SUMMARY and EXPLANATION of the TEST
Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the Beta genus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States.

The BinaxNOW COVID-19 Antigen Test is a rapid lateral flow immunocassay for the qualitative detection of SARS-CoV-2 directly from anterior nasal swabs, without viral transport media. The BinaxNOW COVID-19 Antigen Test kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLES of the PROCEDURE
The BinaxNOW COVID-19 Antigen Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from direct anterior nasal swab specimen. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support at two distinct lines and combined with other reagents/label to construct a test strip. This test strip and a well to hold the specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card.

To perform the test, an anterior nasal swab specimen is collected by the patient, then 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes.

REAGENTS and MATERIALS
Materials Provided
Test Cards (22): A cardboard, book-shaped hinged test card containing the test strip
Extraction Reagent (22): Bottle containing 4 mL of extraction reagent
Nasal Swabs (22): Sterile swab for use with BinaxNOW COVID-19 Antigen Test Patient Instructions for Use (1)
Individual Test Sheet (1)

PRECAUTIONS
1. For in vitro diagnostic use.
2. This test has not been FDA cleared or approved but has been authorized by FDA under an EUA.
3. Wear a safety mask or other face covering when collecting anterior nares swab specimen from a child or another individual.
4. Use of gloves is recommended when conducting testing.
5. Keep testing kit and kit components out of the reach of children and pets before and after use.
6. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
7. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bb-b(30)(B), unless the declaration is terminated or authorization is revoked sooner.
8. Proper sample collection and handling are essential for correct results.
9. Do not use a kit that has been opened and/or tampered with.
10. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
11. Do not dip the swab into the liquid reagent or other liquid before inserting the swab into the nose.
12. Do not touch swab tip when handling the swab sample.
13. Do not use kit past its expiration date.
14. Do not mix components from different kit lots.
15. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card or swab.
16. Dispose of kit components and patient samples in household trash.
17. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold bottle vertically, 1/2 inch above the swab well, and add drops slowly.
18. The Reagent Solution contains a harmful chemical (see table below). If the solution contacts the skin or eyes, flush with copious amounts of water. If irritation persists, seek medical advice: https://www.poison.org/contact-us-1-800-222-1222

TABLE

<table>
<thead>
<tr>
<th>Chemical Name/CAS</th>
<th>GHS Code for Each Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Azide/26628-22-8</td>
<td>Acute Tox. 2 (Oral), H300</td>
<td>0.0125%</td>
</tr>
<tr>
<td></td>
<td>Acute Tox. 1 (Dermal), H310</td>
<td></td>
</tr>
</tbody>
</table>

STORAGE and STABILITY
Store kit between 35.6 - 86°F (2-30°C). Ensure all test components are at room temperature before use. The BinaxNOW COVID-19 Antigen Test is stable until the expiration date marked on the outer packaging and containers.
**DIRECTIONS FOR RUNNING THE BINAXNOW COVID-19 AG CARD SELF TEST**

Carefully read instructions prior to starting test. 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.

### A. PREPARE FOR THE TEST

<table>
<thead>
<tr>
<th>1 Swab</th>
<th>1 Test Card in Pouch</th>
<th>1 Dropper Bottle (not included)</th>
<th>Timing Device</th>
</tr>
</thead>
</table>

**DO NOT** touch any parts on the inside. Handle card only by edges. Card must stay FLAT on table for entire test.

1. Remove test card from pouch and lay flat on table. The card must stay flat on the table for the entire test.

Make sure the blue control line is present in the result window. If a blue line is not present, **do not** use this card.

Open card flat on table. You may bend the spine in the opposite direction to help the card lay flat.

2. Remove dropper bottle cap. Hold dropper bottle straight over top hole, not at an angle.

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

**Note:** False negative result may occur if less than 6 drops of fluid are put in the hole.

### B. COLLECT NASAL SAMPLE

1. **Keep fingers away from the swab end.**

2. Open swab package at stick end. Take swab out.

3. **Swab both nostrils carefully as shown.**

   - 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.

4. Using medium pressure, rub the swab against all of the inside walls of your nostril.

   Make at least 5 big circles. Do not just spin the swab.

   Each nostril must be swabbed for about 15 seconds.

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

**Stop**

Check: Did you swab BOTH nostrils?

**Note:** False negative result may occur if the nasal swab is not properly collected.
C. PERFORM THE TEST

1. Keep card FLAT on table.

6. Insert swab tip into bottom hole.

- Firmly push the swab tip from the bottom hole until it is visible in the top hole.
- Do not remove the swab from the card.

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

- Do not skip this step.

8. Peel adhesive liner off. Be careful not to touch other parts of card.

- Close left side of card over swab. Press firmly on the two lines on right edge of card to seal.

- Keep card face up on table.

- DO NOT move or touch the card during this time.

9. Wait 15 minutes.

- Read the result at 15 minutes.

- Do not read the result before 15 minutes or after 30 minutes.

Note: A control line may appear in the result window in a few minutes but a sample line may take as long as 15 minutes to appear.

Note: Results should not be read after 30 minutes.

D. INTERPRET RESULTS

A. Check for Positive COVID-19 Result

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

- **Positive Result:** If you see two pink/purple lines (one on the top half and one on the bottom half), this means COVID-19 was detected.

- **CONTROL**

- **SAMPLE**

- **Positive**

- **Positive**

- Look very closely! The bottom line can be very faint. Any pink/purple line visible here is a Positive Result.

- Below are photos of actual positive tests. On the right, note how faint the bottom line can get.

B. Check for Negative COVID-19 Result

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

- **Negative Result:** If you see only one pink/purple line on the top half, where it says “Control” this means COVID-19 was not detected.

- **CONTROL**

- **SAMPLE**

- No Line

C. Check for Invalid Result

- If you see any of these, the test is invalid. An invalid result means this test was unable to determine whether you have COVID-19 or not. A new test is needed to get a valid result.

- Please contact Technical Support at +1 833-637-1594

- **CONTROL**

- **SAMPLE**

- Blue control line only

- No lines seen

- Pink/purple sample line only

- Blue control line AND pink/purple sample line

Note: See other side to read about what your results mean.

E. DISPOSE THE TEST KIT

- Throw away all used test kit components in the trash.

F. REPORT YOUR RESULTS

- Please share your test result with your health care provider.