The novel coronaviruses belong to the genus. 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 infectious source. Based on the current epidemiological data, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

The Flowflex COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals aged 2 years or older. The Flowflex COVID-19 Antigen Home Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

**INTENDED USE**

COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals aged 14 years and older or with adult-like symptoms. The Flowflex COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the qualitative detection of the antigen. This antigen is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results indicate the presence of SARS-CoV-2 antigen. But clinical history and diagnostic test results need to be confirmed. False-negative results can occur if the test is read before 15 minutes or after 30 minutes.

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 test components.

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

The Flowflex COVID-19 Antigen Home Test is a qualitative test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens.

The Flowflex COVID-19 Antigen Home Test is performed using anterior nasal swab specimens. The Flowflex COVID-19 Antigen Home 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.

**PRECAUTIONS**

- Do not use on anyone under two years of age. Keep test kit materials out of the reach of children and pets, before and after use.
- Do not open the kit contents until ready to use. If the test cassette is open for more than 1 hour, invalid results may occur.
- Do not use the test after the expiration date shown on the test cassette pouch.
- Do not use kit components after the expiration date shown on the test cassette pouch.
- Do not reuse any kit components. Do not use with multiple specimens.
- Do not use the test for diagnosis or monitoring of immune response.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercing from the nose before starting the test. Do not use on anyone who is prone to nosebleeds or has had facial injuries or head/surgery in the past 6 months.
- Do not test for the presence of SARS-CoV-2 antigen immediately after a nasal irrigation.

**SUMMARY AND EXPLANATION**

The Flowflex COVID-19 Antigen Home Test is a qualitative test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens. The Flowflex COVID-19 Antigen Home Test is performed using anterior nasal swab specimens. The Flowflex COVID-19 Antigen Home 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.

**INTERPRETATION OF RESULTS**

- **POSITIVE** Two distinct red lines appear. One red line in the control line region (C) and the other red line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected, and the patient is very likely to be infected with the virus and presumed to be contagious. Results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and contact tracing) in making clinical diagnosis and patient management decisions. Patient management should follow current CDC guidelines.
- **NEGATIVE**: Only one red line appears. One red line in the control line region (C). This means that the flow cassette with SARS-CoV-2 antigen was not detected, and the patient is very likely not to be infected with the virus and presumed to be non-contagious. Results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and contact tracing) in making clinical diagnosis and patient management decisions. Patient management should follow current CDC guidelines.
- **INVALID**: Control line fails to appear. Insufficient specimen volume or incorrect operation is the most likely reason for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, call (800) 838-9502 for assistance.

**SPECIMEN COLLECTION AND PREPARATION**

The Flowflex COVID-19 Antigen Home Test is performed using anterior nasal swab specimens. Wash or sanitize your hands before and after testing. To collect an anterior nasal swab sample:

1. Gently insert the entire absorbent tip of the swab head into 1 nostril (1% to 1% of an inch) with children, the maximum depth of insertion into the nostril may be less than 1/4 of an inch, and you may need to have a second person to hold the child’s head while swabbing.

**Note:** A false negative result may occur if the nasal swab specimen is not properly collected.

2. Firmly sub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen. Do not allow the swab to come in contact with any nasal drainage that may be present on the swab. Repeat this in the other nostril using the same swab.

3. Remove the swab from the nostril and place into the extraction buffer tube.

**QUALITY CONTROL**

Internal procedural controls are included in the test. A red line appearing in the control line region (C) of an internal procedural control indicates that the procedural control line indicates that the flow of specimen has been added and background flow has occurred. If the procedural control line does not develop in 15 minutes, the test result is consider invalid, and repeating with a new cassette is recommended.
12. A positive or negative test result does not rule out co-infections with other pathogens such as other viral symptoms within two weeks of study enrollment. The study was conducted in a simulated home setting. COVID-19 and 64 asymptomatic patients. All subjects were screened for the presence or absence of COVID-

<table>
<thead>
<tr>
<th>Positive Percent Agreement (PPA)</th>
<th>Negative Percent Agreement (NPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>93% (95% C.I.: 81% – 98%)</td>
<td>Specificity: 98%</td>
</tr>
<tr>
<td>Negative</td>
<td>Specificity: 98%</td>
</tr>
<tr>
<td>96% (95% C.I.: 91% – 99%)</td>
<td>Sensitivity: 99%</td>
</tr>
<tr>
<td>93% (95% C.I.: 81% – 98%)</td>
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</tbody>
</table>

The Limit of Detection (LoD) of the FlowCovid-19 Antigen Home Test was determined using dilutions of the heat-inactivated SARS-CoV-2 virus (USA-WA1/2020). Nasal swabs from healthy donors were collected and used for the LoD studies. The PBS buffer (pH 8.0) or saline was used as the clinical matrix to be used as the diluent. Inactivated SARS-CoV-2 virus dilution was used in this negative clinical matrix pool to generate viral titers for LoD testing. The LoD was determined as the lowest virus concentration that was detected ≥ 95% of the time. On this basis, the LoD of this matrix was shown to be ≥ 2.5 x 10^3 TCID50/mL.

11. Test results should be correlated with other clinical data available to the physician.

12. A negative test result does not rule out co-infections with other pathogens such as other viral infections.

13. A positive test result may not indicate infection in patients who have been previously exposed to SARS-CoV-2 virus.

14. A negative test result is not intended to rule out other viral or bacterial infections.

Cytokine Analysis

The performance of FlowCovid-19 Antigen Home Test was established in an all-comers clinical study conducted between March 2021 and May 2021 with 172 nasal swabs self-collected or paired-collected by another study participant from 108 individual symptomatic patients (within 7 days of onset) suspected of COVID-19 and 38 asymptomatic subjects. 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 home setting environment at two study sites in the USA. All patients performed the test unassisted and interpreted the result, using only the product labeling. The FlowCovid-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>Potential Cross Reactions</th>
<th>Concentration</th>
<th>TCID50/mL</th>
<th>Test Concentration</th>
<th>Cross-Reactivity Results</th>
<th>Interference Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>1.50 x 10^5</td>
<td>1.50 x 10^5</td>
<td>2.50 x 10^5</td>
<td>No cross-reactivity</td>
<td>No interference</td>
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