BinaxNOW™ COVID-19 Ag Card Quality Control Procedure

BinaxNOW™ COVID-19 Ag Card has built-in procedural controls and daily quality control is recommended, and **should be recorded for each test run.**

- An untested BinaxNOW™ COVID-19 Ag Card has a blue line present at the Control Line position, which is an internal procedural control**. 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**.
- 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.
- The clearing of background color from the result window is a *negative background control.* **The background color in the window should be light pink to white within 15 minutes.**
- Background color should not hinder reading of the test.
- **External Positive & Negative Controls**: Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correct. BinaxNOW™ COVID-19 Ag Card kits contain a Positive Control Swab and Blank Sterile Swabs that can be used as a Negative Control Swab – These swabs will monitor the entire assay.
- **Quality control testing must be performed:**
    1. **When a new shipment box of BinaxNOW™ COVID-19 Ag Card kits is received**
    2. **When a new untrained operator performs the test.**
- Testing sites may test further controls in order to conform to local, state, and/or federal regulations, accrediting groups, or lab's standard QC procedures.

<u>Quality Control Procedure:</u>

*Ensure that all test components are at room temperature (15º-30ºC) before use.

*Remove the test card from its pouch just prior to use and **<u>lay it flat</u>**.

*Be sure there is a blue line present at the Control Line prior to running the test (*discard the test card if there is no blue line*).

<u>Step 1</u>: Add the extraction reagent to the BinaxNOW COVID-19 Ag Card by holding the bottle **vertically** (NOT at an angle), hovering ½ inch above the TOP HOLE, slowly adding eight (8) drops. DO NOT touch the card with the dropper tip while dispensing.

<u>Step 2</u>: Insert *either* the **positive control swab <u>OR</u> a blank negative control** swab into the **BOTTOM HOLE** and firmly push upwards so that the swab tip is **visible** in the **TOP HOLE.**

<u>Step 3</u>: Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). **Do not remove swab**.

Step 4: Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read results in the window **15 minutes** after closing the card (*Note: 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*).

Results Interpretation:

Negative: A negative specimen 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.

Positive: A positive specimen 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 line is positive**.

Invalid: 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.

If the correct control results are not obtained, do not perform patient tests or report patient results. Before testing patient specimens, Abbott Technical Services should be contacted at 1-800-257 9525 between 8am-8pm EST Monday-Friday or by emailing ts.scr@abbott.com. Reports to the FDA (such as suspected false positive or false negative test results) can be made online (see https://www.accessdata.fda.gov/scripts/medwatch/index.cfm).

Disposal: All components of this kit should be discarded as **Biohazard waste**, according to Federal, State, and local regulatory requirements.