COVID-19 Update: FDA authorizes first diagnostic test where results can be read directly from testing card

Today, the U.S. Food and Drug Administration issued an emergency use authorization for the first antigen test where results can be read directly from the testing card, a similar design to some pregnancy tests. This simple design is fast and efficient for healthcare providers and patients and does not need the use of an analyzer.

"This new COVID-19 antigen test is an important addition to available tests because the results can be read in minutes, right off the testing card. This means people will know if they have the virus in almost real-time. Due to its simpler design and the large number of tests the company anticipates making in the coming months, this new antigen test is an important advancement in our fight against the pandemic," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health.

HOW IT WORKS:

A healthcare provider swabs the patient's nose and twirls that sample on a test card with a testing reagent added. After waiting 15 minutes, the healthcare provider reads the results directly from the testing card. One line indicates a negative result; two lines indicate a positive result.

WHERE IT CAN BE USED:

This test could be used at point-of-care settings, like a

doctor's office, emergency room or some schools. This test has been authorized for use in patients suspected of COVID-19 by their healthcare provider within seven days of symptom onset. Given the simple nature of this test, it is likely that these tests could be made broadly available. According to the test manufacturer, Abbott, it plans to make up to 50 million tests available monthly in the U.S. at the beginning of October 2020.

TEST DETAILS:

In general, antigen tests are very specific, but are not as sensitive as molecular tests. Due to the potential for decreased sensitivity compared to molecular assays, negative results from an antigen test may need to be confirmed with a molecular test prior to making treatment decisions. Negative results from an antigen test should be considered in the context of clinical observations, patient history and epidemiological information.

The emergency use authorization was issued to Abbott Diagnostics Scarborough, Inc for its BinaxNOW COVID-19 Ag Card.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

New Bedford City Councilor Hugh Dunn tests positive for COVID-19

Ward 3 City Councilor Hugh Dunn confirmed on his Facebook page that he has tested positive for COVID-19.

"I am one of nearly six million Americans who has tested positive for COVID-19.

I am lucky to be able to say that I am currently recovering comfortably at home and hope to test negative soon. Because I have been practicing social distance, to the best of my abilities, I am aware of who I have been in contact with and have notified those impacted and have also determined when I contracted the virus. All those who I have contacted have, thankfully, tested negative. A full recovery is my top priority at this time, and I plan on continuing to recuperate in isolation until my doctor gives me the go-ahead to return to my daily life. I do not anticipate that my condition will prevent me from continuing to represent the voters of Ward 3, and I look forward to attending the next meeting remotely. I encourage you to join me in taking the test, even if asymptomatic, by visiting a Stop the Spread testing site:

https://www.mass.gov/info-details/stop-the-spread"

His announcement came just 30 minutes before he attended via Zoom the FY2021 budget cut session Monday evening. He had missed seven previous city council meetings leading up to the budget cut meeting.

Massachusetts State Police arrest suspicious man out after curfew, state's first

Because of COVID-19 some towns and cities considered high-risk have effected a curfew as a way to limit the spread of the virus. One of those cities is Brockton who has implemented the curfew from 11:00pm to 5:00am and outside of police, the exception to the curfew is for any essential workers.

Massachusetts State Police are assisting local police to enforce the curfew and on Sunday, just past midnight, a state trooper on patrol noticed what appeared to be a suspicious man without a mask near a parked vehicle at 535 Westgate Drive.

The trooper asked the man if he was responding to an emergency or if he was one of the essential workers exempt from the curfew. The man was noticeably nervous and began to act suspiciously.

The trooper conducted a search and found a loaded .40 caliber Smith & Wesson pistol with a high-capacity magazine and ammunition in the vehicle's center console.

34-year old Jair Barros, of Brockton, was placed under arrest and charged with a number of gun-related offenses in addition to violation of the city's coronavirus restrictions.

Massachusetts

receives

federal approval for additional unemployment funds

Massachusetts currently has the highest unemployment rate in the country at 10.2%, but there some great news for residents without a job because of the worldwide COVID pandemic: Federal Emergency Management Administration Administrator Pete Gaynor announced he has approved the state's request for additional unemployment funds after weekly \$600 federal aid expired.

FEMA's grant funding means those who are currently unemployed will receive \$300 in federal funds. Since Governor Baker has already stated that he would agree to accept President Trump's extended unemployment benefits plan, that means there will be an additional \$100 bringing the total funds to \$400.

For those who have been concerned about the loss of income at the end of July when the \$600 checks they had been receiving, expired: the new payments will be made retroactive to Aug. 1.

As of July, the state's unemployment 16.1%, a drop of 1.6% drop from June with most of the jobs being lost in construction, hospitality, and transportation.

Massachusetts man gives "COVID hugs" to Walmart shoppers

The Springfield Police Detective Bureau is seeking your help to identify this individual from an incident at the Walmart on Boston Road on Saturday, August 15th around 7:10pm.

