INTENDED USE
The 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 from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

RESULTS

STORAGE AND STABILITY

MATERIALS

The kit can be stored at temperatures between 2 - 30 °C. The test is stable until the expiration date printed on the sealed pouch.

INTENDED USE
The SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care testing. SARS-CoV-2 Antigen Rapid Test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.

SUMMARY
The novel coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. People infected with the virus develop respiratory symptoms such as cough, fever, fatigue. In severe cases, it can lead to pneumonia. 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.

PRINCIPLE
The SARS-CoV-2 Antigen Rapid Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab specimens. When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the anti-SARS-CoV-2 antibody-coated particles, which have been pre-coated on the test strip. The antigen-antibody complexes move across the test strip to the reaction area and are captured by a line of antibody bound on the membrane. Test results are interpreted visually at 15-30 minutes based on the presence or absence of visually colored lines. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENT
The test cassette contains anti-SARS-CoV-2 antibodies. The positive control swab contains SARS-CoV-2 recombinant antigen pre-coated on the swab.

PRECAUTIONS
For professional in vitro diagnostic use only. Do not use after the expiration date. Do not use, drink, or smoke in the area where the specimens or kits is handled. Do not use the test if the pouch is damaged. Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves, mask and eye protection when specimens are being tested. The used test should be discarded according to local regulations. The used test should be considered potentially infectious and be discarded according to local regulations. Humidity and temperature can adversely affect results. This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.

The test line for a high viral load sample may become visible within 15 minutes, or as soon as the sample passes the test line.

The test line for a low viral load sample may become visible within 30 minutes.

The kit can be stored at temperatures between 2 - 30 °C.

The test is stable until the expiration date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not use after the expiration date.

The kit is shelf-stable. Do not refrigerate or freeze.

MATERIALS

- Test Cassettes
- Positive Control Swab
- Disposable Swab*

The Disposable Swabs are produced by another manufacturer.

- Personal Protective Equipment
- Timer

MATERIALS PROVIDED
- Extraction Buffer Tubes
- Negative Control Swab
- Positive Control Swab
- Negative Control Swab
- Personal Protective Equipment
- Timer

- Materials Required But Not Provided
- Extraction Buffer Tubes
- Extractor Pipette

SPECIMEN COLLECTION AND PREPARATION

- The SARS-CoV-2 Antigen Rapid Test can be performed using nasal swab specimens.

- Testing should be performed immediately after specimen collection, or at most within one (1) hour after specimen collection, if stored at room temperature (15-30°C).

- To collect a nasal swab sample:
  1. Carefully insert a Disposable Swab, provided with your kit, into one nostril. Using gentle rotation, push the swab up to 2.5 cm (1 inch) from the edge of the nostril.
  2. Rotate the swab 5 times against the mucosa inside the nostril to ensure sufficient specimen collection.
  3. Using the same swab, repeat this process in the other nostril to ensure that an adequate amount of specimen is collected from both nasal cavities.

- 4. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer tubes.

DIRECTIONS FOR USE

Allow the test and extraction buffer to reach room temperature (15-30 °C) prior to testing.

1. Use an extraction buffer tube for each specimen to be tested and label each tube appropriately.
2. Unscrew the dropper cap from the extraction buffer tube without squeezing.
3. Insert the swab into the tube and wait for 30 seconds. Then rotate the swab at least 5 times while squeezing the sides of the tube. Take care to avoid splashing contents out of the tube.
4. Using the same process, use the swab to extract the liquid from the swab.
5. Screw the dropper cap firmly onto the extraction buffer tube containing the sample. Mix thoroughly by swirling or flicking the bottom of the tube.
6. Remove the test cassette from the foil pouch and use it as soon as possible.
7. Place the test cassette on a flat and clean surface.
8. Add the processed specimen to the sample well of the test cassette.
   a. Unscrew the small cap from the dropper tip.
   b. Insert the extraction buffer tube with the dropper tip pointing downwards and hold it vertically.
   c. Gently squeeze the tube, dispensing 4 drops of the processed specimen into the sample well.
9. Wait for the colored line(s) to appear. The result should be read at 15-30 minutes. Do not read the result after 30 minutes.

