The BinaxNOW COVID-19 Antigen Self Test is intended for non-prescription self-use and, as applicable for an adult to test a user 2 years of age or older without the assistance of a healthcare provider. The BinaxNOW COVID-19 Antigen Self Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

**SUMMARY and EXPLANATION of the TEST**

Concomitants 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 genus. The virus can cause mild to severe respiratory illness and spread globally, including the United States.

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

**PRINCIPLES of the PROCEDURE**

The BinaxNOW COVID-19 Antigen Self Test is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from direct anterior nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and well to hold the swab 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 this test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visual detectable purple or blue color lines. Results should not be read after 30 minutes.

**STORAGE and STABILITY**

- **Temperature:** The kit should be stored at room temperature (68°F to 77°F) and does not need to be refrigerated before use.
- **Expiration:** The kit is valid for 24 months from the manufacture date. The expiration date is located on the outer packaging and containers.
- **Handling:** Do not touch the test strip after removing the outer packaging and containers.

**DIRECTIONS FOR RUNNING the BINAXNOW COVID-19 CARD SELF TEST**

**Before starting.** Carefully read instructions prior to starting test. It is recommended gloves (not provided) also be used during testing.

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

**A. PREPARE FOR THE TEST**

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

1. Swab
2. 1 Test Card in Pouch
3. 1 Dropper Bottle
4. Timing Device (not included)

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

**Outside of Card**

**Inside of Card**

**B. COLLECT NASAL SAMPLE**

1. **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.

2. **At least 5 big circles**
   - Do not just spin the swab.
   - Each nostril must be swabbed for about 15 seconds.

3. **At least 5 big circles**
   - Using the same swab, repeat step 5 in your other nostril.

**Do not touch card with tip.**

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

1. 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.**

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.

3. Hold dropper bottle straight. Y ou may bend the spine in the opposite direction to help the card lay flat.

**DO NOT touch the test strip.**

4. **6 drops**
   - Make at least 6 drops over the bottom hole.
   - Y ou may bend the spine in the opposite direction to help the card lay flat.

5. **At least 5 big circles**
   - Do not put 6 drops on 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 more than 6 drops of fluid are put in the hole.

**A. PREPARE FOR THE TEST**

1. Swab
2. 1 Test Card in Pouch
3. 1 Dropper Bottle
4. Timing Device (not included)

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

**Outside of Card**

**Inside of Card**

**B. COLLECT NASAL SAMPLE**

1. **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.

2. **At least 5 big circles**
   - Do not just spin the swab.
   - Each nostril must be swabbed for about 15 seconds.

3. **At least 5 big circles**
   - Using the same swab, repeat step 5 in your other nostril.

**Do not touch card with tip.**

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

1. 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.**

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.

3. Hold dropper bottle straight. Y ou may bend the spine in the opposite direction to help the card lay flat.

**DO NOT touch the test strip.**

4. **6 drops**
   - Make at least 6 drops over the bottom hole.
   - Y ou may bend the spine in the opposite direction to help the card lay flat.

5. **At least 5 big circles**
   - Do not put 6 drops on 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 more than 6 drops of fluid are put in the hole.
C. PERFORM THE TEST

1. Keep card 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 the drops.
6. Do not step this tip. Leave the swab in the card for the remainder of the test.

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

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.

Note: False negative results can occur if specimen swabs are not twirled within the test card. False negative results may occur if inadequate extraction buffer is used (e.g., <6 drops).

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.

C. Check for Invalid Result

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

1. Do NOT remove swab.
2. Peel adhesive liner off. Be careful not to touch other parts of card.
3. Peel close left side of card over swab. Press firmly on the two lines on right edge of the card to seal.
4. Keep card face up on table.

1. Do NOT move or touch the card during this time.
5. Wait 15 minutes.
6. 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. Results should not be read after 30 minutes.

D. REPORT YOUR RESULTS

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

Note: If you do not have symptoms, a second test should be taken at least 24 hours (and no more than 48 hours) between tests.

