



# BinaxNOW™ COVID-19 Ag CARD

## Aculabs Client Protocol

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**NOTICE: PLEASE READ ALL INSTRUCTIONS CAREFULLY AND IN FULL BEFORE PERFORMING TEST.**

*The BinaxNOW™ COVID-19 Ag CARD is approved under Emergency Use Authorization (EUA) Only. Any deviation from the protocol is not permitted and will change test from waived to laboratory-developed and you will need to validate the test and get state-approval to perform testing. The protocol must be followed as it is written.*

**SECTION 1A) STORAGE:**

- Kits can be kept at 2-30°C until expiration.
- Do not return the nasal swab to the original paper packaging.
- Swab must be tested immediately; if immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

**SECTION 1B) USAGE:**

- Only nasal swab is approved. You can use only the swab provided with the kit.
- Positive Swab Control (included in the kit) and Negative Swab Control (sterile unused swabs) will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Make sure to follow the protocol for the controls.

**SECTION 1C) RESULTS:**

- Result must be read promptly at 15 minutes and not before; result should not be read after 30 minutes.
  - Individuals with color-impaired vision may not be able to adequately interpret test results. Please see the included color blindness screening sheet in this packet to determine any issues related to result interpretation.
  - The performance of the assay was established for patient tested within 7 days of the symptoms onset.
  - Negative results for patients with onset of symptoms >7days should be treated as presumptive and confirmed with molecular assay if needed for clinical management.
  - The positive agreement is 75% (25% of patient with COVID-19 with onset of symptoms >7days will be negative in this test) and negative agreement is 92%.
  - All results must be reported to relevant public health authorities.
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## SECTION 2) PERFORMING THE TEST:

**1. Collecting nasal swab:** To collect a nasal swab sample, carefully insert swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinate (less than one inch into the nostril). Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril. Using the same swab, repeat the same sample collection in the other nostril.

**2. Swab must be tested immediately;** if immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

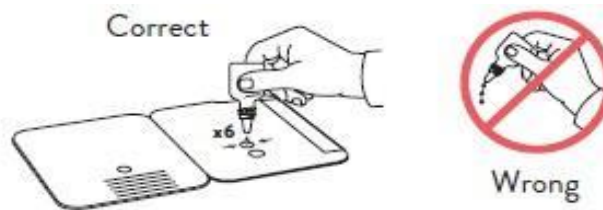
**3. You need to perform positive & negative control for each shipment received and for each untrained operator.**

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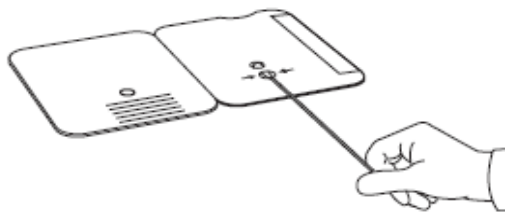
## SECTION 3) PROCEDURE FOR PATIENT SPECIMENS:

Open the test card just prior to use, lay it flat, and perform assay as follows. The test card must be flat when performing testing; do not perform testing with the test card in any other position.

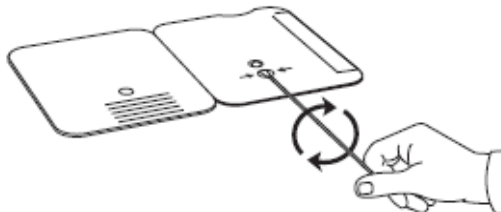
A. Hold Extraction Reagent bottle vertically. While hovering 1/2 inch above the TOP HOLE, slowly add 6 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.



B. Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.



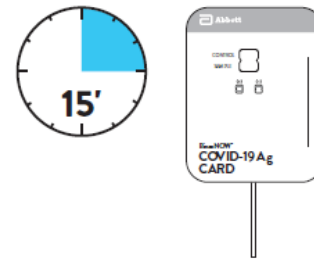
C. Rotate (twirl) swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.



