

To provide more rapid COVID-19 diagnostic testing to entities who need it, the Lake County Health Department (LCHD) is working with Illinois Department of Public Health (IDPH) to distribute the BinaxNOW™COVID-19 Antigen Tests to appropriate entities within our community. **BinaxNOW™COVID19 Antigen Tests are antigen tests purchased by the federal government and disseminated to states for distribution.** These tests provide more rapid results than the RT-PCR tests.

### Role & Responsibility of Lake County Health Department

In this process, **the Lake County Health Department is responsible to complete the following:**

- Order BinaxNOW™COVID-19 Antigen Tests after receiving order forms from entities that meet all the requirements on the [LCHD BinaxNOW™COVID-19 Antigen Tests Checklist](#).
- Schedule and facilitate the pick-up of BinaxNOWCOVID-19 Antigen Tests.
- Provide a standing order to entities who do not have a medical director if all the requirements on the [LCHD BinaxNOW™COVID-19 Antigen Tests Checklist](#) are met.
- If capacity permits, LCHD may fit test N95 masks for healthcare professionals performing the test. At a minimum, Lake County Health Department will provide a list of agencies that may be contracted to perform N95 mask FIT testing.
- Report distribution of BinaxNOW™COVID-19 Antigen Tests to the State.

#### **The Lake County Health Department will not:**

- Obtain a CLIA certification waiver for an entity.
- Provide training for, or administration of, the BinaxNOW™COVID-19 Antigen Tests.

### Protocol for Obtaining BinaxNOW™COVID-19 Antigen Tests

#### 1. Entities will contact their appropriate Lake County Health Department Liaison.

- If an entity does not have a Lake County Health Department Liaison, they can contact the Communicable Disease program at (847) 377-8130.

#### 2. Liaisons will review the [LCHD BinaxNOW™COVID-19 Antigen Tests Checklist](#) with ordering entities.

- Liaisons will inform the entities that they must meet all requirements on checklist. If feasible, liaisons may choose to help entities meet individual requirements.
- **Lake County Health Department will not administer BinaxNOW™COVID-19 tests for external entities or report for them.**

3. Entities will obtain [ordering forms](#) from their designated Liaisons or on the Lake County Health Department website and submit the completed forms to Lake County Health Department.
  - The first time an entity places an order, a completed [LCHD BinaxNOW™COVID-19 Antigen Tests Checklist](#) should accompany their order request to demonstrate they have met the needed requirements.
  - **Completed order forms should be submitted to Lake County Health Department via email at [COVIDtesting@lakecountyil.gov](mailto:COVIDtesting@lakecountyil.gov).**
  - Lake County Health Department will submit orders to Illinois Department of Public Health (IDPH) for BinaxNOW™COVID-19 Antigen tests.
  - Order forms will be forwarded to the Emergency Response Center to be used during fulfillment and IDPH distribution reporting.
4. Illinois Department of Health (IDPH) will ship tests to the Lake County Health Department and the tests will be received by Lake County Health Department Emergency Response Center staff.
5. Lake County Health Department will notify the entity who placed the order that tests have arrived and provide pick up time.
  - On Tuesdays, the Emergency Response Center will pull the specified number of tests for each order and schedule pick up with appropriate entities.
  - **Effective 1 August 2021: Entities will pick up tests on Thursdays (at the prescheduled time) at the Lake County Emergency Management Gurnee storage location (905 Lakeside Dr., Unit 7, Gurnee, IL 60031)**

## LCHD BinaxNOW™COVID-19 Antigen Tests Checklist

All entities must be able to meet the following requirements in order to obtain and administer BinaxNOW™COVID-19 Antigen Tests:

1. Entity has a CLIA Waiver to perform the test.
  - Information on how to obtain a [CLIA waiver](#)<sup>3</sup> and [CLINICAL LABORATORY IMPROVEMENT AMENDMENTS \(CLIA\) \(illinois.gov\)](#) application (**form CMS-116**)<sup>4</sup> can be found on the [IDPH Website](#).
    - Check the box titled, "CLIA Waiver" and complete Sections I – VI and IX – X.
    - In Section VI, Waived Testing, enter test name under Abbott BinaxNOW™ COVID-19 Ag Card Point of Care SARS-CoV-2 Diagnostic Test.
    - For entities without a formal Lab Director/Owner, managerial professional with current employment status at the facility and responsible for the quality

- assessment and monitoring of tests performed should be entered (i.e. Superintendent, Lead Nurse, etc.)
- For section IX, Type of Control, check the box that most appropriately describes your facility.
    - Schools should check box O9 and enter Public School District
  - For detailed instructions refer to pages 8-12 on the CLIA application.
  - A CLIA Waiver is needed for each location testing will be performed. ○ One application form can be used to request a CLIA waiver for multiple site locations.
  - Professionals conducting antigen tests must comply with [CLIA regulations](#)<sup>1</sup>
  - All entities must either have or obtain a CLIA waiver, or a 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](#)<sup>2</sup>
2. Entity must have reviewed and agreed to follow the POC testing guidance from CDC/IDPH. <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>
  3. Entity must identify and use a separate area/room in which POC testing will be performed.
  4. Entity has designated and trained licensed healthcare professional(s) who will perform Point-of-Care (POC) testing.
    - The State recommends that those administering the test and performing the swabbing be a **licensed** healthcare professional (any level) if it is within their scope of practice.
      - The Food and Drug Administration (FDA) does not require any specific qualification or license to administer BinaxNOW™COVID-19 Antigen Test but requires that the professional using the test be “appropriately trained in performing and interpreting the results.”
      - Final approval of the designated professionals is with the provider who provides the order.
    - In order to assure the efficacy of the BinaxNOW™COVID-19 Antigen rapid test, anyone administering the test must attend a training.
      - Live virtual trainings are through the State.
      - [Online, self-paced training is offered through Abbott.](#)
      - Additionally, testing personnel new to CLIA-waived testing should complete [CDC's online training module](#)<sup>6</sup>.

