

PURPOSE: To ensure there is an operating procedure for administering Abbott's BinaxNOW COVID-19 Ag

SCOPE: This procedure applies to anyone administering Abbott's BinaxNOW COVID-19 Ag.

RESPONSIBILITIES: It's the responsibility of XX's Director of Nursing to ensure this process is followed and any administering staff are appropriately trained prior to administration.

REFERENCES:

- <https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html>
- In- Service Training Form (FHR-012)

DEFINITIONS:

BinaxNOW COVID-19 Ag- A lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from nasal swab specimens collected from individual who are suspected of COVID-19.

Direct Exposure- An individual who has had close contact (within 6 feet for a total of 15 minute or more) with a confirmed positive individual without a mask.

RN- Registered Nurse

LPN- Licensed Practical Nurse

FSSA- Indiana Family and Social Services Administration

PPE- Personal Protective Equipment

PROCEDURE:

Training: The agency's director of nursing will ensure all RNs and LPNs are trained appropriately to administer the BinaxNOW COVID-19 test. This will be done by having them first review the informational session put on by Indiana Department of Health and FSSA titled: *BINAXNOW- An informational session for congregate residential and sheltered providers* (December 17, 2020). Once this is complete, each nurse should have an in-service training form (FHR-012) completed and signed off by the director of nursing and put into their HR file. To ensure consistency and continuity with testing administration, only an RN or LPN can administer the BinaxNOW test.

Record Retention: As it relates to the administering of Abbott's BinaxNOW COVID-19 test, XX will ensure documentation is maintained for a minimum of 2 years from the date of testing.

Reordering: It is the responsibility of the nursing assistant to ensure the agency has adequate supplies of testing kits. When additional testing kits are needed, a request should be submitted to the following link

<https://forms.office.com/Pages/ResponsePage.aspx?id=ur-ZIQmkE0-wxBi0WTPYje0OYLmwhVJPIXmS0qxDKj9UMFBXNVEzODIYTzk0UFhIM1JUOVhJNk1CWC4u>

Scheduling: When there is an individual wanting tested for COVID-19 due to direct exposure or the display of symptoms (related to COVID-19), an appointment will need to be made with the agency's nursing assistant (testing will be administered Monday through Friday from 8:00am to 2:00pm). Prior to scheduling an individual for testing the nursing assistant should complete the patient report form (everything should be filled out minus the test results, tester's initials, and reviewer's initials). Once this is complete, the nursing assistant should view each trained nurse's outlook calendar to check availability for test administering. Once there is a confirmed date, the nursing assistant should inform the patient of the date and send a confirmation calendar invite to the administering nurse as well as the agency's director of nursing. The confirmation should have the designated time of the test (30 minutes should be given for the entire process), the individual being tested last name and the administering nurse's name.

Prior to Administration

The administering RN/LPN will ensure the following

- All components are at room temperature
- Test card is open just prior to use
- Test card is flat for use
- The Blue Control Line is present

Patient Interaction: Prior to specimen collection, the administering nurse will go over the patient report and ensure all information gathered by the nursing assistant is correct. Once all information is confirmed, the nurse should explain the procedure.

Key things to highlight:

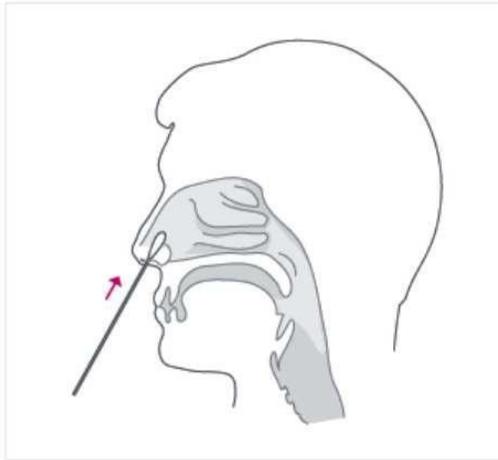
- Swab will be inserted less than an inch into the nose and rotated 5 times. Same process will be repeated on the other side.
- The BinaxNOW test is a rapid COVID-19 test. Results will be available 15 minutes after starting the test.
- If the patient is experiencing nasal congestion, have them blow his/her nose before swabbing.
- Before swabbing, have the patient sit in a chair, back against a wall. If the patient is self-swabbing, standing may be more comfortable.

