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BinaxNOW

1 message

Brewer, Kasha <kbrewer@nd.gov>

Tue, Jan 5, 2021 at 2:32 PM

To: "jessica@downtownminot.com" <jessica@downtownminot.com>

I for got to ask how many people are in your association? Also let me know if you need help filling out any of the documents or any questions or concerns you may have. Then when everything is all filled out and complete, just go ahead and send it back to my email.

Very Respectfully

NDDoH BinaxNOW Liaison Kasha

Sent from [Mail](#) for Windows 10

4 attachments



BinaxNOW Collection Model - Rev. 1.pdf
66K



BinaxNow Screening Planning Checklist for Non-Healthcare Setting (Fillable) - Rev. 2 (1).docx
76K



North Dakota PowerApps Licensure.docx
26K



Self Managed BinaxNOW Screening Model.pptx
1695K

Managed Binax Screening Model

^Room should be ventilated with door closed (observation window if possible)

Lead Medical Staff (optional) perform control tests

Staff pre-register at testreg.nd.gov (prefer prior to screening day)

Asymptomatic staff enter*

*Symptomatic staff should get tested at clinic or LPH testing location

Screening staff verify registration and scan Binax card

Pick up card and write name and birthday

Screening staff add reagent to card

1. Keep Binax Card flat/horizontal at all times
2. Enter Swabbing Room and close door ^
3. Remove mask
4. Swab both nasal passages by rotating the swab on each side for 5 seconds
5. Place swab in Binax card
6. Rotate swab 3 times clockwise/to the right
7. Close card
8. Write start time on plastic bag (current time)
9. Write read time on plastic bag (current time + 15 min)
10. Place card in plastic biohazard sample bag and seal
11. Sanitize hands
12. Put mask on
13. Disinfect table surface
14. Return Binax card to screening table

Required Personnel:
 1- Medical staff (optional, may be volunteer)
 1-Registration data entry
 1-Add reagent to Binax card
 2-Timing and resulting of sample
 1-Results entry into Dynamics

#Note result on bag with sharpie or sticker

Screening staff monitor times and read results at 15 minutes #

Pick up fact sheet

Exit Screening Area

Dispose of Binax card in biohazard waste container after result read, entered into Dynamics

Data entry of results by screening staff

Conduct full cleaning of the sample collection room at the end of the event

Color Key

Screening Staff Action
Screening Subject Action

SELF MANAGED BINAX SCREENING MODEL



NORTH
Dakota | Health
Be Legendary.™

NORTH
Dakota | Unified Command
Be Legendary.™

AGENDA

- General Concept of Operations (CONOPS)
- Benefits
- Facts and Assumptions
- Process and Test Site Flow
- Resources and Supplies
- Current Pilot Projects
- Next Steps



GENERAL CONCEPT OF OPERATIONS

- Organizations will use non-medical trained operators to self-collect and perform BinaxNow antigen tests. At least 1 medical staff or volunteer is encouraged but not required.
- Asymptomatic staff.
- Test weekly.
- State provides initial BinaxNOW test training support.
- State provides MS Dynamics technological resources.
- State maintains a supply chain for tests.

GENERAL CONCEPT OF OPERATIONS

- State liaison works with organization to complete eligibility checklist
 - Personnel/volunteers to manage testing event
 - Training
 - Dynamics access and licenses
 - Identify location/room for testing
 - Biohazard waste management
 - HAN Assets order of Binax Test Kits

GENERAL CONCEPT OF OPERATIONS

- Test results reported through Dynamics App.
- Positive cases can be removed from your work environment immediately.
- Case Management and Contact tracing occur as part of the ongoing disease control process.

BENEFITS

- Screening events can be worked into the overall organizations schedule.
- Near immediate test results, (about 15 minutes), allowing asymptomatic positive individuals to be removed from business setting quickly.
- Process is easily repeatable, systematic, and sustainable long term.

FACTS

- Organizations have to be approved for a Clinical Laboratory Improvement Amendment (CLIA) waiver certificate – One-time fee of \$185. Public Schools are included under a blanket waiver from DPI.
- Organizations are not subject to HIPAA regulations and NDDoH non-disclosure agreement is not required
- PPE/supplies will not need to be provided to organizations from the State Medical Cache
- N95 respirators are not required in this model.

ASSUMPTIONS

- Organizations will be given access to MS Dynamics
- The organization will need to have access to at least one iPad or iPhone.
- Licenses to Dynamics/Power Apps will be available to the organization at no cost.