PERFORMANCE CHARACTERISTICS

Clinical Performance

Clinical performance characteristics of BinaxNOW COVID-19 Antigen Test were evaluated in an ongoing multi-site prospective study in the U.S. A total of 41 (2 investigational sites, 19 non-sterile site) were included in the study. Patient results were interpreted at the participating study centers, patients had to be presenting at the participating study centers with suspected COVID-19 within 7 days of symptom onset. All subjects were enrolled in BinaxNOW COVID-19 Antigen Test Self. Under the observation and coaching of a clinical site staff member trained as a proctor, the subject self-collected one (1) nasal swab and performed the BinaxNOW COVID-19 Antigen Test. Test results were interpreted and recorded by the subject or other home user and independently by the proctor. Patients of pediatric subjects under the age of 14 in Legally Authorized Representatives of adult Subjects unable to perform self-collection collected one (1) nasal swab from the subject, performed the BinaxNOW COVID-19 Antigen Test, then interpreted and recorded the result for the study. An FDA Emergency Use Authorization real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study. The performance of BinaxNOW COVID-19 Antigen Test Self was established with 53 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

BinaxNOW COVID-19 Antigen Self Test Performance within 7 days of symptom onset against the Comparator Method

<table>
<thead>
<tr>
<th>Days Since</th>
<th>Symptom Onset</th>
<th>Cumulative</th>
<th>Cumulative</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset</td>
<td>RT-PCR</td>
<td>Antigen</td>
<td>Antigen</td>
<td>Total</td>
<td>Agreement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive (%)</td>
<td>Positive (%)</td>
<td>Positive (%)</td>
<td></td>
<td></td>
<td></td>
<td>Positive (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-2</td>
<td>100</td>
<td>100</td>
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<td>100</td>
</tr>
<tr>
<td>3-4</td>
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</tr>
<tr>
<td>5</td>
<td>100</td>
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<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
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<td></td>
<td>100</td>
</tr>
<tr>
<td>6</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td></td>
<td></td>
<td>100</td>
</tr>
</tbody>
</table>

A cohort of patients who presented with symptom onset greater than seven days were enrolled in the clinical study (n = 165). The positive agreement in patients with symptoms greater than seven days was 80% (95% CI: 70.6% - 89.5%). The negative agreement was 99% (95% CI: 98.8% - 99.9%). False negative results are more likely after eight days or more of symptoms.

E. DISPOSE THE TEST KIT

Throw away all used test kit components in the trash.

F. REPORT YOUR RESULTS

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

Note: If you do not have symptoms, a second test should be taken at least 24 hours (and no more than 48 hours) between tests.
For 140.6 TCID50/mL. (i.e., concentration at which at least 19 out of 20 replicates tested positive). Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this swab specimens were eluted in PBS. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in the natural nasal swab matrix pool to generate virus dilutions for testing. Contained nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure. The LOD was determined as the lowest virus concentration that was detected ≥95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The BinaxNOW COVID-19 Antigen Test LOD in natural nasal swab matrix was confirmed 140.6 TCID50/mL.

| Limit of Detection (Analytical Sensitivity) | BinaxNOW COVID-19 Antigen Test limit of detection (LOD) was determined by evaluating different concentrations of heat inactivated SARS-CoV-2 virus. Pretreated negative natural nasal swab specimens were eluted in PBS. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in the natural nasal swab matrix pool to generate virus dilutions for testing. Contained nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure. The LOD was determined as the lowest virus concentration that was detected ≥95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The BinaxNOW COVID-19 Antigen Test LOD in natural nasal swab matrix was confirmed 140.6 TCID50/mL. |

| Limit of Detection (LOD) Study Results | For 140.6 TCID50/mL. (i.e., concentration at which at least 19 out of 20 replicates tested positive). Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this swab specimens were eluted in PBS. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in the natural nasal swab matrix pool to generate virus dilutions for testing. Contained nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure. The LOD was determined as the lowest virus concentration that was detected ≥95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive). The BinaxNOW COVID-19 Antigen Test LOD in natural nasal swab matrix was confirmed 140.6 TCID50/mL. |

| Cross Reactivity (Analytical Specificity) and Microbial Interference | Cross reactivity and potential interference of BinaxNOW COVID-19 Antigen Test was evaluated by testing 37 commensal and pathogenic microorganisms (8 bacteria, 14 viruses, 1 yeast and pooled human nasal wash) that may be present in the nasal cavity. Each of the organism, viruses, and yeast were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (45 TCID50/mL). No cross-reaction or interference was seen with the following microorganisms when tested at the concentration presented in the table below. |

| Endogenous Interfering Substances | The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the BinaxNOW COVID-19 Antigen Test at the concentrations listed below and were found not to affect test performance. |