Test Administration

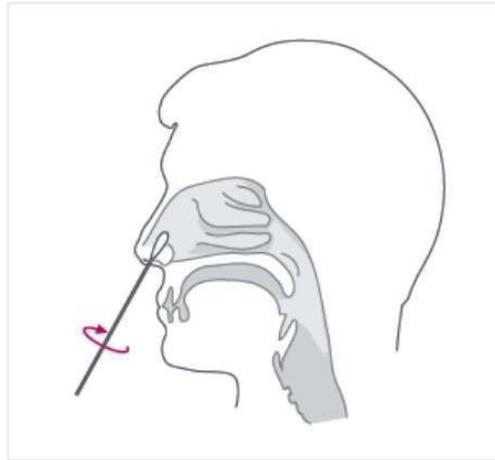
Swabbing: Once the administering RN/LPN has explained the process and ensured they have on full PPE; they should begin the process of administration.

- Insert the nasal swab into the nostril exhibiting the most drainage or congestion
- Using gentle rotation, push the swab until resistance is met
 - o At the level of the nasal turbinates
 - o Less than one inch into nostril
- Rotate the swab 5 times or more against the nasal wall

- Slowly remove the swab
- Using the same swab, repeat sample collection in the other nostril



1 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.



2 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 and then slowly remove from the nostril.

3 Using the same swab, repeat sample collection in the other nostril.

Performing the BinaxNOW test

Step 1:

- Hold extraction reagent bottle vertically to ensure adequate volume
- Add 6 drops for a Patient test
- Add 8 drops for a Quality Control test

Step 2:

- Insert swab into the bottom hole of the test card
- Firmly push swab upward until the swab tip is visible in the top hole

Step 3:

- Rotate swab shaft **3 times clockwise (to the right)**.
- False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card

Step 4:

- Peel off adhesive liner from the right edge of the test card
- Close and securely seal the card
- To ensure proper test performance read results at 15 minutes and not before. **RESULTS SHOULD NOT READ AFTER 30 MINUTES OF ADMINISTRATION**

Test Result Interpretation

- **Negative**
 - o One pink/purple colored line in the top half of the window, in the control line position. This indicated a negative result and no antigen detected



- **Positive**

- Two pink/purple colored lines in both the control and sample line position. This indicates COVID-19 antigen was detected. Any visible pink/purple line is positive.



****Please note that the test is invalid and should be repeated if:**

- Only the sample line is present
- No lines are present
- Blue Control Line remains blue



Specimen Collection Safety: The following PPE **IS REQUIRED** for BinaxNOW specimen collection:

- Gown
- N-95
- Face Shield or goggles
- Gloves

Quality Control Log: To ensure the validity of BinaxNOW test, external positive and negative controls must be ran in the following situations

- Once with each new shipment received
- Once for each untrained operator
- When required by local, state and or federal regulations

The nursing assistant should complete the external positive and negative controls as well as complete the Quality Control Log. When the external controls are not operating as designed the nursing assistant should inform the director of nursing and contact the technical service at 800-257-9525. At **NO TIME** should a testing kit be utilized if controls are not operating as designed or the testing kit is past its expiration date.

Temperature Log: The nursing assistant will ensure the testing kits are stored at a temperature of 2-30 degrees Celsius each workday. The nursing assistant will record the temperature (each workday) on the temperature log and make any necessary adjustment if the temperature is off.

Reporting Requirements: The nursing assistant will be responsible for submitting all COVID-19 test to Indiana Department of Health (both negative and positive) within 24 hours of testing using REDCap (<https://redcap.isdh.in.gov/surveys/?s=ER98AJW9RX>).

** For participants of XX, the designated program will still need to submit a BDDS Report for any positive individuals.

** For any employee of XX who has a positive result, their results must be submitted to <https://forms.office.com/Pages/ResponsePage.aspx?id=ur-ZIQmkE0-wxBi0WTPYjdeGrSGv-DIHozfF9fg56KdUNVZFWUc3Q0EzWjdWTlo0SkM0WfK4T1E2Qy4u>