

Norfolk County-8 Coalition

MDPH/LBOH WEBINAR 11/24/2020



Inter-agency Staff on the Webinar

- Jana Ferguson, Assistant Commissioner, DPH
- Ron O'Connor, Office of Local and Regional Health, DPH
- Suzanne Crowther, Communications Office, DPH
- Dr. Catherine Brown, Bureau of Infectious Disease and Laboratory Sciences, DPH
- Pejman Talebian, Bureau of Infectious Disease and Laboratory Sciences
- Helene Bettencourt and Anne Gilligan, Department of Elementary and Secondary Education
- Michael Flanagan, Mary Dozois, and Adam Kinney, Department of Labor Standards
- Gerben Scherpbier and Sarah Wallach, Executive Office of Energy and Environmental Affairs
- Cheryl Sbarra, Massachusetts Association of Health Boards
- Chief Jeff Farnsworth, Massachusetts Chiefs of Police Association

Announcements:

Brief updates and reminders:

Next webinar—Tuesday, December 1st at 3:00 pm.

Thanksgiving Day enforcement of gatherings order—Recorded message from Commissioner Bharel about how to adjust Thanksgiving Day plans. **Q:** Should LBOH enforce gathering orders?

A: The message that needs to continue to be disseminated is how to celebrate safely and reminding residents how important it is make safe decisions.

Order No. 53 (Early closing of certain businesses): reminder that there are businesses that are allowed to be open after 9:30 pm. Please refer back to [Order No. 53](#).

Guidance for municipal leaders on testing programs—you can use CARES Act funding for this (through December, use this money now). Next week, DPH is doing an evaluation about testing and what makes the most sense, financial reality, looking at vendors, and reconsidering some Stop the Spread sites. We understand there is a regional need for funding. Questions about Stop the Spread sites—**Q:** Can municipalities have a Stop the Spread site in their communities?
A: There are time limited testing units that can come to your community and made available to address certain clusters. “Rapid response type events”

LBOH/CTC surge staffing: We hear you that there is a need for additional surge staffing at the local level and CTC. About 250 – 300 people being added each week to CTC. First activity in their orientation is their training program. CTC training will teach people how to do contact tracing work. Training is designed only for contact tracing (type of information you need to collect). CTC training available to LBOH, APHVC, or MRC Volunteers. DPH will not be doing outreach to APHVC or MRC volunteers to sign up for these trainings. CTC training does not cover how to use MAVEN, this is a separate and additional training. If people are already in MAVEN but would like a refresher on contact tracing, use CTC training.

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EMS first responder letter (sent out by Ron O'Connor on Friday, November

20th): “...Consistent with Massachusetts COVID-19 Command Center guidance, EMS providers and first responders are not required to quarantine following an exposure to COVID-19, provided the EMS provider or first responder is not experiencing any COVID-19 symptoms and continues to self-monitor for symptoms.” Link in this letter provides more information to EMS/first responders—take a look. **Q:** What is included in first responder category? **A:** Really talking about fire/police.

Town meeting guidance resource: As of yesterday, a reminder was sent out to make the guidance clearer. Provisions about the town meeting guidance are the same, nothing new to learn. Share with town moderators/boards.

Get Back Mass Campaign: New public awareness campaign about wearing a mask, keeping distance, and getting tested. The intended audience is the COVID-19 care free group who do not want to be lectured on what not to do. The campaign is designed to reframe the need to practice public health measures by wanting to go back to normal, not to limit freedoms. Materials available include posters and videos. www.mass.gov/lists/get-back-mass-materials

BinaxNOW Validation Study Results: Collaboration between DPH, Lawrence General, Boston Children’s Hospital, and Broad Institute due to concerns about trusting results from antigen tests. Tests being supplied to the state by the federal government, designed to be used in schools and LTCFs. Reminder—PCR tests detect the genetic material of the virus, very sensitive and can pick up even small amounts of virus/virus particles. Antigen tests detect protein on surface of COVID-19 virus, and are not as sensitive. At low level of virus (beginning of infection, or later end of infection) PCR test will say you’re positive, but antigen test is likely to be negative. Dr. Brown is starting to become convinced about antigen tests being reliable for people who are actively infected. In cases where PCR test comes back positive, but antigen comes back negative, this is because there may be a low level of the virus at the same aligning with beginning of infection or end of infectious period.

