City of Philadelphia Public Health Department 2230 Cottman Avenue Philadelphia PA 19149 BinaxNOW™ COVID-19 Ag Card - Training Checklist

| FACILITY/LABORATORY: | |
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| | |
| USER NAME: | USER ID: |

| USER NAME: USER ID: | | |
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| ITEM DETAIL C | I | |
| ITEM DETAILS | USER'S INITIALS | DATE |
| BinaxNOW™ COVID-19 Ag CARD - KIT OVERVIEW The user acknowledges being shown and understands the following kit components and | USER S INITIALS | DATE |
| 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. | | |
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| SPECIMEN COLLECTION, STORAGE AND HANDLING | USER'S INITIALS | DATE |
| The user acknowledges being shown; sample collection and storage conditions in the package | | |
| insert: | | |
| 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, 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 | USER'S INITIALS | DATE |
| TEST PROCEDURE FOR QUALITY CONTROL & PATIENT TESTING | | |
| The User follows instructions for QC and Patient Testing of BinaxNOW™ COVID-19 Ag Card. | | |
| 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 Sold test and with appropriate OC or Patient Identification information. | | |
| Label test card with appropriate QC or Patient Identification information. | | |
| For External QC | | |
| 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 | | |

| | ITEM DETAILS | |
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| | 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. | 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 NOT touch the card with the dropper | |
| | tip while dispensing. | |
| 2. | Insert sample 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. | |
| | | |

| USER SIGNATURE | _DATE |
|-------------------|-------|
| | |
| TRAINER SIGNATURE | _DATE |