INTERPRETATION OF TEST RESULTS

NEGATIVE: Only one control line control line appears in the control region (C). No apparent colored lines appear in the test line region (T). This means that no SARS-CoV-2 antigen was detected.

POSITIVE: Two distinct colored lines appear. One line in the control line region (C) and the other line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected.

*NOTE: The intensity of the color in the test line (T) may vary depending on the level of the SARS-CoV-2 antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL
Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Positive and Negative control swabs are supplied with each kit. These control swabs should be used to ensure that the test cassette and that the test procedure is performed correctly. Follow the "DIRECTIONS FOR USE" section to perform the control test.

The control swabs are the last step of the following circumstances:
1. When new lot of tests are used and/or when a new operator performs the test.
2. At periodic intervals as dictated by local requirements, and/or by the user’s Quality Control procedures.

LIMITATIONS
1. The SARS-CoV-2 Antigen Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of SARS-CoV-2 antigens in nasal swab specimens only. The intensity of the test line does not necessarily correlate with the level of virus in the test specimens.
2. Specimens should be tested as quickly as possible after specimen collection and at most within the hour following collection.
3. Use of viral transport media may result in decreased test sensitivity.
4. A false-negative test result may occur if the level of antigen in a specimen is below the detection limit of the test or if the specimen was collected incorrectly.
5. Test results should be correlated with other clinical data available to the physician.
6. A positive test result does not rule out co-infections with other pathogens.
7. A positive test result does not differentiate between SARS-CoV and SARS-CoV-2.
8. A negative test result is not intended to rule out other viral or bacterial infections.
9. A negative result, from a patient with symptom onset beyond seven days, should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.
10. If the differentiation of specific SARS viruses and strains is needed, additional testing is required.
PERFORMANCE CHARACTERISTICS

The performance of SARS-CoV-2 Antigen Rapid Test was evaluated with 605 nasal swabs collected from individual symptomatic patients who were suspected of COVID-19. The results show that the relative sensitivity and the relative specificity are as follows:

<table>
<thead>
<tr>
<th>Bacteria</th>
<th>Relative Sensitivity: 97.1% (93.1%-98.9%)*</th>
<th>Relative Specificity: 99.5% (98.2%-99.9%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rhinovirus</td>
<td>3.15 x 10^4 TCID50/mL</td>
<td>No</td>
</tr>
<tr>
<td>Human coronavirus</td>
<td>1 x 10^4 TCID50/mL</td>
<td>No</td>
</tr>
<tr>
<td>Chlamydia trachomatis</td>
<td>3.13 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>1.36 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Mycobacterium tuberculosis</td>
<td>1.72 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Mycoplasma pneumonitis</td>
<td>7.90 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>1.38 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td>2.32 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>4.10 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Pneumocystis jiroveci</td>
<td>8.63 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Yeast</td>
<td>1.57 x 10^4 CFU/mL</td>
<td>No</td>
</tr>
<tr>
<td>Pooled human nasal wash</td>
<td>-</td>
<td>No</td>
</tr>
</tbody>
</table>

**RESULTS**

<table>
<thead>
<tr>
<th>Antigen</th>
<th>Concentration</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 Antigen</td>
<td>2.4 mg/mL</td>
<td>3/3 negative</td>
</tr>
<tr>
<td>Enterovirus</td>
<td>0.9% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td>Whole Blood</td>
<td>4% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td>Mucin</td>
<td>0.9% v/v</td>
<td>3/3 negative</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>15% v/v</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Homeopathic</td>
<td>1.10 D10</td>
<td>3/3 negative</td>
</tr>
<tr>
<td>Oxymetazoline</td>
<td>15% v/v</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>15% v/v</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Phenol</td>
<td>15% v/v</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>15% v/v</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Phenol</td>
<td>15% v/v</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Phenylalanine</td>
<td>15% v/v</td>
<td>3/3 positive</td>
</tr>
<tr>
<td>Physiological Swabs</td>
<td>-</td>
<td>No</td>
</tr>
</tbody>
</table>

**Interfering Substances**

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated. Each substance was tested in the absence or presence of SARS-CoV-2 virus at low positive level. The final concentration of the substances tested are listed below and were found not to affect test performance.

**BIBLIOGRAPHY**


**INTERFERENCE**

Interference was observed with the following microorganisms when tested at the concentration presented in the table below. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.