Abbott

# SCALE UP COVID-19 ANTIBODY TESTING

With a rapid lateral flow, fingerstick IgG/IgM assay

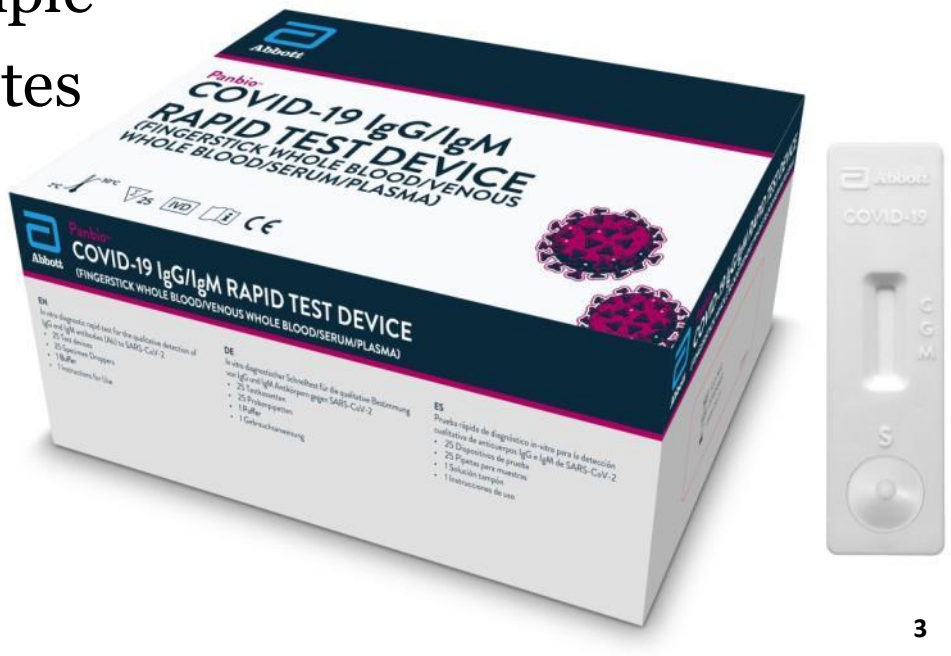

FOR EXTERNAL USE

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


# Introducing the Panbio™ COVID-19 IgG/IgM Rapid Test Device

# Product Overview

- Lateral Flow Rapid Test Device
- Detects IgG/IgM antibodies caused by SARS-CoV-2
- Antibody test are utilized to determine if someone was previously infected
- Separate test lines for IgG and IgM
- 20µL fingerstick blood sample
- Time to result: 10-20 minutes
- Simple test procedure



# Kit Contents

## Materials Provided:

- 25 Test Devices individually pouched
- 25 Specimen droppers
  (for fingerstick whole blood only)
- 1 Buffer (3mL/vial)
- 1 Instructions for Use


## Materials Required but Not Provided:

- Specimen collection equipment and containers
- Micropipette
- Lancet (for fingerstick whole blood only)
- Cotton wool or gauze pad (for fingerstick whole blood only)
- Centrifuge
- Timer
- Biohazard waste containers for sharps and non-sharps

# Intended Use

The Panbio™ COVID-19 IgG/IgM Rapid Test Device (Fingerstick Whole Blood/Venous Whole Blood/Serum/Plasma) is an *in vitro* diagnostic rapid test for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma, venous and fingerstick whole blood.

The Panbio™ COVID-19 IgG/IgM Rapid Test Device (Fingerstick Whole Blood/Venous Whole Blood/Serum/Plasma) 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.

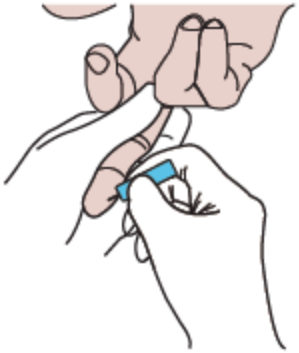
The test provides preliminary test results. Negative results will not preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decision.

The test is not intended to be used as a donor screening test for SARS-CoV-2.

