The COVID-19 Antibody Rapid test will detect antibodies 5 to 7 days after symptoms first appear.

The test will show clear results in 15 minutes, unlike a PCR test, which can take hours.

The COVID-19 Antibody Rapid Test is cost effective, at approx. 5% of the cost of a PCR test.

IgM/IgG DETECTABLE TEST WINDOW

- PCR & ANTIGEN TESTING
  - Can be used in the first seven days
- BOTH TESTS MAY BE LESS RELIABLE BETWEEN 7-10 DAYS
- ANTIBODY TESTING
  - Can be used after 7-10 days

As antibodies rise, the virus decreases

We don't yet know how long these antibodies stay in our system

Authorized Laboratories:

Use of this test with all authorized specimen types is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.

This test is also authorized for use with fingerstick whole blood specimens only at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

4 Easy Steps

1. Clean the site
2. Draw blood
3. Pipette blood sample on device
4. Add buffer and read results
**TEST PROCEDURE & READING RESULTS**

1 DROP OF BLOOD ➔ 2 DROPS OF BUFFER ➔ WAIT 15 MINUTES

**READ RESULTS**

NEGATIVE
The coloured line in the control line region (C) changes from blue to red. No line appears in the test line regions M or G.

The result is Negative.

**IGM POSITIVE**
The coloured line in the control line region (C) changes from blue to red, and a coloured line appears in test line region M.

The result is anti-COVID-19 IgM Positive.

**IGG POSITIVE**
The coloured line in the control line region (C) changes from blue to red, and a coloured line appears in test line region G.

The result is anti-COVID-19 IgG Positive.

**IGG AND IGM POSITIVE**
The coloured line in the control line region (C) changes from blue to red, and two coloured lines appear in test line regions M and G.

The result is anti-COVID-19 IgM and IgG Positive.

**INVALID**
Control line is still completely or partially blue, and fails to completely change from blue to red. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the kit immediately and contact your distributor.
ASSURETECH

FOR IgM DETECTION

KIT CONTAINS:
• 20 - In Vitro Diagnostic Devices (IVDD)
• 20 - 10 uL pipettes (for whole blood)
• 20 - Alcohol wipes
• 20 - One-time-use safety lancets (automatic, spring loaded, with retractable blade)
• 1 - Bottle of buffer
• 1 - Product insert

METHOD

<table>
<thead>
<tr>
<th>COVID-19 IgG/IgM Rapid Test</th>
<th>PCR+</th>
<th>PCR-</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM+</td>
<td>74</td>
<td>2</td>
<td>76</td>
</tr>
<tr>
<td>IgM -</td>
<td>5</td>
<td>225</td>
<td>230</td>
</tr>
<tr>
<td>TOTAL</td>
<td>79</td>
<td>227</td>
<td>306</td>
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</tbody>
</table>

FOR IgG DETECTION

METHOD

<table>
<thead>
<tr>
<th>COVID-19 IgG/IgM Rapid Test</th>
<th>PCR+</th>
<th>PCR-</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgG+</td>
<td>82</td>
<td>3</td>
<td>85</td>
</tr>
<tr>
<td>IgG -</td>
<td>1</td>
<td>224</td>
<td>225</td>
</tr>
<tr>
<td>TOTAL</td>
<td>83</td>
<td>227</td>
<td>310</td>
</tr>
</tbody>
</table>

CLINICAL DATA

SARS-COV-2 ANTIGEN AND IGM/IGG ANTIBODY TEST RESULTS AND CLINICAL SIGNIFICANCE

<table>
<thead>
<tr>
<th>TEST RESULTS</th>
<th>SIGNIFICANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCR (Ag)</td>
<td>IgM Ab</td>
</tr>
<tr>
<td>+</td>
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