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BinaxNOW Standard Operating Procedure for Local Health Departments

March 15, 2021

Available electronically at: https://www.coronavirus.kdheks.gov/DocumentCenter/View/1621/LHD-BianaxNOW-SOP

The BinaxNOW™ COVID-19 test is a lateral flow test that detects the presence of protein antigens from SARS-CoV-2 in individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. This diagnostic test does not require any instrumentation to test the specimen and instead determines a COVID-19 negative or positive result using a test card.

Training Requirements for BinaxNOW Test Administration

Personnel conducting the test need to complete the online training (links below). They will also need to perform a validation using the positive and negative controls located in each new box of kits, before patient testing. BinaxNOW trainings: https://www.globalpointofcare.abbott/en/support/product-installation- training/navica-brand/navica-binaxnow-ag-training.html

- KDHE BinaxNOW video: https://www.coronavirus.kdheks.gov/170/Healthcare-Providers (under Videos tab)

Quality Control

There is one set of controls (one positive and one negative) in each box of 40 tests. Quality control must be completed prior to using any tests in a single box. Perform quality control when opening a new box of test kits.
Follow the directions on the procedure card to complete quality control for each new box.

Materials Provided Per Kit

- Test Cards (40): A cardboard, book-shaped hinged test card containing the test strip

- Extraction Reagent (1): Bottle containing 10 mL of extraction reagent

- Nasal Swabs (40): Sterile swabs for use with BinaxNOW™ COVID-19 Ag Card test
- Positive Control Swab (1): Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab
- Negative Control Swab: The use of a sterile patient swab ensures appropriate negative results are obtained
- Product Insert (1)

Testing Population

- This test is best used as a diagnostic test on persons that are symptomatic or asymptomatic and it has been 5 – 7 days since their exposure.
- For diagnostic purposes, persons should **not** be tested with the BinaxNOW card if it has been over seven days since their onset of symptoms; instead testing with a molecular assay (PCR) is recommended.
- This test can also be used for the regular, ongoing screening and testing of asymptomatic and unexposed groups of people for early detection of disease.
- There is a higher chance of false positives when used for this purpose so a positive patient should have a nasopharyngeal swab collected within 48 hours and tested via regular workflow PCR for confirmation at either the state lab or a reference lab.

Specimen Collection and PPE Considerations

- If the specimen collection is self-administered and a trained observer is conducting the test:
    - Best practice to have observer open the test card and the swab right before administering the test.
    - They should wash or sanitize their hands and then wear gloves.
    - Observer should then place the six drops of reagent into the top hole of the card.
    - Ask patient to wash/sanitize their hands. Give them the nasal swab and instruct on proper specimen collection technique.
    - The observer is advised to keep a minimal 6-foot distance from patient during specimen collection.
- If the specimen is collected by a trained person
    - Best practice is to have trained staff open the test card and the swab right before administering the test.
    - They should wash or sanitize their hands and then wear gloves.
    - Trained staff should then place the six drops of reagent into the top hole of the card.
    - Trained persons are required to wear PPE
    - Required PPE include:
        - Gown
        - Surgical mask / respiratory protection
        - Eye protection (e.g., face shield, goggles)
        - Gloves

Specimen Collection Procedures

- Only the swab provided in the kit is to be used for nasal swab collection.
- Have the patient gently blow their nose into a tissue.
- 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 turbinates (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.]
- For best performance, nasal swabs should be tested immediately after collection.
- Do **not** put the swab back in the original packaging
  - It is best to test the swab immediately.
  - If testing is not occurring right away, place the swab in a sterile plastic tube and cap tightly.
  - Keep at room temperature.
  - The Swab can be tested up to one hour, after that it is no longer viable
- A used swab and test kit is considered medical waste; dispose of swabs and used test kits in a biological hazard bag.
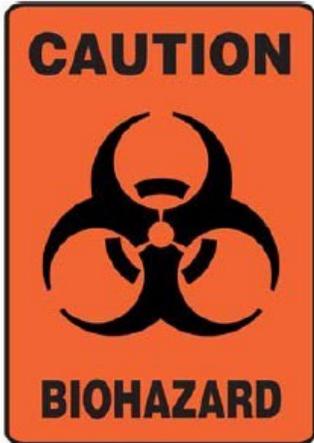

Test Procedure

- Refer to the package insert for instructions for conducting the test.

