10/21/2020

Local Health Department BinaxNOW Allocation Guidance

Background

The Federal Government has begun a distribution program of a new antigen test: the Abbott BinaxNOW. The Abbott BinaxNOW test is a fast-acting antigen test granted an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) to detect the presence of SARS-CoV-2 viral protein. The BinaxNOW test is administered through an anterior nares swab that is then inserted into a credit-card sized test, where a reagent is added. These tests are inexpensive, point-of-care (POC) tests, with results available within 15 minutes. This distribution program has two separate channels:

- **The Federal Government is sending BinaxNOW tests directly to long-term care (LTC) facilities in Illinois.** The Federal Government has relayed to the State that it is prioritizing distributing BinaxNOW tests directly to LTC facilities with Clinical Laboratory Improvement Amendment (CLIA) waivers in counties with either 5%-10% positivity or 10%+ positivity. The State had no role in the selection of LTC facilities that are receiving these tests or the volume of BinaxNOW tests sent to each LTC facility. The Federal Government has indicated these shipments are likely to continue through at least the end of the year. The latest copy of the distributions provided to the State is available at DPH.antigentesting@illinois.gov. Further updates will be made available to local health departments if significant changes in the distribution occur.

- **Distributions from the Federal Government to the State of Illinois.** In addition to the tests for LTC facilities, the Federal Government is providing BinaxNOW tests directly to the State. The Federal Government and Abbott have conveyed that these shipments to the State will continue on a weekly basis through at least the end of the calendar year and will total more than 3 million tests. The State plans to distribute these shipments through the following steps:
    - **Local Health Departments (LHDs)**. The majority of initial shipments received by the State will be shared with LHDs for distribution on a per capita basis. Each LHD will tailor their response to the specific needs in their jurisdiction under a number of broad and flexible options. As LHDs distribute or use the tests, the State expects weekly follow-up shipments will continue to replenish their supply.
    - **State Priority Groups.** Additionally, the State intends to reserve some portion of the tests for distribution to various priority groups, including Federally Qualified

Health Centers (FQHCs) serving vulnerable populations that need tests beyond what their LHD can provide; pilot testing programs in K-12 schools; testing in State-owned facilities (including State-owned LTC facilities); and pilot testing programs in correctional facilities. In the future, the State also may allocate tests to additional priorities identified.

Allowable uses and distributions of this test by local health departments

The State of Illinois is permitting a wide range of possible uses for these tests to encourage LHDs to tailor their approach to meet the priority needs of their communities. The LHD may distribute the tests directly to partners and organizations or instead use some or all of the allotment to perform testing directly. The LHD may use its allotment in any combination of the uses listed below. Each LHD has discretion to prioritize distribution to the following categories based on disease spread in its jurisdiction and access to RT-PCR testing.

The permissible options for distribution or use by an LHD are:

- Direct testing by the LHD or LHD partner – The LHD may conduct direct testing using the BinaxNOW test or contract with any partner or vendor to conduct the testing on the LHD's behalf. This testing can be made available to the greater community or focus specifically on outbreaks. If used in outbreak situations, a follow-up PCR test in addition to the Abbott BinaxNOW test may be recommended.

- Distribution to congregate or other similar settings – Congregate settings have been greatly impacted by the COVID-19 pandemic. LHDs may distribute the tests for use in congregate settings including the following:
    - *LTC facilities* – as a supplement to the direct federal testing shipments or to LTC facilities that did not receive those shipments.
    - *Jails* – distribution and/or testing in jails or other corrections facilities. Note that the Illinois Department of Corrections operates its own testing program and does not need to be included in LHD allotment planning.
    - *See the Illinois Department of Public Health LTC antigen testing guidance **here** for testing in LTC settings.*

- Distribution to schools, essential workplaces, and entities providing services to vulnerable populations – Schools, essential workplaces, and entities providing services to vulnerable populations are critical. LHDs should work with health care providers to ensure that appropriate healthcare personnel are available to conduct such tests. (Please see the relevant guidance on testing in these setting ***here***). LHDs may distribute tests for use in these settings:
    - *K-12 education* – distribution to and/or testing with health care providers in or around local schools that prioritizes students attending classes over extracurricular activities.