ASSUMPTIONS

- Participating organizations and asymptomatic staff will commit to testing weekly on an ongoing basis.
- Organization can obtain a contract for or method of disposal of biohazard waste.
- Sufficient supplies of BinaxNOW tests will be available to the state to support the plan on a continual basis.
- Organizations will need to acquire minimal non-medical PPE for testing off of the economy.

ASSUMPTIONS

- State can provide/coordinate “Train the Trainer” teams

PROCESS

- Interested organizations will contact the appropriate Program Manager.

Program	Program Manager	Email	Phone number
Long-term Care	Seth Fisher	sefisher@nd.gov	701-328-8232
K-12/Private/tribal schools	Theresa Fewless	fewlesst@nd.gov	701-328-2270
NDUS/Private/Tribal Colleges	Robert "Joe" Lies	rlies@nd.gov	701-425-4522
Medical Providers	Nicole Brunelle	nbrunelle@nd.gov	701-328-2322
Congregate Settings/1st Responders	Neil Johnson	neiljohnson@nd.gov	701-328-8130
Legislative/State Agencies	Bill Brown	babrown@nd.gov	701-425-4518
Pharmacies doing LTC Vax	Sarah Berreth	sberreth@nd.gov	701-328-2270
Business Screening	Al Hanson	allanhanson@nd.gov	701-425-5870
Community/ Tribal Screening	Pat Flanagan	patrick.r.flanagan.mil@mail.mil	701-333-6901

PROCESS

- The organization coordinates with state liaison to complete checklist to prepare for implementing testing system
- Pre-event one-time training of staff
 - All staff (Trained Operators) – BinaxNOW Modules 1-4 (Total 10 minutes)
 - Dynamics data entry staff only - video (12 minutes)