**Note:** False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.

D. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.

E. In an untested BinaxNOW™ COVID-19 Ag CARD, there will be a blue line present at the Control Line position. In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working. If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.

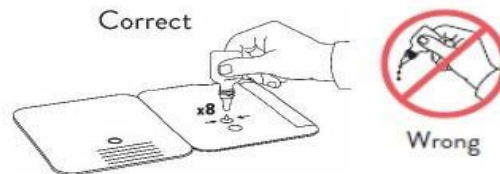


**Note:** When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.

**SECTION 4) PROCEDURE FOR BINAXNOW™ SWAB CONTROLS:**

Open the test card just prior to use, lay it flat, and perform assay as follows.

A. Hold Extraction Reagent bottle vertically hovering 1/2 inch above the TOP HOLE, slowly add 8 DROPS to the TOP HOLE of the swab well. DO NOT touch the card with the dropper tip while dispensing.

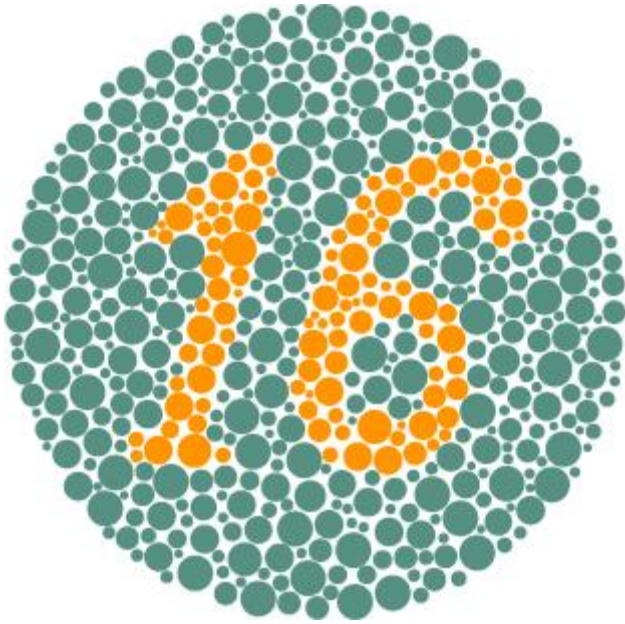


B. Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.

**SECTION 5) RESULT INTERPRETATION:**

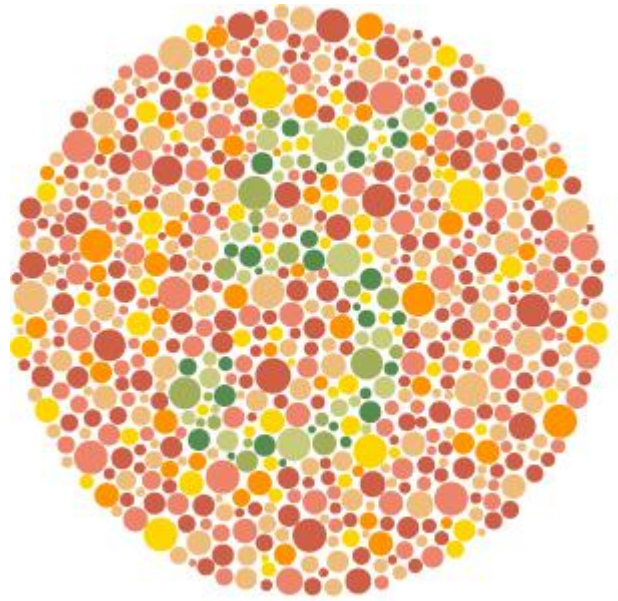
<p><b>Negative</b> A <b>negative specimen</b> will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.</p>	
<p><b>Positive</b> A <b>positive specimen</b> will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint sample Line. Any visible pink/purple colored line is positive.</p>	
<p><b>Invalid</b> If no lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated.</p>	