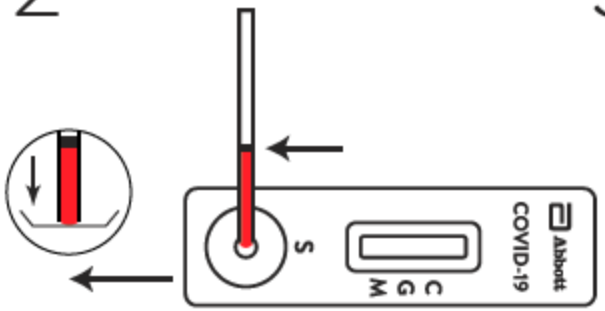
# Fingerstick Test Procedure

Consult Instructions for Use for complete procedure

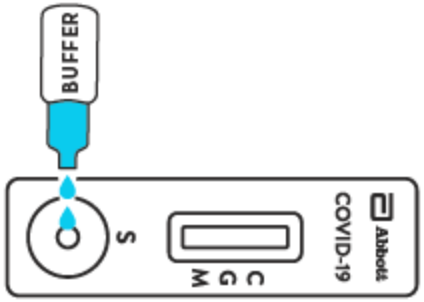
1 PUNCTURE FINGER WITH STERILE LANCET



2 ADD 20 µL SAMPLE



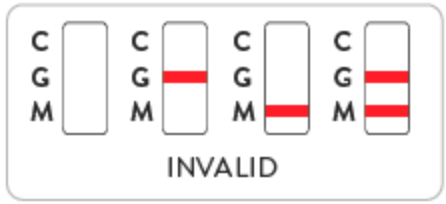

3 ADD 2 DROPS OF BUFFER




4 READ RESULTS AT 10 MINUTES

DO NOT READ AFTER 20 MINUTES



# Performance

**Sensitivity: 95.8%** (95%CI: 85.7%~99.5%)

**Specificity: 94.0%** (95%CI: 83.5%~98.7%)

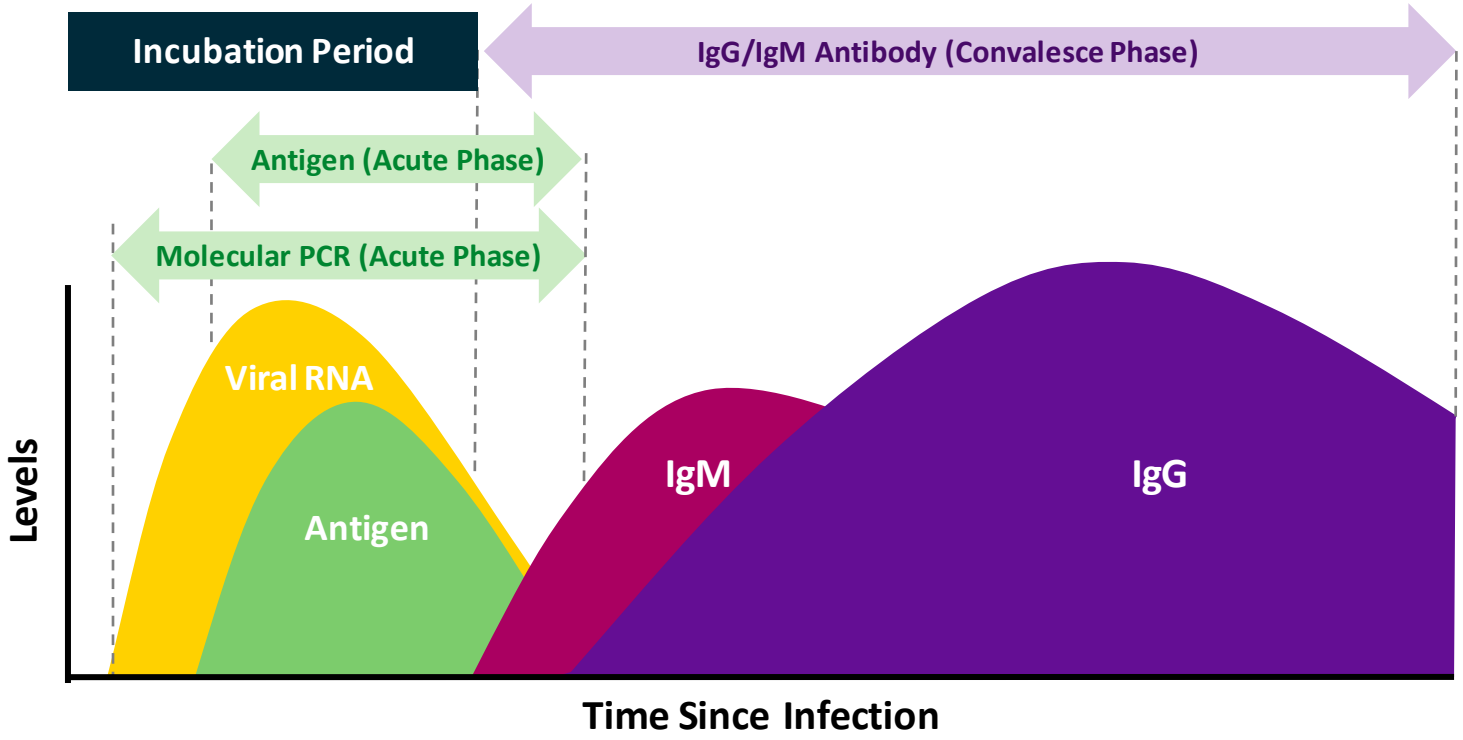
| | | PCR Positive | Clinical Negative | Total |
|---|---|---|---|---|
| Panbio™ COVID-19 IgG/IgM Rapid Test Device Result | IgG or IgM Positive | 46 | 3 | 49 |
| | IgG and IgM Negative | 2 | 47 | 49 |
| | Total | 48 | 50 | 98 |