5. Entity has registered in the Abbott BinaxNOW™ COVID-19 Antigen Reporting Survey via the State of Illinois [OR](#) if a long-term care facility (LTCF), has registered and reports through CDC's National Healthcare Safety Network (NHSN).
  - The entity must report all antigen testing (negative and positive results) to the State of Illinois through a unique [Abbott BinaxNOW reporting survey](#)<sup>5</sup>
  - Information needed will include CLIA number, ordering provider, entity name, address, phone number, the type of testing platform, and the point of contact email and phone number.
  - Once the 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 entity and can be shared with other staff who will be reporting results.
  - If the entity is a LTCF that is registered and reporting all test results through NHSN, this entity must ONLY report via [NHSN](#). In this instance, there is no need additionally report cases via Abbott BinaxNOW reporting survey<sup>5</sup>.
  - All entities must report only POSITIVE test results to Lake County Health Department with the Lake County Health Department [COVID-19 lab reporting form](#).
6. A provider standing order for the testing is in place.
  - 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 LCHD can issue standing orders.
  - If necessary, once all other items on this checklist are met, standing orders can be obtained by contacting the Lake County Health Department testing team at [COVIDtesting@lakecountyil.gov](mailto:COVIDtesting@lakecountyil.gov). The testing team will ensure all other criteria has been met on the checklist prior to working with the Lake County Health Department Medical Epidemiologist to issue a standing order.
7. Professional(s) who will perform POC testing have been appropriately trained to perform the test as required under [CLIA rules](#)<sup>1</sup>.
8. Entity must have appropriate personal protective equipment (PPE) available for professional(s) who will perform POC testing.
  - Professionals must use [appropriate PPE when collecting and handling samples](#)<sup>7</sup>.
  - Recommended PPE for professionals performing point of care testing includes a fit-tested N95 respirator, face shield, gown, and gloves.

9. Entity must have a process for disposal of infectious waste materials created through the testing process.
  - Any entity performing testing must be prepared to follow proper medical waste handling and disposal guidelines.
  - All components of the BinaxNOW™ COVID-19 test kit, as well as gloves used by persons administering the test and any grossly contaminated PPE, should be discarded as infectious waste.
  
10. Entity must have the ability to adhere to the federal requirements for reporting test results.
  - Entities that perform POC testing must report each individual positive and negative test result to state and local public health officials, per the Control of Communicable Disease Code, in addition to the patient/parent/guardian according to the instructions below.
  - Anyone at the school or entity performing the testing may enter the data.
  - **Each positive and negative test result must be reported to the IDPH system within 24 hours**
  - **Entities must [report all positive test results](#) to Lake County Health Department via fax at (847) 984-5680 within 24 hours.**
  
11. Entity must have a process for parental consent if minors will be tested.
  - Parental Consent is required if testing minors.
  - Each entity is responsible for **working with their legal representative** to develop a form or tool to obtain proper parental consent.

## Additional Information

1. While Entities can charge for the service of delivering the test, no entity can charge for the BinaxNOW™ COVID-19 test supplies themselves.
  - No distribution of BinaxNOW™ COVID-19 Antigen Test may result in the consumer being charged directly for COVID 19 testing above and beyond what insurance will pay.
  
2. The federal Public Readiness and Emergency Preparedness Act (PREP Act, Pub. L. 109148) 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™ COVID-19 Antigen 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 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.

### **Document References:**

1. "CDC Clinical Laboratory Improvement Amendments (CLIA)"  
<https://www.cdc.gov/clia/index.html>
2. "Research Testing & Clinical Laboratory Improvement Amendments of 1988 CLIA Regulations" <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-andCLIA.pdf>
3. "CDC How to Obtain a CLIA Certificate of Waiver"  
<https://dph.illinois.gov/content/dam/soi/en/web/idph/files/publications/clia-how-obtain-certificate-waiver-041316.pdf>
4. "Clinical Lab Improvement Amendments (CLIA) Application for Certification" [CLINICAL LABORATORY IMPROVEMENT AMENDMENTS \(CLIA\) \(illinois.gov\)](https://www.illinois.gov/CLIA)
5. "IDPH COVID Point of Care (POC) Reporting Registration"  
<https://redcap.dph.illinois.gov/surveys/?s=XJARKWRP7E>
6. "CDC Training: Ready? Set? Test! Patient Testing is Important. Get the Right Results"  
<https://www.cdc.gov/labtraining/training-courses/ready-set-test.html>
7. "CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19"  
<https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>
8. IDPH Guidance on Rapid Point of Care Testing" <https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>