<table>
<thead>
<tr>
<th>Substance</th>
<th>Active Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endogenous</td>
<td>Whole Blood</td>
<td>2% w/w</td>
</tr>
<tr>
<td>OTC Nasal Drops</td>
<td>Phenytoin</td>
<td>15% w/w</td>
</tr>
<tr>
<td>OTC Nasal Gel</td>
<td>Sodium Chloride (i.e. NaCl)</td>
<td>5% w/w</td>
</tr>
<tr>
<td>OTC Nasal Spray 1</td>
<td>Cinnamyl</td>
<td>15% w/w</td>
</tr>
<tr>
<td>OTC Nasal Spray 2</td>
<td>Oxytetracycline</td>
<td>15% w/w</td>
</tr>
<tr>
<td>OTC Nasal Spray 3</td>
<td>Fluorocinolide</td>
<td>5% w/w</td>
</tr>
<tr>
<td>Streptococcus</td>
<td>Berezovskae, Menthol</td>
<td>0.95% w/w</td>
</tr>
<tr>
<td>OTC Homeopathic Nasal Spray 1</td>
<td>Galachamica Sinusia, Sinusitis, Luffa opperculata</td>
<td>20% w/w</td>
</tr>
<tr>
<td>OTC Homeopathic Nasal Spray 2</td>
<td>Zynoon glomerum (i.e. Zynum)</td>
<td>5% w/w</td>
</tr>
<tr>
<td>OTC Homeopathic Nasal Spray 3</td>
<td>Aleurel</td>
<td>16% w/w</td>
</tr>
<tr>
<td>OTC Homeopathic Nasal Spray 4</td>
<td>Fucusacite Properitate</td>
<td>5% w/w</td>
</tr>
<tr>
<td>Oral Throat Pain Spray</td>
<td>Phenol</td>
<td>15% w/w</td>
</tr>
<tr>
<td>Anti-Singal Drug</td>
<td>Tamfuz (Ocham Khan Phospha)</td>
<td>0.5% w/w</td>
</tr>
<tr>
<td>Antibiotic, Nasal Ointment</td>
<td>Mupirocin</td>
<td>0.25% w/w</td>
</tr>
<tr>
<td>Antibacterial, Systemic</td>
<td>Tobramycin</td>
<td>0.0004% w/w</td>
</tr>
</tbody>
</table>

1 Testing demonstrated false negative results at concentrations of 5 mg/mL (0.5% w/v). Standard dose of nasal ointment: 20 mg (2% w/w) of mupirocin in single-use 1-gram tubes. No high dose hook effect was observed when tested with up to a concentration of 1.6 x 10^6 TCID50/mL. Inactivated SARS-CoV-2 virus with the BinaxNOW COVID-19 Antigen Test.

Healthy volunteers, including individuals (n=50) and caregivers (n=50), participated in the study. Each individual or caregiver pair participated in a 6-minute session with a study moderator. The usability evaluation session included one simulated use of the BinaxNOW COVID-19 Antigen Test, knowledge tasks, and opportunities to provide feedback.

The sponsor also submitted an usability study for the eInstruction. The goal of the usability study was to demonstrate that lay users can use paper instructions or digital (mobile app or websites) instructions (i.e., paper Quick Reference Guide (QRG), digital app, Quick Reference Instructions (QRI), or website electronic Instructions for Use (eIFU)) to perform the test steps for the BinaxNOW COVID-19 Antigen Test successfully.

The study was conducted at usability labs in Chicago, IL, USA on June 15 – June 23, 2021. A total of 60 lay users, including individuals (n=30) and caregivers (n=30), participated in the study. Each individual or caregiver pair participated in a 6-minute session with a study moderator. The usability evaluation session included one simulated use of the BinaxNOW COVID-19 Antigen Test, knowledge tasks, and opportunities to provide feedback.

<table>
<thead>
<tr>
<th>Symbols</th>
<th>This symbol indicates the product is for single-use only. It is not to be re-used.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>This symbol indicates that you should consult the instructions for use.</td>
</tr>
<tr>
<td></td>
<td>This symbol indicates the name and location of the product manufacturer.</td>
</tr>
<tr>
<td></td>
<td>This symbol indicates the product’s catalog number.</td>
</tr>
<tr>
<td></td>
<td>DVD</td>
</tr>
<tr>
<td></td>
<td>The symbol indicates the total number of tests provided in the kit.</td>
</tr>
</tbody>
</table>

| Technical Support Advice Line | US +1 833-637-1594 ts.ser@abbott.com |

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IN195151-508 Rev. 4 2022/05