This suspect took an item out of a victims hands and then gave him a hug. He told the victim "Just giving you a Covid hug. You now have Covid." The suspect then started laughing and walked away. The victim, who is a cancer survivor, had never seen the suspect before.

This suspect had done this to other customers as well.

If you have any information on who this is, please contact our Detective Bureau at 413-787-6355, leave us a private message on Facebook or anonymously Text-A-Tip, Text CRIMES (2-7-4-6-3-7), type SOLVE and your tip.

Acushnet Fire Chief: "We are dismayed by the state's lack of interest in bringing COVID testing to Acushnet

A MESSAGE FROM FIRE CHIEF KEVIN GALLAGHER:

"Earlier this week, the Acushnet Board of Selectmen endorsed a proposal to have the Fire & EMS Department conduct community-based testing for Covid-19. EMTs will be trained in test administration and the services of a certified lab will be secured. The goal is test results in 24–36 hours.

Because private insurance does not typically cover testing for people not experiencing COVID symptoms, those who are asymptomatic, the Selectmen have authorized the use of CARES ACT funds received from the state for this important project. All tests will be offered free of charge.

While the details of the plan are still being formalized (a formal document will be submitted to the Selectmen for their review at their September 8th meeting) we are creating our plan based on the following "Phases." Each phase builds off each other:

PHASE ONE: At the request of any town department, trained EMTs will respond and conduct tests based on the situation presented. This is designed to assist the schools in their reopening plans as well as the plans to open town buildings to the public. An example of Phase One; following the guidance offered by the state, the schools have reason to send a cohort home and recommend testing. Instead of multiple families making numerous calls to physicians and testing locations, our team would coordinate testing at an Acushnet site for the staff, students, and their immediate families. All testing results would be returned at the same time benefiting next step decisions.

PHASE TWO: Testing of high-risk populations.

PHASE THREE: Scheduled in advance testing open to all town residents.

We have been dismayed by the state's lack of interest in bringing free COVID testing to Acushnet as part of their "Stop the Spread" initiative. It was decided that we would take action on our own. The local benefits are real. For example, our Health Department would receive a head start initiating contact tracing as the results will come to us directly via a secured portal a period of time prior to formal notification from the state. This will help Acushnet stop the spread!

This is a big task and one we did not envision carrying out back in January, however, these are not common times. The goal is a community-level testing plan that addresses immediate needs, high-risk groups and the public at large. The cooperation of town departments has been strong as has the leadership of the Boards of Selectmen and Health. We look forward to getting to work."

#TestingWeGotThis

Massachusetts mandates flu vaccinations for students

The Massachusetts Department of Public Health has mandated required flu shots by Dec. 31 for all students 6 months or older who attend child care, pre-school, school and college throughout the state.

Officials stated concern for the high risk to the public if they were to catch both COVID-19 with its respiratory impact combined with also having the flu.

Dr. Larry Madoff, the medical director of the department's Bureau of Infectious Disease and Laboratory Sciences explained "Every year, thousands of people of all ages are affected by influenza, leading to many hospitalizations and deaths. It is more important now than ever to get a flu vaccine because flu symptoms are very similar to those of COVID-19 and preventing the flu will save lives and preserve health care resources."

However, there are exemptions for religious or medical reasons and those children who are homeschooled. In addition, the exemption extends to any higher education students who are completely off-campus *and* engaged in remote learning only.

Ocean State Job Lot donates masks, shields and hand-sanitizer to New Bedford Fire Department

"Recently, our EMA Director, Brian Nobrega met up with Mike Reardon from Ocean State Job Lot to receive a generous donation of protective KN95 masks, face shields and gallons of hand sanitizer to be distributed to our first responders.

Keeping our members and community safe is our #1 priority. Thanks so much to all who made this donation possible!"-New Bedford Fire Department.

Nearly 1 million ballots sent to Massachusetts voters

Chris Van Buskirk State House News Service

The secretary of state's office has already mailed out almost 950,000 ballots in advance of the Sept. 1 primary election, representing nearly a quarter of the state's 4.5 million registered voters.

The estimate of ballots mailed so far comes as the United States Postal Service faces increased scrutiny over whether it

will be able to deliver mail-in ballots on time for local clerks to count them. USPS officials set off an uproar in late July when they warned states that deadlines for requesting and casting mail-in ballots are incongruous with the Postal Services' delivery standard.

But on Tuesday, Postmaster General Louis DeJoy issued a statement saying that he would suspend operational initiatives "that have been raised as areas of concern as the nation prepares to hold an election in the midst of a devastating pandemic" until after the election, to avoid the appearance of effects on electoral mail.

DeJoy also announced the expansion of a leadership task force on election mail. He said retail post office hours will not change, mail processing equipment and collection boxes "will remain where they are," no mail processing facilities will be closed, and overtime will be approved as needed.