# Specifications

| | |
|---|---|
| **Sample Types** | Fingerstick whole blood, venous whole blood, serum/plasma |
| **Sample Size** | -Fingerstick and venipuncture whole blood: 20µL<br>-Serum/plasma: 10µL |
| **Test Time** | 10 minutes, do not read after 20 minutes |
| **CE Mark** | Yes |
| **Sensitivity** | 95.8% |
| **Specificity** | 94.0% |
| **Storage** | 2°–30°C |
| **Shelf Life** | 12 months |
| **Qty per kit** | 25 tests |
| **Control** | Procedural control included within the test |
| **Cat No** | ICO-T402 |

# Diagnosis Overview: IgG/IgM

# General Viral Response In Patient




NOTE: this is a typical viral patient response and is not specific to COVID-19

**In the case of COVID-19 (SARS-CoV-2 virus) the duration of the different stages of infection is still under investigation.** COVID-19 is estimated to have a mean incubation period of 6.4 days.[1]

- Many patients can be asymptomatic during the incubation phase

1. Lai CC, Shih TP, Ko WC, et.al. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges. Int J Antimicrob Agents. 2020; Mar 55(3): 105924.doi: https://doi.org/10.1016/j.ijantimicag.2020.105924

# Growing Need for Rapid Point-of-care Tests

*"Development of rapid and accurate point-of-care tests which perform well in field settings are especially useful…*

*This would markedly improve early detection and isolation of infected patients and, by extension, identification of contacts."*[1]

**-Report of the WHO-China Joint Mission on Coronavirus Disease 2019**

1. https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf

# Using IgG/IgM to Track Outbreak Expansion[1]

- IgG/IgM result is an indication of exposure to the virus
- Cannot be used solely for treatment or decision but can provide an indication of contact or potential infection
- Quickly identifying potential cases is key when tracking expansion of outbreak

1. https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf

# COVID-19 Patient Response in Literature

- **Different sources note 80% of COVID-19 cases seem to be asymptomatic or with mild symptoms.**
  - Molecular Diagnostic used for patients with symptoms, and in some countries, only very sick patients.
  - Asymptomatic patients can spread the virus without knowing.

- **IgM appears to show up earlier compared to other viral infections, approximately day 3 to 5 following infection.[1]**
  - IgM is an important biomarker, specifically for asymptomatic patients.
  - IgM has a short duration, estimating 2 to 4 weeks, but more data specific to COVID-19 is needed.

- **IgG also shows up earlier during COVID-19 infection.**
  - Testing for IgG/IgM can be a very effective diagnostic complement on asymptomatic patients.
  - Help identify potential asymptomatic patients quickly, increase contact case finding and reinforce quarantine need.

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia, (Trial Version 7), March 3, 2020; http://www.kankyokansen.org/uploads/uploads/files/jsipc/protocol_V7.pdf

# Lateral Flow Allows Rapid Scale Up of Testing Capacity

# Scaling Up with the Panbio COVID-19 IgG/IgM Test

- Make testing more widely available
- Address urgent testing shortfall
- Decentralized testing can help to alleviate overcrowding in hospitals
- Reserve central facilities for seriously ill
- Useful in drive-through, home visit, point-of-care, or lab settings

# Empower frontline workers


**Panbio™**
COVID-19 IgG/IgM
Rapid Test Device



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