Reading Results

- A negative specimen will not have any color change on the specimen line. The Control line will give a single pink/purple colored Line in the top half of the window, . The Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

- A positive specimen will give a pink/purple-colored lines for the specimen line and also on the Control line. The Positive on the Specimen line means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint pink color on Sample Line. If both pink/purple-colored lines are visible the test is considered positive.

Positive Result
- Pink/Purple Control Line
- Pink/Purple Sample Line
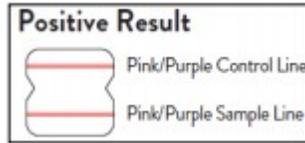
- Tests are considered invalid if:
  - No control lines are present
  - Only the Sample Line is present
  - Blue Control Line does not change to pink
- All invalid tests should be repeated.

Invalid Result
- No Control Line
- Blue Control Line Only
- Sample Line Only
- Blue Control Line / Sample Line
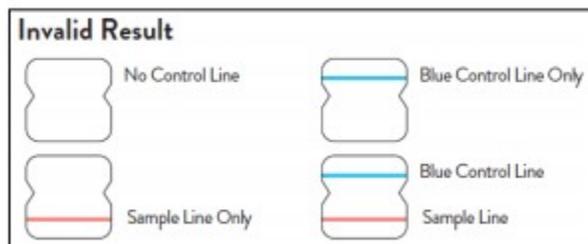
- A positive result may be a false positive and can be confirmed by a molecular assay (PCR).
- Confirmation should be a nasal or nasalpharyngeal swab and should be collected within 48 hours of the positive antigen result.
- These confirmatory swabs can be sent to Kansas Health and Environmental Laboratories or a reference lab.

Reporting Results

- Reporting all laboratory results by using the EpiTrax online disease reporting portal, https://diseasereporting.kdhe.ks.gov is required.
- At the website, download the Online Reporting Portal User Guide which will give you instructions on how to register to use the disease reporting portal.
- Once you have access to the site, use the Bulk Upload button. The screenshot below is what the Bulk Upload page looks like.
- This page has two additional downloads you will need.
  - Download the template and the instructions document.
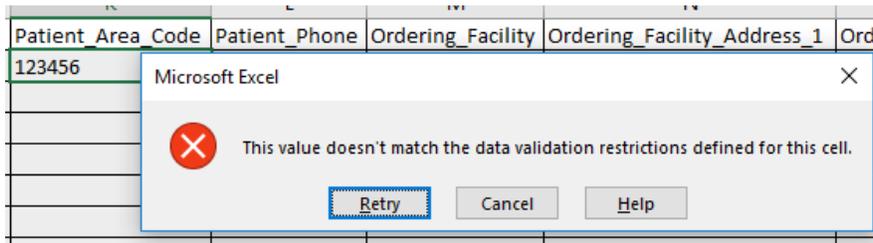 - The instructions explain each of the columns you will need to complete in the file.

- Always download a new Template from the Portal. A good workflow to follow is when you upload your completed file, download a new Template.
  - If you use the same template, some background formatting that isn't visible inside the template will cause the file to fail when we import the data.
- Each of the column headers have tips on how to enter the data. Click on the column header and the tip will display.
- Should you enter data that doesn't meet the data formatting or match the data set, you will see an error message. An example of an error message is on the screenshot below.
- We have programmed the template so that when the Facility is entered, the Ordering Facility and Performing Lab auto populate. Don't worry, the values can be overwritten.
- And if you are doing a large number of reports, you can copy and paste the values into the fields.

- Use the template drop downs to select the values where available
- Be sure the dates are formatted correctly – check the required format
- Do not use commas in the data
- Save the file as CSV (comma delimited) when complete
- Email your first spreadsheet for approval before submitting through the Bulk Upload Portal to: kdhe.epitraxadmin@ks.gov and in the subject line, enter "Encrypted: <Your LHD>"
- KDHE Surveillance Staff will review and work with you to correct any errors so that your upload will be successful.