**Plate 1**



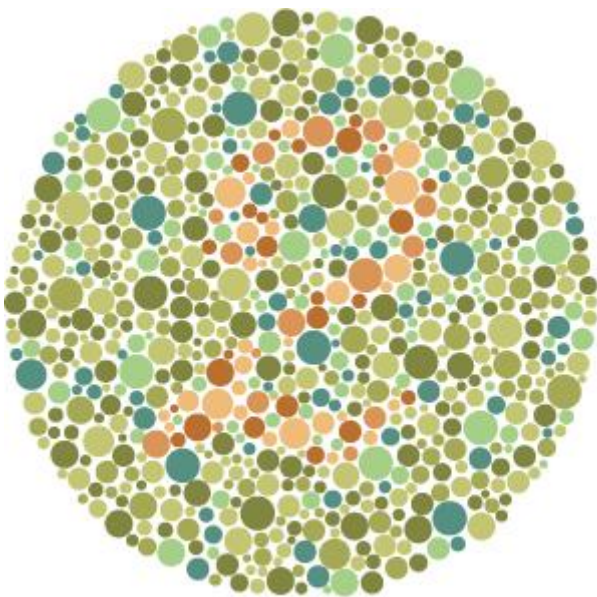
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**Plate 3**



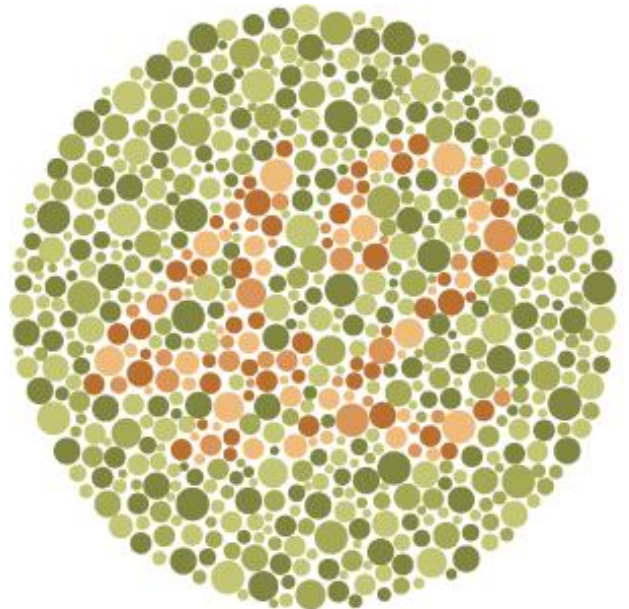
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**Plate 2**



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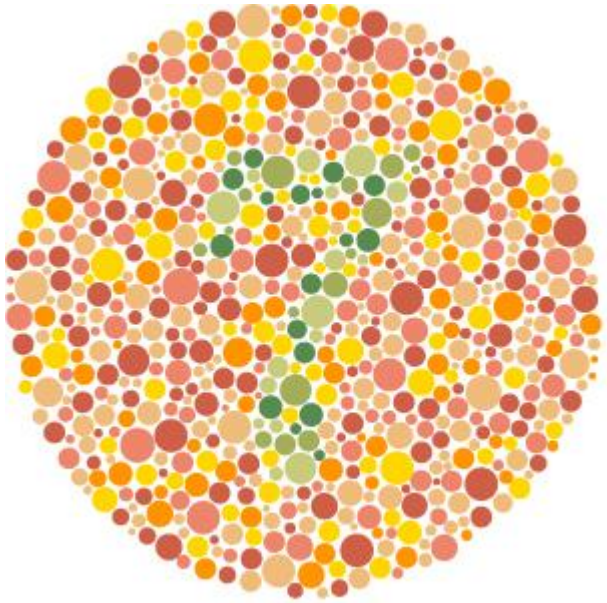
**Plate 4**