Problems with other antigen tests are that they come back positive but with a negative PCR. What was the antigen test detecting that the PCR test was not? The false positive is what was raising the concern for us. *(Following information is supplemented with slide on next page)* BinaxNOW test—the credit card size piece of cardboard is the test. You open the card (on left hand side) add some drops, take nasal swab and stick it into the card, twist it around, wait 15 minutes, and you will get lines that look like a pregnancy test (on the right hand side).

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Procedure for Patient Specimens

Open the test card just prior to use, lay it flat, and perform assay as follows. The test card must be flat when performing testing; do not perform testing with the test card in any other position.

- 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.
- Insert sample into BOTTOM HOLE and firmly push upwards so that the swab tip is visible in the TOP HOLE.
- Twirl swab shaft 3 times CLOCKWISE (to the right). Do not remove swab.



Note: False negative results can occur if the sample swab is not rotated (twirled) prior to using the card.

Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.







RESULT INTERPRETATION

Note: In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position. In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working. If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.

Negative A negative specimen will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.	 Pink/Purple Control Line
Positive A positive specimen will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint	 Pink/Purple Control Line Pink/Purple Sample Line

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Sample Line. Any visible pink/purple colored line is positive.	Invalid Result
Invalid If no lines are seen, or if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated.	 No Control Line
	 Sample Line Only
	 Blue Control Line Only
	 Blue Control Line Sample Line

Sensitivity—ability of a test to correctly identify those with the disease (true positive)

Specificity—ability of the test to correctly identify those without the disease (true negative).

These are standard metrics, and the numbers can be used to solve for Positive Predictive Value (PPV) and Negative Predictive Values (NPV). The PPV means the likelihood that someone who tests positive actually has the disease. If 90% is the PPV, then 90% chance you have the disease. NPV is the same approach but opposite. If 90% is NPV, then there is a 90% chance you do not have the disease.

When the Abbott company went to FDA, data showed that the test had 97% sensitivity and 98.5% specificity with 102 samples, only 1 person who was positive on the antigen tested negative through PCR. Small sample size, and it was done on people who were adults over the age of 21 and had symptom onset within 7 days of the test. Lawrence General study went to see the larger sample size for children and adults, symptomatic and asymptomatic. Over 1600 people were tested by both BinaxNOW and PCR tests, slightly lower sensitivity 82%, but still very good specificity. PPV is 96% which is great, and a NPV of 97%. Out of 1600 cases, only 6 false positives. Looking back at MAVEN data with other antigen tests, we were seeing something like 25-33% false positives. False negatives occur when antigen is negative but PCR is positive. We would expect this with antigen test because it only detects when there is a high viral load, and what we found was that in false negatives, in general, the cycle threshold value from the PCR (number from the PCR test) showed that those people actually had low viral loads, and did not expect the antigen test to detect them. This is good news; it means the test

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was performing the way we expected it to. Test is relatively easy to use, and even when other people were administrating the test we got reliable results. Also, test does not work if outside temp is below 59 degrees. For the rest of the study, able to maintain temperature at appropriate level. The higher cycle threshold, the lower the virus. If you have questions email Dr. Brown.



Binax Ag (package insert)

BinaxNOW Ag	RT-PCR – Sx ≤7d		
	Positive	Negative	Total
Positive	34	1	35
Negative	1	66	67
Total	35	67	102
Sensitivity: (34/35) 97.1%			
Specificity: (66/67) 98.5%			

Note: No published performance data for Ag card use in individuals < 21 years old.

Binax Ag (DPH/Lawrence General)

BinaxNOW Ag	Total Population: Asymptomatic and Symptomatic		
	RT-PCR (CDC: N2)		
	Positive	Negative	Total
Positive	153	6	159
Negative	33	1422	1455
Total (11.5% prevalence)	186	1428	1614

Sensitivity: **82.3%** (95% CI 76.0% - 87.5%)

Specificity: **99.6%** (95% CI 99.1 - 99.9%)

PPV: 96.2% (95% CI 92.0% - 98.3%)

NPV: 97.7% (95% CI 96.9% - 98.3%)