Secretary of State William Galvin said about 149,000 ballots have been returned to local clerks and he expects mail-in voting will help boost participation while taking into account public health guidelines. The state's top election official said "a lot of people" who requested ballots were primarily motivated by voting in the November general election, adding that more than a million people asked for ballots for the general election.

"This has been a very tedious effort to get all these ballots out. It was a very large mailing, and it had a great response, but it required a great deal of work at the local level to put these ballots out especially in a timely way," he said at a Tuesday press conference.

Attorney General Maura Healey on Tuesday announced a lawsuit to prevent the Trump administration from cutting back USPS operations as the elections approach. Galvin said his office has been in contact with Healey's, providing the attorney general "detailed information."

"The Postal Service has been able to provide ballot delivery even during wars. So I don't understand why this would be such a problem," Galvin said Tuesday. "This is a national issue. It needs to be addressed. My experience with the Trump administration through the census has been the only way to remedy bureaucratic problems that they create is to go to court. And I think that is the right answer here too."

In a Twitter thread posted to the social media website on Tuesday, Healey said the Trump administration is attempting to "slow down the Postal Service to rig the election."

"Like many of this Administration's policies, its changes to USPS are illegal. Modifications to the Postal Service with a nationwide impact on mail service must be submitted to the Postal Regulatory Commission," she wrote on Twitter. "Trump can't just wake up and unilaterally disrupt our mail system."

Gov. Charlie Baker said he was "uncomfortable" commenting on whether he would support potential litigation without knowing more information.

"Usually, the role we play, if they ask us to play one, is on a sort of amicus basis to just give a discussion about what the implications of whatever the issue are, would be," he said at separate Tuesday press conference. "And that's our way usually of supporting those kinds of initiatives. I'm not aware that they've asked us for that. If they were to ask us we obviously would respond."

Out of concern for Postal Service delays, Galvin said his office made sure that the application and ballot mailings went out as early as possible. Additionally, the secretary of state's office advised localities to have drop boxes available at secure locations for voters to drop off their ballots.

"That gave voters the opportunity to make sure they return

their ballot as quickly as possible as well and make sure that any disruption or delay in Postal Service would not have any effect on them," he said.

A law signed by Gov. Charlie Baker on July 6 directed the secretary of state to send out mail-in ballot applications by July 15. Galvin told reporters nearly a week before the date that would not meet the deadline set out in the legislation unless the Legislature provided funding.

Election reform and voting rights advocates and the secretary of state disagreed over permissible funding sources to mail out ballot applications and a group of seven nonwhite voters, Common Cause Massachusetts, and MassVOTE filed a lawsuit in an attempt to force the secretary to mail applications.

The governor's office agreed to advance funds included in a \$1.14 billion COVID-19 supplemental budget so Galvin's could move forward with mailing vote-by-mail applications.

The rush to solidify new vote-by-mail laws in the state came as a response to the COVID-19 public health crisis. Residents have three options for voting in the primary election, regular in-person voting, voting-by-mail, and a seven-day early in-person voting period that starts Saturday.

Voters who chose to vote-by-mail can track their ballots on the secretary of state's webiste, a measure that Galvin said would ensure residents know their ballots were cast.

Galvin said state and local officials "are going to great lengths" to make sure that voters who choose to head to the polls will be safe. Polling locations will observe social distancing guidelines, institute precautions for workers like PPEs and plexiglass guards, and space out voting booths.

"In fact, I would suggest to you that it'll be safer than going to many supermarkets," he said. "For those that wish to vote in person, who perhaps have delayed some final decisions

on choices in the primary, and don't want to avail themselves of voting by mail, voting in person is an option."

St. Luke's Hospital hasn't had a COVID-19 patient since August 11

As of Saturday, August 15, St. Luke's Hospital in New Bedford has not had a confirmed or suspected COVID-19 patient since August 11. On August 11, the Massachusetts Department of Health reported three "Hospitalized Total COVID patients — suspected and confirmed" at St. Luke's with none of them in the ICU.

Three has been the highest suspected or confirmed COVID-19 patient count at St. Luke's Hospital for the month of August. The hospital has reported between zero and three suspected or confirmed COVID-19 cases for the entire month of August but hasn't reported a case in five days.

According to the Massachusetts Department of Public Health's COVID-19 dashboard, the vast majority of hospital admissions for COVID-19 are suspected. For example, 148 people were admitted to the hospital for COVID-19, but out of those 126 were suspected and only 22 were confirmed.

22,969 people were tested resulting in 366 new positive COVID-19 results in Massachusetts on August 15. Additionally, 14 new COVID-19 related deaths were reported. To date, 114,095 people have tested positive with 8,596 COVID-19 related deaths reported in Massachusetts. The current positive test rate in the state remains at a 1.4% low.