**Abbott BinaxNOW™ COVID-19 Ag Card - Training Checklist**

**FACILITY/LABORATORY:**

**USER NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ USER ID:**

| **ITEM DETAILS** |  |  |
| --- | --- | --- |
| **BinaxNOW™ COVID-19Ag CARD - KIT OVERVIEW** | **USER’S INITIALS** | **DATE** |
| The user acknowledges being shown and understands the following kit components and precautions in the package insert:   * Kit Storage temperature * Lot number and expiration date * Package Insert including Precautions and Limitations * BinaxNOW™ COVID-19 Ag Card Procedure Card * Extraction Reagent * Swabs provided in the BinaxNOW™ COVID-19 kit * Patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal. * Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19. |  |  |
| **SPECIMEN COLLECTION, STORAGE AND HANDLING** | **USER’S INITIALS** | **DATE** |
| The user acknowledges being shown; sample collection and storage conditions in the package insert:   * Perform Hand Hygiene and don gloves, N-95/KN-95, gown, and Face Shield. * For use with direct nasal swab specimens with swabs provided in the kit ONLY * To collect a nasal swab sample, carefully insert the 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 sample collection in the other nostril. * Direct nasal swabs should be tested as soon as possible after collection 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 and time collected, 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. DO NOT RETURN THE SWAB TO ITS ORIGINAL PACKAGING |  |  |
| **SAMPLE PREPARATION**  **TEST PROCEDURE FOR QUALITY CONTROL & PATIENT TESTING** | **USER’S INITIALS** | **DATE** |
| The User follows instructions for QC and Patient Testing of BinaxNOW™COVID-19Ag Card. Team members will wear Face Shield and N-95/KN-95 while in the Testing Lab.  The User follows instructions for Patient testing as outlined in the package insert and BinaxNOW™ COVID-19 Ag Card Procedure Card:   * Bring all materials and patient sample to room temperature * Immediately prior test testing open pouch and remove test card and place on a flat surface * Label test card with appropriate QC or Patient Identification information   **For External QC**   1. **Follow instructions for external controls.** Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly adds **8 DROPS** to the **TOP HOLE** of the swab well. DO NOT touch the card with the dropper tip while dispensing. 2. Insert the (+) or (-) control swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE.** 3. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab. 4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. 5. Read result in the window 15 minutes after closing the card. It is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.   **For Patient Testing**   1. 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. 2. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE,** slowly add **6 DROPS** to the **TOP HOLE** of the swab well. DO NOTtouch the card with the dropper tip while dispensing. 3. Insert sample swab into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE.** 4. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab. 5. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. 6. Read result in the window 15 minutes after closing the card. It is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes. 7. Record all results on the Abbott Internal Controls and Testing Log, including the Blue Control Line Present Before Testing, the Resident Test Results, and the Positive and Negative Internal Control results on the test log. Positive Internal Control = The pink-to-purple line at the “Control” position is considered an internal positive procedural control. Negative Internal Control = The background color in the window should be light pink to white within 15 minutes to be considered a negative internal procedural control. |  |  |

**USER SIGNATURE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**TRAINER SIGNATURE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DATE\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**