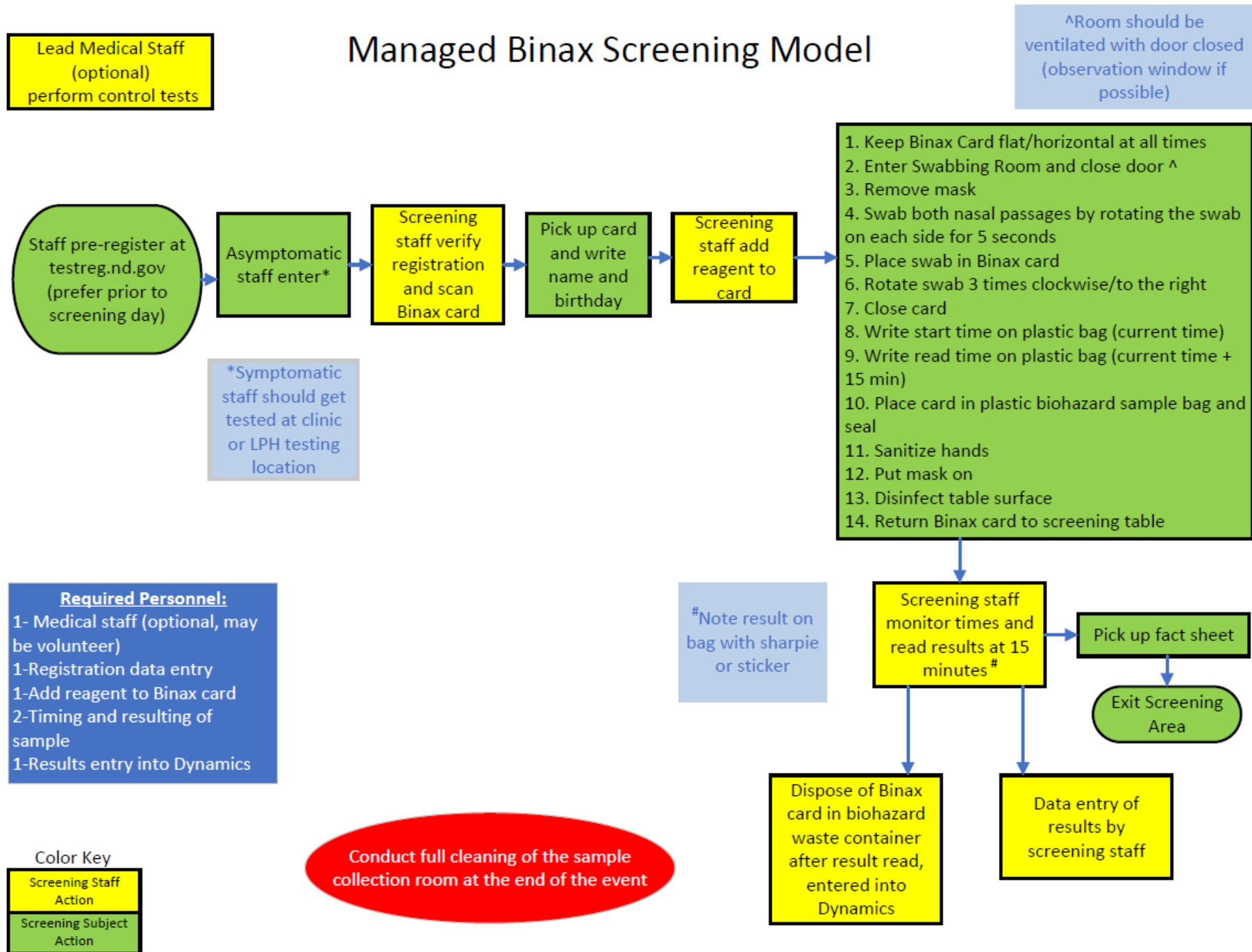
PROCESS

- Set up testing location
- Initial on-site training with “Train the Trainer” teams
- On site Testing Process as per flow chart



TEST SITE FLOW

Managed Binax Screening Model



HUMAN RESOURCES

- 5 test staff to accomplish throughput of estimated 30 tests per hour (can be done with fewer staff at reduced throughput)
 - 1-Registration data entry
 - 1-Add reagent to test card
 - 2-Timing and resulting of test
 - 1-Entry of test results into Dynamics
 - Recommend at least 1 volunteer medical person included in this team
- Team of 2 Trainers (State and NDNG) at first event **only**

SUPPLIES AND EQUIPMENT

- Binax test kits
- iPads or iPhones w/ app
- Sealable clear plastic bags at least 8.5 in. X 3.5 in.
- Red Biohazard garbage bags (large)
- Trash cans to hold biohazard bags
- Smaller trash cans for non-hazardous garbage
- Gloves (non-medical grade)

SUPPLIES AND EQUIPMENT

- Reliable Wi-Fi or cellular data (cellular runs slower)
- Hand sanitizer
- Disinfectant wipes
- Clock or stop watches/timers
- Tables, chairs
- Pens and permanent markers
- All personnel wear regular face masks in common areas (no N-95 needed)

North Dakota Dynamics/PowerApps Licensure:

Name:Click or tap here to enter text.

Work Address:Click or tap here to enter text.

Phone: Click or tap here to enter text.

Facility Name:Click or tap here to enter text.

Email:Click or tap here to enter text.

Role/title:Click or tap here to enter text.

Name:Click or tap here to enter text.

Work Address:Click or tap here to enter text.

Phone: Click or tap here to enter text.

Facility Name:Click or tap here to enter text.

Email:Click or tap here to enter text.

Role/title:Click or tap here to enter text.

Name:Click or tap here to enter text.

Work Address:Click or tap here to enter text.

Phone: Click or tap here to enter text.

Facility Name:Click or tap here to enter text.

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Role/title:Click or tap here to enter text.

Name:Click or tap here to enter text.

Work Address:Click or tap here to enter text.

Phone: Click or tap here to enter text.

Facility Name:Click or tap here to enter text.

Email:Click or tap here to enter text.

Role/title:Click or tap here to enter text.



BinaxNow Screening Planning Checklist for Non-Healthcare Settings

To participate in BinaxNow Rapid Antigen screening for COVID-19, complete the check list and return to:

Program	Program Manager	Email	Phone number
Long-term Care	Seth Fisher	sefisher@nd.gov	701-328-8232
K-12/Private/tribal schools	Theresa Fewless	fewlesst@nd.gov	701-328-2270
NDUS/Private/Tribal Colleges	Robert "Joe" Lies	rlies@nd.gov	701-425-4522
Medical Providers	Nicole Brunelle	nbrunelle@nd.gov	701-328-2322
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Business Screening	Al Hanson	allanhanson@nd.gov	701-425-5870
Community/ Tribal Screening	Pat Flanagan	patrick.r.flanagan.mil@mail.mil	701-333-6901

Requesting organization: Click or tap here to enter text.

Address: Click or tap here to enter text.

Point of Contact Name: Click or tap here to enter text.

Email: Click or tap here to enter text.

Phone: Click or tap here to enter text.

