COVID-19 IgM/IgG Antibody Rapid Test

Rapid Results in 15 Minutes
Make Decisions Based on Reliable Results

COVID-19 FACTS

- COVID-19 (SARS-COV-2) is mainly transported through respiratory droplets
- Symptoms of COVID-19 may appear 2-14 days after exposure and can range from mild to severe and may even result in death
- Symptoms mainly include fever, cough and shortness of breath

QUICKLY SCREEN → QUARANTINE

- 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
- The test is easy to administer and can be performed by health personnel with no specific medical training

4 Easy Steps

1. CLEAN THE FINGER
2. PIERCE TOP OF FINGER WITH LANCET
3. PIPETTE BLOOD SAMPLE ON DEVICE
4. ADD BUFFER AND READ RESULTS

IgM/IgG Detectable Test Window

On-Site Testing Specialists 5308 Park Ave, Bethel Park, PA 15102
Phone: (866) 833-2101
www.ostsus.com
COVID-19
IgM/IgG Antibody Rapid Test

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.
### 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 Test)</td>
<td>IgM Ab</td>
</tr>
<tr>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
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<td>+</td>
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</tbody>
</table>

### Clinical Summary of COVID-19 IgM/IgG

#### For IgM Detection:

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

Relative Sensitivity: 93.7% (86.0% - 97.3%)*
Relative Specificity: 99.1% (96.8% - 99.8%)*
Overall Agreement: 97.7% (95.4% - 98.9%)*
*95% Confidence Interval

#### For IgG Detection:

<table>
<thead>
<tr>
<th>Method</th>
<th>Convalescent Samples</th>
<th>PCR-</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 IgM/IgG Rapid Test</td>
<td>IgG+</td>
<td>82</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>IgG-</td>
<td>1</td>
<td>224</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>83</strong></td>
<td><strong>227</strong></td>
<td><strong>310</strong></td>
</tr>
</tbody>
</table>

Relative Sensitivity: 98.8% (93.5% - 99.8%)*
Relative Specificity: 98.7% (96.2% - 99.5%)*
Overall agreement: 98.7% (96.7%-99.5%)*
*95% Confidence Interval