- *Local colleges and universities* - distribution to and/or testing with health care providers in or around local college and universities.
- *First responder testing* – distribution to and/or testing of local fire department, police department, emergency medical services, or other first responder services and/or workplaces.
- *Essential workforce and critical infrastructure testing* - distributions to and/or testing of essential workplaces and/or critical infrastructure employees.
- *Homeless services* – distribution to and/or testing in homeless services and facilities.
- *Public housing, other high-density housing* – distribution to housing facilities that may pose a potential risk for virus spread.
- *See the Illinois Department of Public Health Rapid Point-Of-Care Testing for COVID-19 in Schools and Other Community Settings guidance **here**.*

- Distribution to health care providers including hospitals, FQHCs, rural health clinics ("RHCs"), doctor's offices, and others – Frontline health care providers often have the systems and structures in place to initiate or to expand antigen testing quickly and effectively. For LHDs who do not have ready entities in other categories, distribution to health care providers may be the best use of initial shipments (and potentially future shipments as well). LHDs should also consider partnering with health care providers to provide testing in facilities such as schools, essential workplaces and other entities providing services that are not capable of testing on their own. This could include:
  - *FQHCs and RHCs* - for community testing, partnering to support another testing priority, or testing within the FQHC/RHC.
  - *Local hospitals* – for community testing, partnering to support another testing priority, or testing within the local hospital.
  - *Doctor's offices* - for community testing, partnering to support another testing priority, or testing within the provider's office.
  - *Home Health Aides and Hospice* – for testing aides that interact with vulnerable populations.
  - *Other health care providers.*
  - *See the Illinois Department of Public Health provider antigen testing guidance **here** for testing in provider settings.*

- Other – the above is meant to encourage significant flexibility for LHDs to meet the testing needs of their communities. If your LHD has identified a testing need that is not listed, email DPH.antigentesting@illinois.gov to discuss making the use allowable by adding it this guidance.

Restrictions on uses

While there is significant flexibility for LHDs to tailor usage of these tests, there are some absolute restrictions. Failure to abide by these restrictions can result in the LHD being

prohibited from receiving future test supplies and, in the case of theft or fraud, potential prosecution of those involved to the fullest extent of the law:

- These tests may not be sold by the LHD, anyone the LHD distributes the test to, or its agents. It is illegal for *anyone* to sell these tests.
- While entities can charge for the service of delivering the test, no entity can charge for the BinaxNOW test supplies themselves. No distribution of BinaxNOW tests may result in the consumer being charged directly for COVID-19 testing above and beyond what their insurance will cover.

Key items to consider

Refer to the IDPH LTC, Health Care Provider, and K-12/Community Settings POC Antigen testing guidance for considerations on the use of these devices in the community.

Additional items to consider when determining the most effective use of the BinaxNOW tests. Some entities (e.g., hospitals) may already be equipped to start testing, while others (e.g., schools) may require significant effort to put the needed components into place.

- *CLIA Waiver* – Users conducting antigen tests must comply with CLIA regulations. All entities must either have or obtain CLIA wavier, or higher CLIA certification, and meet all requirements to perform that testing. For more information, see the Centers for Medicare & Medicaid Service's (CMS) summary of the CLIA regulations. Information on how to obtain a CLIA waiver is available here. The form to obtain a CLIA waiver is available here.
    - Email DPH.CLIA@Illinois.Gov with CLIA related inquiries

- *Provider Order* – All tests must be performed under the direction of a health care provider's order. These orders can be issued by health care providers on an individual basis, or health care providers or LHDs can issue standing orders. LHDs should refer to their current standing order for flu and/or HIV testing, or previously issued standing orders for H1N1 in 2009, as templates for COVID-19 testing orders. LHDs may seek standing orders through their respective medical directors, or other, authorized physicians. LHDs should work with entities that receive the BinaxNOW tests to ensure that an order can be obtained.