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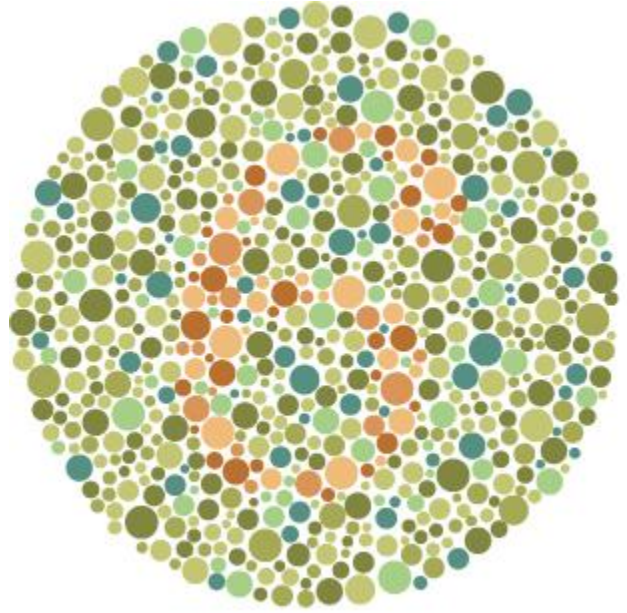


**Plate 5**



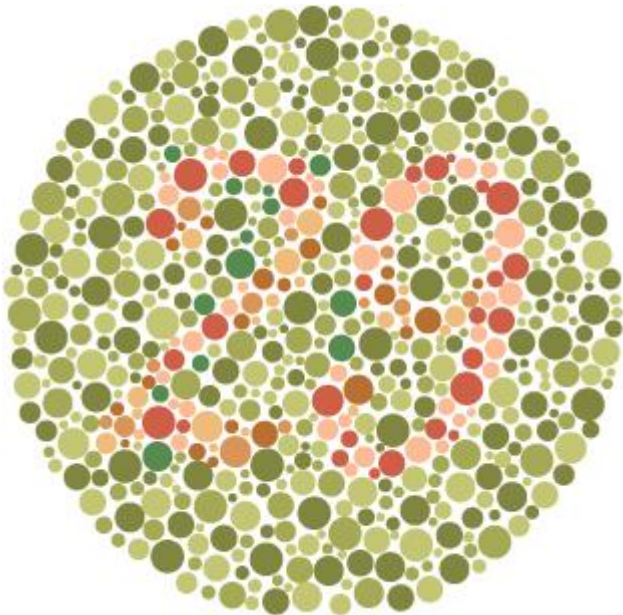
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**Plate 7**



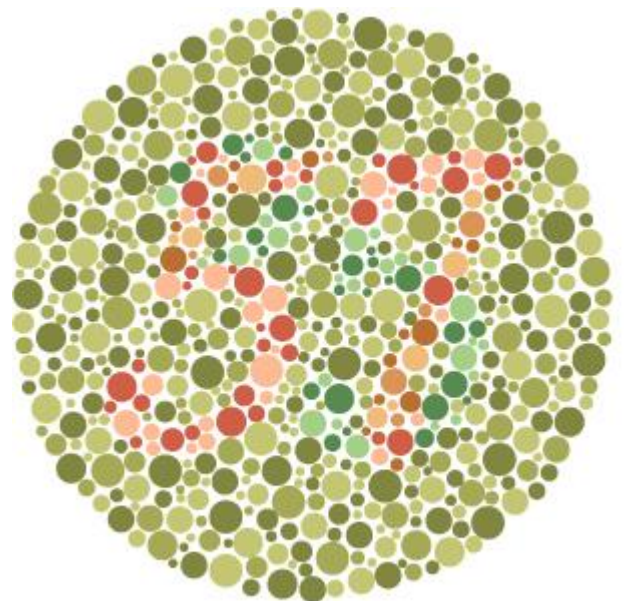
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**Plate 7**



What number do you see on this plate? \_\_\_\_\_

**Plate 8**



What number do you see on this plate? \_\_\_\_\_