Required Elements	Explanation and Assistance	Documentation of Completion
<p>CLIA Certificate</p>	<p>The Clinical Laboratory Improvement Amendments of 1988 (CLIA) extend jurisdiction of the Department of Health and Human Services to regulate all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.</p> <p>The CLIA application can be found at www.ndhealth.gov/HF/NDCLIA.htm</p> <p>Contact the ND CLIA Office at clialab@nd.gov or 701-328-2352 for assistance. There is a \$185 fee for a CLIA waiver.</p> <p>If entities already have a CLIA certificate for laboratory testing, they do not need to submit a new application for COVID19 screening. They do need to add BinaxNOW to the certificate.</p> <p>CLIA is tracking entities who are performing COVID19 screening, so we do ask entities to send an email to clialab@nd.gov to let us know that they have added COVID19 screening. They should include their CLIA number, a statement that the lab director has approved the addition of the COVID19 screening, and the name of the method being used.</p> <p>Public Schools do NOT have to apply for a CLIA waiver as they are covered by a Dept. of Public Instruction waiver. Non-public/private schools will have to apply for a CLIA waiver.</p>	<p>Please provide your CLIA certificate number. (This will be verified by the Dept. of Health staff)</p> <p>Click or tap here to enter text.</p>

<p>Identify staff to perform data entry related to registration of individuals and screening results. The Dynamics app for iPad or iPhone is the preferred data system. Android devices will work at a slower rate.</p>	<p>These support staff will assist individuals to register through https://testreg.nd.gov/ and assure test results are entered into a system that reports to the ND Department of Health. Prior to utilizing the Dynamics App, a Dynamics license must be obtained for all personnel utilizing the App. They then would receive a username and password in order to access the App. It is recommended that each organization have a <u>minimum of 2 and maximum of 6 people</u> identified for data entry.</p>	<p>Provide information for the staff that will be utilizing the Dynamics app on the separate North Dakota Dynamics/PowerApps Licensure form.</p>
<p>Point of contact trained on BinaxNow collection and reporting.</p>	<p>Training modules and video links below: https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html Modules 1,2,3, and 4 are required for the point of contact and all staff being screened. Total time required is approximately 10 minutes.</p> <p>The screening procedures video below is highly recommended: https://www.youtube.com/watch?v=NsUk61bTlBE</p> <p>BinaxNow in Dynamics: https://www.youtube.com/watch?v=rzNWh-BSZQg&feature=youtu.be</p>	<p>Name: Click or tap here to enter text.</p> <p>Phone #: Click or tap here to enter text.</p> <p>Email: Click or tap here to enter text.</p> <p>Title / Role: Click or tap here to enter text.</p> <p>Organization Name: Click or tap here to enter text.</p> <p>Address:</p>
<p>Identify testing location</p>	<p>Specimen collection should be completed in an area with good ventilation.</p>	<p>List identified test location. Click or tap here to enter text.</p>
<p>Identify reporting process</p>	<p>All results, both positive and negative, <u>must</u> be reported to the ND Department of Health.</p> <p>➤ For those organizations that have access to iPads/iPhones with the Dynamics App, they will have the ability to register individuals and report their results to the state. Please refer to the Dynamics Training video for guidance. <u>THIS IS THE PREFERRED METHOD.</u> Android devices will work, but are slower</p>	<p>Indicate the system that will be used to report BinaxNow test results to ND Department of Health. Click or tap here to enter text.</p>

	<p>➤ The organization will be required to have Wi-Fi (preferred) or cellular data on the iPads/iPhones/Androids in order to use the Dynamics App</p> <p>For technical assistance on reporting please call 701.328.2378 or email mbenz@nd.gov, slrenton@nd.gov, or bschram@nd.gov</p>	
Biohazard Waste Disposal (Non-Medical Facilities)	<p>Identify a plan for biohazard waste disposal. The primary waste will be the actual BinaxNow tests and gloves used by the individual reading the results.</p> <p>Possible plans could include - conduct screening in cooperation with Local Public Health, local Emergency Medical Services, or clinics; contract with an approved Biohazard waste disposal company; etc.</p>	<p>Document management plan: Click or tap here to enter text.</p>
Request BinaxNow tests	<p>Once the checklist has been approved the POC can then request tests through the Health Alert Network assets website. Please order what you will need for 2 weeks.</p> <p>http://hanassets.nd.gov/</p> <p>Please call 701-328-0707 with any HAN questions.</p>	<p>Once completed, the facility/agency name and information will be added to a list that can be cross referenced by the Dept. of Health Warehouse staff.</p>

Checklist Approved by (Internal Office Use Only):

Name: Click or tap here to enter text.

Signature: