



## DIGIVAL™ and BinaxNOW™ Influenza A&B Card 2 Training Checklist

FACILITY/LABORATORY: \_\_\_\_\_

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

ITEM DETAILS		
<b>DIGIVAL™ SYSTEM OVERVIEW</b>	<b>USER'S INITIALS</b>	<b>DATE</b>
<p>The user acknowledges being shown and understands the purpose of the following components:</p> <ul style="list-style-type: none"><li>• <u>User Manual and Quick Start Guide</u></li><li>• Analyzer on/off power button, touch screen, reader drawer and tray</li><li>• Power cord and power port</li><li>• USB connectors and purpose</li><li>• Printer (if applicable) with power cords, connectors and paper</li><li>• Barcode scanner functions</li><li>• Touch screen functions (Read Test, Read QC, Calibration Check, Test History, Settings, Preferences, Log Out)</li><li>• Understands default setting of “Read Now mode” or “Walk Away mode”</li><li>• Serial number location and Technical Support contact #</li><li>• Calibration check frequency, proper cleaning and maintenance</li></ul>		
<b>BINAXNOW™ INFLUENZA A&amp;B CARD 2 KIT OVERVIEW</b>	<b>USER'S INITIALS</b>	<b>DATE</b>
<p>The user acknowledges being shown the following kit components and understands storage conditions, precautions, lot # and expiry dates</p> <ul style="list-style-type: none"><li>• Procedural card</li><li>• Package Insert</li><li>• Nasal swabs</li><li>• Elution Solution Vials and transfer pipettes</li><li>• BinaxNOW™ Influenza A&amp;B Card 2 procedure Positive and Negative control swabs</li></ul>		
<b>BINAXNOW™ INFLUENZA A&amp;B CARD 2 SAMPLE REQUIREMENTS</b>	<b>USER'S INITIALS</b>	<b>DATE</b>
<p><b>Sample Requirements</b></p> <ul style="list-style-type: none"><li>• User has been provided appropriate sample collection support documents and training resources.</li><li>• User has reviewed package insert for ACCEPTABLE collection swabs and sample storage conditions and sample testing conditions.</li></ul>		

BINAXNOW™ INFLUENZA A&B CARD 2 WITH THE DIGIVAL™ QC AND PATIENT TEST PROCEDURE	USER'S INITIALS	DATE
<p><b>Test Procedure for QC or Patient sample</b></p> <ol style="list-style-type: none"> <li>1. User follows Universal Precautions when handling samples.</li> <li>2. User follows proper labeling of QC or Patient samples.</li> <li>3. User puts swab to be tested (QC or Patient swab) into the elution solution vial.</li> <li>4. User rotates the swab vigorously 3 times keeping the swab at the bottom of the vial and minimizing bubbles.</li> <li>5. User presses the swab against the side of the vial while turning swab during removal. Swab is discarded into bio hazardous waste container.</li> <li>6. User removes a test card from the pouch and will prepare to remove the liquid from the test vial for testing.</li> <li>7. User squeezes the top bulb of the transfer pipette and then places the tip into the test sample vial.</li> <li>8. User slowly releases pressure on the bulb while the tip is still inserted into the liquid of the test sample vial pulling the liquid into the pipette to completely fill it with no bubbles.</li> <li>9. User then removes the pipette and prepares to express the entire contents of the pipette onto the top half of the WHITE sample pad on the test card.</li> </ol> <p><b>NOTE: The contents of the pipette must be expressed onto the pad in a continuous flow to allow the pad to absorb the sample without interruption.</b></p> <ol style="list-style-type: none"> <li>10. User then peels off the adhesive liner from the test card and closes the card securely.</li> <li>11. User then follows appropriate steps and timing for either “Read Now” or “Walk Away Mode”.</li> </ol> <p><b>NOTE: for “Read Now” mode test cards should be closed with a minimum of 2 minutes between each test card.</b></p>		
DIGIVAL™ CALIBRATION	USER'S INITIALS	DATE
<p><b>Calibration Check (every 30 days)</b></p> <ol style="list-style-type: none"> <li>1. User selects Calibration Check from the Home page.</li> <li>2. User opens the drawer and removes the tray.</li> <li>3. User places the Calibration Check Card into position.</li> <li>4. User closes the drawer and allows calibration to complete.</li> <li>5. When complete, user opens the drawer, removes the Calibration Check Card and returns it to its protective storage bag.</li> <li>6. User replaces the tray and closes the drawer.</li> </ol>		



DIGIVAL™ QC AND PATIENT TESTING	USER'S INITIALS	DATE
<p style="text-align: center;"><b>Quality Control</b></p> <ol style="list-style-type: none"> <li>1. User enters Operator ID then "OK".</li> <li>2. User selects "Read QC" on the menu.</li> <li>3. User scans the Test Device ID with the barcode scanner or manually enters the Test Device ID.</li> <li>4. User selects Positive or Negative then "OK". User reconfirms information on the next screen then presses "OK" if correct.</li> <li>5. User follows step by step sample preparation in the assay Product Insert. Once inoculated, the test card is sealed.</li> <li>6. User follows steps and timing for "Read Now Mode" or "Walk Away Mode".</li> <li>7. User opens drawer, properly places test card into the tray and closes drawer.</li> </ol> <p style="text-align: center;"><b>Patient Test</b></p> <ol style="list-style-type: none"> <li>1. User enters Operator ID then "OK".</li> <li>2. User selects "Read Test" on the menu.</li> <li>3. User scans the Test Device ID with the barcode scanner or manually enters the Test Device ID.</li> <li>4. User scans or manually enters Patient ID then "OK". Reader reconfirms information on the next screen then presses "OK" if correct.</li> <li>5. User follows step by step sample preparation in the assay Product Insert. Once inoculated the test card is sealed.</li> <li>6. User follows steps and timing for "Read Now Mode" or "Walk Away Mode".</li> <li>7. User opens drawer, properly places test card into the tray and closes drawer.</li> </ol>		
BINAXNOW™ INFLUENZA A&B CARD 2 SAMPLE DISPENSE AND READ NOW OR WALK AWAY MODE	USER'S INITIALS	DATE
<p><b>TEST SAMPLE INNOCUATION</b></p> <p>All test samples and materials must be at room temperature prior to testing.</p> <p>Test swabs are eluted into elution solution vials. The entire contents of the transfer pipette (100ul,) are then dispensed onto the WHITE sample pad in ONE CONTINUOUS FLOW to the top half of the white pad.</p> <p><b>Read Now Mode-</b> Test cards must be inoculated and <u>must sit for 15 minutes BEFORE inserting into DIGIVAL™.</u></p> <p><b>Walk Away Mode-</b> Test cards can be inoculated and immediately placed in the DIGIVAL™.</p>		

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

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

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