Wash or sanitize your hands.

**specimens.** SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from direct anterior nasal swab.

**SUMMARY and EXPLANATION of the TEST**

**INTENDED USE**

The BinaxNOW COVID-19 Antigen Self Test kit contains all components required to carry out an assay diagnostic for COVID-19, when tested at least three times over five days with at least 48 hours between tests.

**REAGENTS and MATERIALS**

**MATERIALS PROVIDED**

- Test Card (1, 2, 4, 5 or 10)
- A cardboard, book-shaped fiber optic card containing the test strip
- Extraction Buffer (1, 2, 4, 5 or 10)
- Batory containing 5 ml of extraction reagent
- Nasal Swabs (1, 2, 4, 5, or 10)
- Sterile swabs for use with BinaxNOW COVID-19 Antigen Self Test

**WARNINGs, PRECAUTIONS and SAFETY INFORMATION**

1. Wash or sanitize your hands. Make sure they are dry before starting.

**BEFORE STARTING**

1. Wash or sanitize your hands. Make sure they are dry before starting.

**A. PREPARE FOR THE TEST**

Your box may contain more than one test kit. Use only 1 of each of the following for each test:

**1 Swab**

- Test Card in Pouch

- 1 Dropper Bottle

- Timing Device (not included)

**B. COLLECT NASAL SAMPLE**

Up to 3/4 of an inch

Insert the entire soft tip of the swab into a nostril (usually 1/2 to 3/4 of an inch).

You do not need to go deeper.

**1. DO NOT touch any parts on the inside. Handle card only by edges.**

Outside of Card

- Top Hole

- Lower Hole

- Test Strip

- Result Window

- Using the same swab, repeat step 5 in your other nostril.

**2. Remove test card from pouch. Make sure the blue control line is present in the result window. Do not use the card if it is not.**

Open the card and lay it flat on the table with the pink side down. You may bend the spine in the opposite direction to help the card lay flat.

**DO NOT touch the test strip.**

**Card must stay FLAT on table for entire test.**

**3. Remove dropper bottle cap. Hold bottle with fingers over top hole, not at tip, and tip down.**

Put 6 drops to top hole. Do not touch card with tip.

**Note:** Negative result may occur if more than 6 drops of fluid are put on the hole.

**医疗卫生用具についての注意**

**For Use Under an Emergency Use Authorization (EUA) Only**

For in vitro Diagnostic Use Only

**INTENDED USE**

The BinaxNOW COVID-19 Antigen Test is a lateral flow immunoassay intended for the qualitative detection of nucleoprotein antigen from SARS-CoV-2.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 2 years or older. The test is authorized to individuals with symptoms of COVID-19 within the first seven days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The BinaxNOW COVID-19 Antigen Test does not differentiate between SARS-CoV-2 and SARS-CoV-1.

**Results are for the identification of SARS-CoV-2 nucleoprotein antigen, which is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic methods is necessary to determine the cause of disease. Individuals who test positive with the BinaxNOW COVID-19 Antigen Test should self-isolate, seek medical advice from their healthcare provider as appropriate and report their test result through the NAVICA app or to their healthcare provider.

**WARNINGS, PRECAUTIONS and SAFETY INFORMATION**

- Use of gloves is recommended when conducting testing.
- Do not touch test strip.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to false positive, false negative, or invalid result.
- Do not touch or wipe the test card or swab.
- Do not read test results after 30 minutes. Results read after 30 minutes may lead to false positive, false negative, or invalid result.
- Do not touch the test strip.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to false positive, false negative, or invalid result.
- Do not use kit past its expiration date.
- Do not open, break, or bend the test card or swab.

**SUMMARY and EXPLANATION of the TEST**

Coronavirus and other viruses which may cause illnesses in humans or SARS-CoV-2 is an enveloped, single-stranded RNA virus of the genus. SARS-CoV-2 causes mild to severe respiratory illness and is spread globally, including the United States.

The BinaxNOW COVID-19 Antigen Test is a qualitative test for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the product under section 564(a)(3) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b(a)(3), unless the declaration is terminated or authorization is rescinded sooner.

**STORAGE and STABILITY**

Store at between 22 to 25°C (72 to 77°F).

**For more information on EUA please visit:** https://www.fda.gov/coronavirus-disease-2019-covid-19-

**Concentration**

- Sodium Azide (0.50% v/v)

- Sodium Azide (0.20% v/v)

- 16 drops

**Bacterial and viral pathogens. It is recommended gloves (not provided) also be used during testing**

**before starting**

1. Wash or sanitize your hands. Make sure they are dry before starting.

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Your box may contain more than one test kit. Use only 1 of each of the following for each test:

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**DO NOT touch the test strip.**

**Card must stay FLAT on table for entire test.**

**3. Remove dropper bottle cap. Hold bottle with fingers over top hole, not at tip, and tip down.**

Put 6 drops to top hole. Do not touch card with tip.

