2020. https://www.cdc.gov/coronavirus/types.html
2. https://www.nytimes.com/interactive/2020/03/11/science/how-coronavirus-hijacks-your-cells.html?

Photo credit: CDC Public Domain https://phil.cdc.gov/Details.aspx?pid=23312

Transmission and Infection

Respiratory droplets enter the body through the nose, mouth or eyes[1]

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 disfunction

High Risk Patient Population[2]

- Elderly, Cardiovascular Disease, Diabetes, Hypertension

1. CDC How COVID19 Spreads 2020. https://www.cdc.gov/coronavirus/2019-ncov/prepare/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

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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

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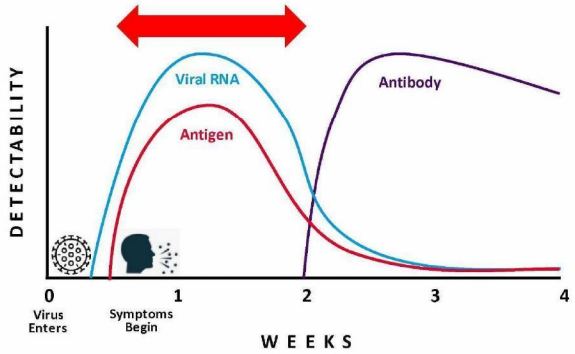
When to Test for Antigen[1,2,3]



1. Sethuraman, N., Jeremiah, SS., 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

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Diagnostic Tests Types and Use[1,2]

	Molecular Test	Immunoassay Tests (Current infection)		Non-disease specific test
		Antigen Test	Antibody Test (Past exposure to virus)	
How does it work?	Detects viral genetic material through a technique called polymerase chain reaction (PCR) to amplify sample	Detects antigen through an enzyme linked immunosorbent assay (ELISA) or lateral flow test.	Detects antibodies through ELISA test. Or lateral flow test, for example	Detects symptoms or signs of disease through scans, imaging or observation
Where is the test taken?	Typically performed in lab although samples may be taken outside of the lab.	May be performed in laboratory or point of care	May be performed in laboratory or point of care	In a hospital, clinic, or point of care depending on equipment required
What is it typically used for?	Testing suspected cases of COVID-19	Testing suspected cases of COVID-19 or candidates for further testing (like PCR)	Assessing infection and/or exposure rates in a community	Screening or triage for further testing
What does a positive result indicate?	Confirms a case of SARS-CoV-2 infection	Confirms a case of SARS-CoV-2 infection or potential infection	Previous exposure to SARS-CoV-2 or potential of previous SARS-CoV-2 infection	Further testing is needed if results suggest possible SARS-CoV-2 infection

1. Kelly-Cirino, C. Special COVID-19 ECHO Session #2 Webinar from African Society of Laboratory Medicine. (06 May 2020). https://aslmorg/wp-content/uploads/2020/04/COVID-19_FIND_ECHO-session-30.05.2020-FINAL.pdf
2. Patel, R., Babady, E., Theel, ES., et al. Report from the American Society for Microbiology COVID-19 International Summit, 23 March 2020: Value of Diagnostic Testing for SARS-CoV-2/COVID-19. https://mbio.asm.org/content/11/2/e00722-20

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**

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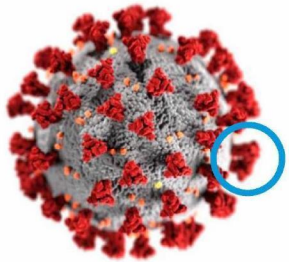
Introducing the Panbio™ COVID-19 Rapid Test Device

