Anti-SARS-CoV-2 Rapid Test

A rapid one-step antibody test

(IgM and IgG)

FDA Emergency Use Authorization (EUA) Approved
Anti-SARS-CoV-2 Rapid Test

When you suspect the worst, time is everything.

**Anti-SARS-CoV-2 Rapid Test** is a rapid, one-step lateral flow assay intended for the qualitative detection and differentiation of IgM and IgG antibodies to the SARS-CoV-2 virus in patients suspected of a COVID-19 infection.

By using a patient’s serum, or plasma specimen, the **Anti-SARS-CoV-2 Rapid Test** offers a turnaround time of only 15 minutes.

Every moment matters in a crisis. We’re here to partner with you in your effort to **SAVE LIVES** by delivering rapid results.
Procedure
Add 5µL of the serum or plasma sample into each sample well. Then add 60µL (2 drops) of the Running Buffer. For each sample, use a separate tip and Cassette.

Please refer to IFU for full interpretation guidelines

<table>
<thead>
<tr>
<th>TEST RESULTS</th>
<th>INTERPRETATION</th>
<th>MOLECULAR TEST NEEDED?</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM neg – IgG neg, no symptoms</td>
<td>Pt not suspected of having COVID-19.</td>
<td>NO</td>
</tr>
<tr>
<td>IgM neg – IgG neg, with symptoms</td>
<td>Pt could have been recently infected and is in the lag period for the test. Retest later or proceed immediately to the molecular test.</td>
<td>YES</td>
</tr>
<tr>
<td>IgM pos – IgG pos</td>
<td>Active case – Pt is infective and must be isolated.</td>
<td>CONFIRMATION RECOMMENDED</td>
</tr>
<tr>
<td>IgM pos – IgG neg</td>
<td>Active case – Pt is infective and must be isolated. Pt has been recently infected.</td>
<td>CONFIRMATION RECOMMENDED</td>
</tr>
<tr>
<td>IgM neg – IgG pos</td>
<td>Pt may have had an infection previously, but recovered. Further molecular testing for the virus is needed to determine if the Pt is still infective to others.</td>
<td>YES</td>
</tr>
</tbody>
</table>

Studies suggest that antibody testing for COVID-19 may provide useful information in managing the infected patient, making determinations as to immune status, and preventing the future spreading of the disease.*

* medrxiv.org/content/10.1101/2020.03.17.20037713v2

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* This test is for use by licensed laboratories and does not apply to at-home testing.
Hardy Diagnostics has a Quality Management System that is certified to ISO 13485 and is a FDA licensed medical device manufacturer.

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