**Note:** False negative result may occur if more than 6 drops of fluid are put on the hole.
C. PERFORM THE TEST

1. Keep swab FLAT on table.

2. Insert swab tip into lower hole.

3. Firmly push the swab tip from the bottom hole until it is visible in the top hole.

4. Do not remove the swab from the card.

5. Turn swab to right 3 times to mix the swab with drops.

6. Do not skip this step. Leave the swab in the card for the remainder of the test.

7. Note: False negative result can occur if swab is not turned.

D. INTERPRET RESULTS

Recheck testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

| Symptoms | Positive | Negative | Oftentimes Wrong Results
|---|---|---|---|
| COVID-19 | Positive COVID-19 | Negative | False negative result can occur if specimen swabs are not twirled within the test card.
| COVID-19 | Negative | Negative | False negative results may occur if inadequate extraction buffer is used (e.g., <6 drops).
| COVID-19 | Negative | Positive | False negative results may occur if specimen swabs are not twirled within the test card.
| COVID-19 | Positive | Positive | False negative results can occur if swab is not turned.
| COVID-19 | Negative | Negative | False negative results may occur if specimen swabs are not twirled within the test card.

E. DISPOSE THE TEST KIT

Throw away all test kit components in the trash.

F. REPORT YOUR RESULTS

Report your test result through the NAVICA app and by contacting your healthcare provider.

RESULT INTERPRETATION

Positive Result

A negative result means that the virus that causes COVID-19 was not detected in the sample. It is very likely that the individual has COVID-19. Do not contact us.

A positive result means that COVID-19 was detected.

Firmware results may indicate the presence of other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive will be contacted by BinaxNOW in the event of a positive test result.

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Negative Result

A negative result means that COVID-19 was not detected.

C. Check for Positive COVID-19 Result

Find result window and look carefully for two pink/purple lines.

Repeat testing does not need to be performed if patients have a positive result at any time.

D. Check for Negative COVID-19 Result

Find result window and look for a single pink/purple line in window.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if you have symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.

C. Check for In Valid Result

If you see any of these, the test is invalid. An invalid result means this test is not reliable to determine whether you have COVID-19 or not. A new test is needed to get a valid result. Re-test with a new swab and new test device.

Do not remove swab.

E. DISPOSE THE TEST KIT

Throw away all test kit components in the trash.

F. REPORT YOUR RESULTS

Report your test result through the NAVICA app and by contacting your healthcare provider.

RESULT INTERPRETATION

Positive Result

A negative result means that the virus that causes COVID-19 was not detected in the sample. It is very likely that the individual has COVID-19. Do not contact us.

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- Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.
The performance of the present test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. The testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. Specimen pools were prepared by the RADx team using pooled clinical samples from the Omicron variant. Results from this dilution series cannot be compared to any devices tested with a different dilution series and do not indicate relative performance compared to other EUA-authorized tests. Comparator methods included EIA and RT-PCR method. The Broad NOW COVID-19 Ag Card detected 100% of true-positive Omicron samples at ≥95% sensitivity. Testing was also compared to traditional EUA-authorized EIA antigen tests (Binax NOW and AxSYM). Omicron dilutions at lower virus concentrations (IC50 values greater than 28) were not detected by the BinaxNOW COVID-19 Ag Card.

Limit of Detection (LOD): Study Results

<table>
<thead>
<tr>
<th></th>
<th>LOD (IC50)</th>
<th>% Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenosine</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Human intercalating (IMPS)</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
<tr>
<td>Rhodamine</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
<tr>
<td>Enterprise-CassieB4</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
<tr>
<td>Human coronavirus OC43</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
<tr>
<td>Human coronavirus 29E</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
<tr>
<td>Human coronavirus NL63</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
<tr>
<td>Human parainfluenza virus 3</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
<tr>
<td>Human parainfluenza virus 4</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
<tr>
<td>Influenza A</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Influenza B</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Respiratory Syncytial Virus</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Bordetella pertussis</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Chlamydia pneumoniae</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Hemophilus influenzae</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Legionella pneumophila</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Mycoplasma pneumoniae</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Streptococcus pyogenes (group A)</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Streptococcus pneumonia</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>1.0 x 10^-5</td>
<td>99.0%</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>1.0 x 10^-6</td>
<td>99.0%</td>
</tr>
</tbody>
</table>

Potential Cross-Reaction: Test Concentration

<table>
<thead>
<tr>
<th>Test</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yeast</td>
<td>1.0 x 10^-5/mL</td>
</tr>
</tbody>
</table>

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing. In vitro analysis using the Basic Local Alignment Search Tool (BLAST) at the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

For patients with a history of allergy to mupirocin, the risk of cross-reactivity can be ruled out.

**M. tuberculosis** No protein sequence homology was found between SARS-CoV-2 and M. tuberculosis, and thus homology-based cross-reactivity can be ruled out.

**M. M. abscessus** No protein sequence homology was found between SARS-CoV-2 and M. M. abscessus, and thus homology-based cross-reactivity can be ruled out.

**C. albicans** No protein sequence homology was found between SARS-CoV-2 and C. albicans, and thus homology-based cross-reactivity can be ruled out.

**Candida glabrata** No protein sequence homology was found between SARS-CoV-2 and C. glabrata, and thus homology-based cross-reactivity can be ruled out.

**C. parapsilosis** No protein sequence homology was found between SARS-CoV-2 and C. parapsilosis, and thus homology-based cross-reactivity can be ruled out.