- *Who Can Swab?* – The FDA, in its authorization and instructions, does not require any specific qualification or license to administer BinaxNOW tests. The FDA only requires that the operator using the test be "appropriately trained in performing and interpreting the results." The State's current recommendation is that those administering the test be any level of healthcare worker to perform the swabbing if currently under their scope of practice, but the final determination is with the issuer of the standing order.

- *Liability Protection* – The federal Public Readiness and Emergency Preparedness Act (PREP Act, Pub. L. 109-148) and subsequent COVID-19 declaration offer liability protection for individuals and entities involved in COVID-19 testing. The federal government has further extended the PREP Act protection to licensed health care practitioners who prescribe or administer point-of-care COVID-19 tests for screening in congregate facilities. This includes licensed health care practitioners prescribing or administering FDA-authorized COVID-19 tests, like the BinaxNOW test, for off-label use to screen asymptomatic individuals in nursing homes, assisted living facilities, long-term care facilities, and other facilities where people congregate to receive care, education, or to work. If a specific end-user is interested in knowing if they are covered by the PREP Act, they should consult with their legal counsel for guidance.

- *Personal Protective Equipment (PPE) requirements* – Appropriate personal protective equipment is required for individuals conducting the tests. Centers for Disease Control and Prevention Guidance for appropriate COVID-19 Specimen Collection can be found here.

- *Parental Consent if Testing Minors* – Any entity testing minors must be prepared to obtain proper parental consent.

- *Disposal Requirements* – Any entity doing testing must be prepared to follow proper medical waste handling and disposal guidelines. All components of the BinaxNOW test kit, as well as gloves used by persons administering the test and any grossly contaminated PPE, should be discarded as infectious waste.

- *Reporting Requirements* – See *required reporting* below.

- *Training* – See *Training* below.

Required reporting

Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS). Under HHS guidance, locations offering point-of-care testing are considered "laboratories," and reporting to HHS is accomplished by transmitting data to state or local public health departments. Two types of reporting are required as part of antigen testing. All antigen tests, positive and negative, must be reported.

- End-User Reporting – All entities that perform POC antigen testing must report each individual positive and negative test result to IDPH according to these instructions:

- Register in IDPH's reporting system with the facility's CLIA certificate number at: https://redcap.link/dph.illinois.gov.poccovid19registration.
- The entity registering for end-user reporting will need its CLIA number, phone number, ordering provider, facility name, address, phone number, the type of testing platform, and the point of contact email and phone number.
- Once the entity's registration has been processed, the individual who submitted the registration will receive an email with a link to begin reporting. This link is unique to the facility and can be shared with facility staff who will be reporting results.
- Each positive and negative test result must be reported to the IDPH system within 24 hours of the test being administered.
- For questions, email dph.elrresp@illinois.gov
- *The LHD is responsible for notifying all entities it distributes the test to about the reporting requirements and must follow up to ensure receiving entities are properly reporting their tests.*

- LHD Distribution Reporting – LHDs are responsible for reporting to the State where they choose to distribute their allocation of BinaxNOW tests. This is critical both for tracking the medical devices in case of an issue and for the ability of the LHD to receive further shipments. The LHD should enter any and all distributions in **here.**

Training

In order to assure the efficacy of the BinaxNOW rapid test, anyone administering the test must attend a training. LHDs are also recommended to attend a training. Live virtual trainings are offered via Webex at the times found here.

Additional self-guided set up and training resources can be accessed here.

Information on future shipments

At this time, the State has a significant amount of BinaxNOW tests and anticipates continuing to receive additional tests on a weekly basis. LHDs are strongly encouraged to expeditiously distribute tests and report these distributions to IDPH, so they can receive rapid replenishment. This is an important component of the COVID-19 response.

The State does not anticipate being short on tests at any point through the end of the calendar year, but if that circumstance does occur, the State may alter volume of replenishments on distributions and end-user reporting and potentially add in factors on positivity rate, equity considerations, or additional factors.

If you would like to accelerate or stop your weekly shipments of BinaxNOW tests, contact DPH.antigentesting@illinois.gov.