Questions Submitted Before the Webinar

- **Six false positive** Ag results [Ag(+)/PCR(-)] found in 1,614 individuals
 - 5 of these were in asymptomatic patients (4 adults, 1 child); 1 in a symptomatic individual >7 days after onset
- Of 34 false negative BinaxNOW results [Ag (-)/ PCR (+)], 31 were paired with **high PCR Ct values** [median Ct=33.8; Mean 33.1 ± 2.3]; three had Ct value < 30.
- **High inter-operator agreement (99.7%; 872/875 tests)**
- If test run **outside temperature limit** in the package insert (<59°F), **sensitivity drops significantly** (for individuals symptomatic ≤ 7 days, drops from 82% to 66%)

Vaccine update from Pejman Talebian (Director, Immunization Division): Phase 1/Phase 2 distribution plan, latest information DPH has is that Pfizer vaccine will likely be approved in early December, initial doses available 12/15 if everything goes to plan. Within 2-3 days after that FDA approval, will meet with Federal Advisory Committee on Immunization Practices (ACIP) and then we can begin distribution of the vaccines. Will be receiving small allocation of vaccines in the beginning. These will be going to acute care hospitals. Two limitations with new

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vaccine: 1) requires to be stored at ultra-cold temps 2) dose increments of 900+ doses. Current assumption is 60k doses by mid-December. 1 box of vaccine per 2 tier hospital. Phase 1 vaccination will be targeted towards COVID-19 facing healthcare workers. Soon behind that will be the Moderna vaccine likely to be approved mid-December. When all is said and done, by the end of December, having several hundred thousand doses to allocate. Current plans are still to target hospitals, multi-specialty practices, and CHCs for phase 1A. Currently, draft [ACIP guidance](#) has healthcare workers and residents of LTCFs as target population. Soon after that, other high risk groups and other essential workers. Up in the air is the exact order of this. ACIP defines essential workers as those working in education centers, food/agriculture, utilities, police/fire/transportation. They are recommended to be vaccinated in Phase 1B, ahead of adults with high risk medical conditions and 65+. Those individuals are recommended to be vaccinated in Phase 1C. That's the current draft guidance. Our (DPH) group has different categorization of essential workers, next few weeks will require us to align the recommendations with ACIP. LHD's and EDS/MRC, all of this will come into play later in vax campaign possibly in Phase 3/Phase 4, and possibly in Phase 2. EDS could be used similarly to flu clinics, but ramped-up considerably. Right now, expecting mass vaccination of the general population by spring 2021. Right now, DPH is still focused on initial distribution phases in January-February in high risk settings.

Questions from emails:

Q: Why do MDPH numbers for school cases K-12 published in the "cluster" table differ so much from DESE reported counts of school related cases? There is a column for total cases, I thought that would reflect ALL school related cases. If not, can MDPH public the total MAVEN count of school related cases? Preferably by geography?

A: Cluster data that is published by DPH is based on case investigation based on LBOH and CTC when there are more than 2 cases in short period of time. [DESE data only represents that has been reported to DESE](#), so numbers will always be different.

Q: A swim team in my town apparently has decided that their team members are basically like employees and can travel to the pool and home and not be subject to quarantine requirements. They say they cannot find anything in writing to prevent their MA team members from traveling to and from the NH pools or vice versa. Is there any clarification on this in writing?

A: No, swim teams are not employees, not exempted from the travel order. If you want this in writing Gerben is happy to support.

Q: If a 1st responder has a household member that tests positive, does the 1st responder quarantine?

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A: No, guidance does not differentiate where you were exposed. As a healthcare worker or first responder, you have to quarantine if you were exposed but get to go to work if you are asymptomatic and masked.

Q: Can 1st responder go to work for another job that doesn't match first responder job definition?

A: No, absolutely not.

Q: Do laundromats fall under sectors not otherwise addressed, can they keep seats for customers if they follow social distancing?

A: Yes, fall under not [otherwise addressed](#). In standards specifically mentions that waiting areas should be closed and customers should be asked to wait outside or in cars until their appointment is available.

Q: Who is in the command Center and do they set the standards for Governor's COVID-19 guidance?

A: Command Center is made up of many agencies in Secretariat. Secretary Sudders is the head of the Command Center. All Secretariats are represented. Standards are developed depending on the sectors, EEA wrote youth and adult sports standards, EEC day care providers, Economic Development wrote sector specific standards, but it's all approved through the Command Center. The Administration is working to make sure it's an all hands approach.

Additional questions please email: Michael.j.coughlin@mass.gov