Flowflex™ SARS-CoV-2 Antigen Rapid Test

Provides an aid in identifying individuals suspected of an active COVID-19 infection by their healthcare provider within the first seven (7) days of the onset of symptoms.
Flowflex SARS-CoV-2 Antigen Rapid Test

The Flowflex SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of an active COVID-19 infection by their healthcare provider within the first seven days of the onset of symptoms.

- Nasal swab specimens
- Results in 15 minutes
- Excellent performance compared to molecular methods
- Room temperature storage

Clinical Performance

The performance of Flowflex SARS-CoV-2 Antigen Rapid Test was established with 304 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The performance of the Flowflex SARS-CoV-2 Antigen Rapid Test was compared to a RT-PCR method.

Clinical Performance of SARS-CoV-2 Antigen Rapid Test

<table>
<thead>
<tr>
<th>Method</th>
<th>RT-PCR</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Results</td>
<td></td>
</tr>
<tr>
<td>SARS-CoV-2 Antigen Rapid Test</td>
<td>Negative</td>
<td>269</td>
</tr>
<tr>
<td></td>
<td>Positive</td>
<td>33</td>
</tr>
<tr>
<td>Total Results</td>
<td></td>
<td>270</td>
</tr>
<tr>
<td></td>
<td></td>
<td>34</td>
</tr>
<tr>
<td></td>
<td></td>
<td>304</td>
</tr>
</tbody>
</table>

PPA: 97.1% (83.8% - 99.9%)*
NPA: 99.6% (97.7% - 99.9%)*
OPA: 99.3% (97.5% - 99.9%)*

*95% Confidence Intervals

Materials Provided

- Test Cassettes
- Quick Reference Instructions
- Extraction Buffer
- Extraction Buffer Tubes
- Negative Control Swab
- Positive Control Swab
- Nasal Swabs
- Package Insert

Test Procedure and Interpretation

1. Place 4 - 5 drops of the processed specimen in the Sample Well.
2. 15 min. (Do not read after 20 minutes)

Results

- Negative
- Positive
- Invalid

Ordering Information

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Catalog No.</th>
<th>Format</th>
<th>Specimen</th>
<th>Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flowflex SARS-CoV-2 Antigen Rapid Test</td>
<td>L031-11815</td>
<td>Cassette</td>
<td>Nasal swabs</td>
<td>25 Tests/Kit</td>
</tr>
</tbody>
</table>

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