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

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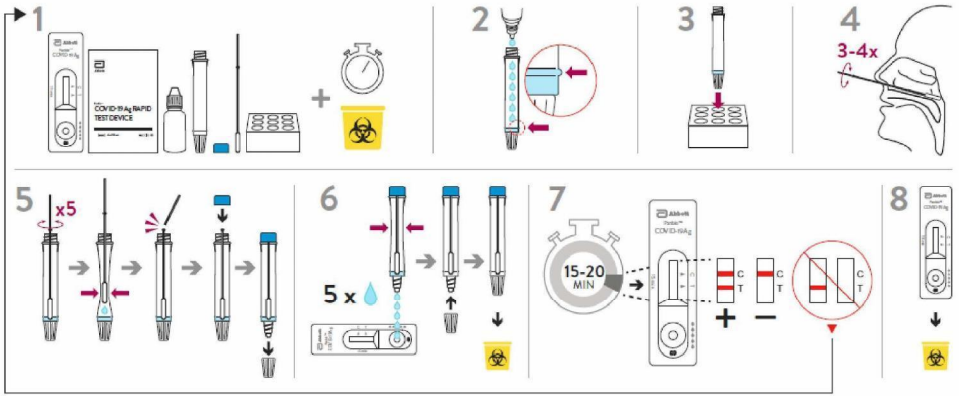
Test Procedure



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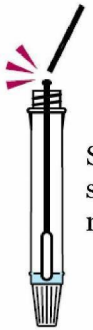
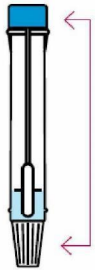
Biohazard Containment Features Help Protect Staff



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



Safely dispose the fully enclosed extraction tube

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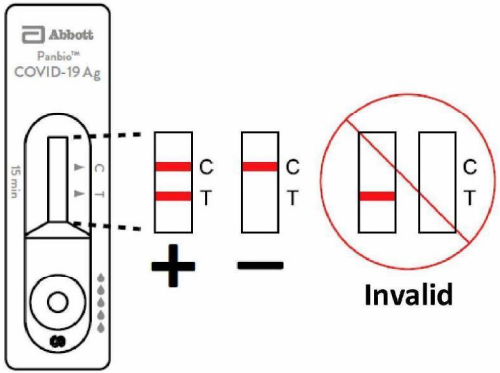
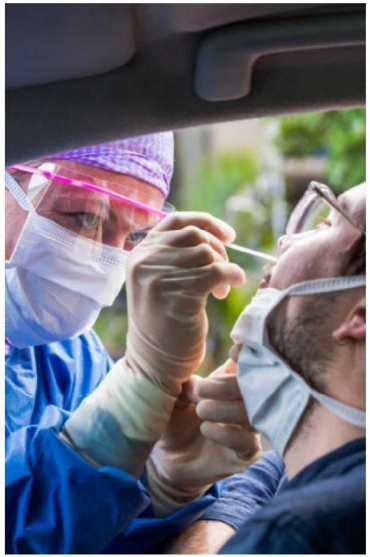
Simple Results Interpretation



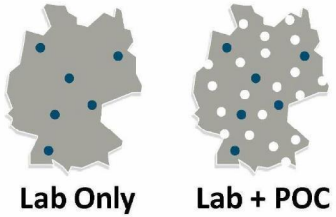
Deploy at Point of Care

- 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



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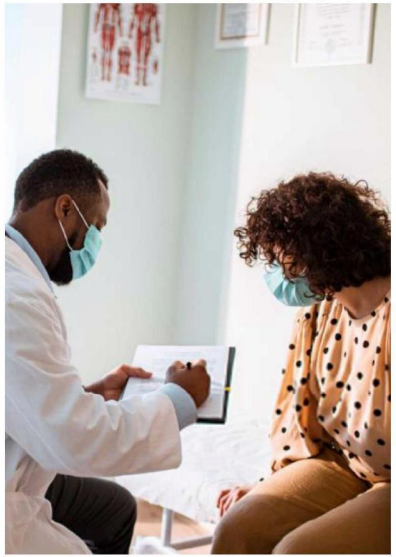
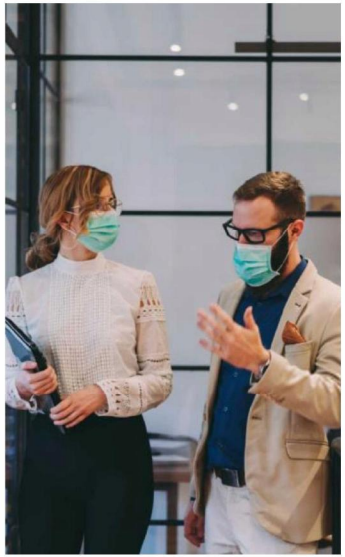
Faster Answers for Patients

- 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

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Ordering Information

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

Languages

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

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