SCALE UP COVID-19 ANTIBODY TESTING

With a rapid lateral flow, fingerstick IgG/IgM assay

PRODUCT NOT AVAILABLE IN ALL COUNTRIES

FOR EXTERNAL USE
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

![Result Interpretation](image-url)
Performance

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

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

<table>
<thead>
<tr>
<th>Panbio™ COVID-19 IgG/IgM Rapid Test Device Result</th>
<th>PCR Positive</th>
<th>Clinical Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgG or IgM Positive</td>
<td>46</td>
<td>3</td>
<td>49</td>
</tr>
<tr>
<td>IgG and IgM Negative</td>
<td>2</td>
<td>47</td>
<td>49</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
<td>50</td>
<td>98</td>
</tr>
</tbody>
</table>
### Specifications

<table>
<thead>
<tr>
<th>Sample Types</th>
<th>Fingerstick whole blood, venous whole blood, serum/plasma</th>
</tr>
</thead>
</table>
| Sample Size  | - Fingerstick and venipuncture whole blood: 20μL  
              - 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

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

¹ Report of the WHO-China Joint Mission on Coronavirus Disease 2019

Using IgG/IgM to Track Outbreak Expansion

- 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

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.**
  – 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.

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

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