Gently insert the entire absorbent tip of the swab head into 1 nostril (½ to ¾ of an inch). With children, the COVID-19 Antigen Home Test test results may occur.

Do not use the test after the expiration date shown on the test cassette pouch.

Do not use the test if the batch number is not visible or if the packaging is damaged.

Do not reseal any components. Do not use with multiple specimens.

Make sure the Oasis Flex is fully opened and the test result is not invalidated.

Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.

Remove any piercing from the test tube. Do not run on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.

Inadequate or improper nasal swab sample collection may result in false negative test results.

Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution.

The test is intended to be read at 15 minutes. If the test is read before 15 minutes or after 30 minutes, false-negative or false positive results may occur, and the test should be repeated with a new test cassette.

Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.

Do not ingest any components.

The reagent solution in the tube contains hazardous ingredients (see table below). If the solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical assistance.

Note: A false negative result may occur if the swab is not swirled at least 30 seconds or rotated 5 times.

Gently squeeze the tube and dispense 4 drops of solution into the Sample Well. Dispose the tube in the trash.

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

Inhalation: If victim ingested or inhaled; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

SKIN Contact: Take off immediately all contaminated clothing. Wash off immediately with plenty of water and soap.

EYE Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing and consult a physician as appropriate.

INGESTION: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep away from fire.

Immunofluorescent possible after aspiration of vomit. Call a physician or Poison Control Center immediately.

To serve as a procedure control, a red line will always appear in the control line region (C). No apparent red line appears in the test line region (T). This means that no SARS-CoV-2 antigen was detected. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results should be treated as presumptive and confirmed with a molecular diagnostic assay, if necessary, for patient management.

The Flowflex COVID-19 Antigen Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens.

The Flowflex COVID-19 Antigen Test is intended for self-use or lay user testing another in a non-laboratory setting. The Flowflex COVID-19 Antigen Home Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

The novel coronavirus belongs to the bet-family. COVID-19 is an acute respiratory infectious disease. Currently, the patients infected by the novel coronavirus are the main source of infection. Asymptomatic infected people can also be an infected source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 4 days. Main symptoms include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Inhalation: If victim ingested or inhaled; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required. If INGESTION: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep away from fire. Immunofluorescent possible after aspiration of vomit. Call a physician or Poison Control Center immediately.

The Flowflex COVID-19 Antigen Test Home Kit will react with the colored anti-SARS-CoV-2 antibody coated particles, which have been pre-coated on the membrane. The membrane of the test cassette contains anti-SARS-CoV-2 antibodies.

The Flowflex COVID-19 Antigen Test Home Kit contains anti-SARS-CoV-2 antibodies.

The Flowflex COVID-19 Antigen Test Home Kit is intended for self-use or lay user testing another in a non-laboratory setting. The Flowflex COVID-19 Antigen Home Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

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The Flowflex COVID-19 Antigen Home Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in anterior nasal swab specimens only. The intensity of the test line does not necessarily correlate to the severity of the infection.

SARS-CoV-2 Concentration in nasal matrix

<table>
<thead>
<tr>
<th>Number of Positives/Total</th>
<th>% Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 x 10^{-9} TCID_{50}/mL</td>
<td>60/90 100%</td>
</tr>
</tbody>
</table>

The Flowflex COVID-19 Antigen Home Test was established in an all-comers clinical study conducted between March 2021 and May 2021. The study evaluated self-collected or collected by another study participant from 108 individual symptomatic patients (within 7 days of onset) suspected of COVID-19 and 64 asymptomatic patients. All subjects were screened for the presence or absence of COVID-19 symptoms within two weeks of study enrollment. The study was conducted in a simulated household environment at two study sites in U.S. All study participants performed the test unassisted and interpreted the results using only the product labeling. Flowflex COVID-19 Antigen Home Test results were compared to an FDA EUA RT-PCR COVID-19 assay to determine test performance in the table below:

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>172</td>
<td>53</td>
</tr>
<tr>
<td>Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Positive Agreement (PPA) | 100% (95%CI: 97% - 100%)
| Negative Agreement (NPA) | 100% (95%CI: 97% - 100%)

Table 2. Performance of the Flowflex COVID-19 Antigen Home Test in Symptomatic subjects

The Flowflex COVID-19 Antigen Home Test was not affected by any of the potentially interfering substances listed in the table below at the concentrations tested:


The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity, were evaluated. A total of 435 samples were analyzed. Each task was completed by all subjects enrolled by unassisted clinicians or healthcare professional users. After the completion of the test, the subject (or Parent/Legal Guardian) completed a test usability and satisfaction questionnaire. Specifically, 98.8% of subjects indicated that it was easy to see and understand the test results. Untrained lay users missed 7.9% of results compared to a healthcare provider, suggesting that lay users should carefully inspect the test cassette for faint lines. The Invalid Test result for the clinical study, the “invalid” result, would result in a no test result.


Potential Interfering Substances

<table>
<thead>
<tr>
<th>Source /Item</th>
<th>Test Concentration</th>
<th>Cross-Reactivity</th>
<th>Interference Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human coronavirus NL63</td>
<td>1.0 x 10^5 TCID_{50}/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>MERS-coronavirus</td>
<td>7.90 x 10^5 TCID_{50}/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Influenza B</td>
<td>1.04 x 10^6 TCID_{50}/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Legionella pneumophila</td>
<td>2.32 x 10^9 CFU/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
<tr>
<td>Yeast</td>
<td>1.61 x 10^10 CFU/mL</td>
<td>No cross-reactivity</td>
<td>No interference</td>
</tr>
</tbody>
</table>

Endogenous Interfering Substances

The performance of Flowflex COVID-19 Antigen Home Test was in an all-comers clinical study conducted between March 2021 and May 2021. The study conducted 28 days of study enrollment. The study was conducted in a simulated household environment at two study sites in U.S. All study participants performed the test unassisted and interpreted the results using only the product labeling. Flowflex COVID-19 Antigen Home Test results were compared to an FDA EUA RT-PCR COVID-19 assay to determine test performance in the table below:

Table 1. Performance of Flowflex COVID-19 Antigen Home Test in ALL subjects