



## BinaxNOW™ Public Health Use Guidance for Local Health Departments in Kentucky

The BinaxNOW™ COVID-19 Ag Test Card is a rapid antigen test with a nasal swab that provides results in as little as 15 minutes. Its Emergency Use Authorization (EUA) is for individuals suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset. However, BinaxNOW™ Ag test cards may also have utility in other situations (e.g., in asymptomatic people), if appropriate guidelines are followed.

The federal government has allocated approximately 1.3 million BinaxNOW™ Ag test cards to the Kentucky Department for Public Health for use during the COVID-19 pandemic response. Local health departments (LHD’s) can request these test cards for use in their jurisdictions.

The purpose of this document is to provide guidance for use of the BinaxNOW™ Ag test cards in a variety of use-case scenarios that could be considered by LHD’s.

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### How might local health departments use the BinaxNOW™ Ag test cards?

Following are three potential ways local health departments might choose to employ BinaxNOW™ Ag test cards:

#### 1. Outbreak response

Scenario: A cluster of cases is identified in a local school classroom, correctional facility, homeless shelter, first responder group (e.g., firehouse or specific crew, EMT crew, police station), in-patient behavioral health or substance use treatment facilities, universities or colleges, critical infrastructure workers, or any other defined group where quick assessment of potential infection might be useful to prevent further transmission.

LHD Response: Define the specific population that was likely exposed and the time frame of exposure. There must be at least 2 days from exposure before testing is likely to detect COVID-19. Employ the BinaxNOW™ Ag test cards to test all persons in the exposed group(s). People who test positive, even if asymptomatic, should be isolated and contact tracing conducted. Those who test negative should continue with quarantine. As those exposed become symptomatic, BinaxNOW™ Ag test cards could be used for rapid turn-around testing, following the usual isolation and contact-tracing procedures for positive results. Those who are symptomatic and test negative should have a confirmatory PCR test performed and be evaluated for alternative explanations for their symptoms, but would remain a case per Kentucky case classification criteria.

#### 2. Testing of symptomatic people in clinical settings

Scenario: Use of federally-issued BinaxNOW™ Ag test cards is appropriate for clinical settings for rapid testing of symptomatic people. This would be recommended for facilities, such as federally-qualified health centers (FQHC’s), rural health centers (RHC’s), rural health clinics, local health departments, or other healthcare facilities working with underserved or high-risk populations. Many of these types of facilities (e.g., FQHC’s, RHC’s) can be encouraged to work with DPH to arrange for direct shipping of BinaxNOW™ Ag test cards from DPH. If the local health department chooses to partner with one of these types of facilities locally or use BinaxNOW™ Ag test cards in its own clinic(s), this would be acceptable use of this resource.

LHD Response: Use with LHD oversight or arrange for distribution of these cards to facilities with CLIA-certification or waiver (see Requirements section below). In this setting, symptomatic patients with positive tests would be considered COVID-19 cases based on the presumptive lab evidence provided by the BinaxNOW™ Ag test card. A negative result in an individual with symptoms consistent with COVID-19 would be only presumptively negative unless an alternative illness was confirmed through testing. Otherwise, this individual would continue as a person under investigation pending verification of the negative antigen test with a negative PCR test. A negative result in an individual with history of specific exposure to COVID-19 would not eliminate the need for quarantine.

### 3. Surveillance testing of defined populations

Scenario: This is a potentially useful strategy for groups of people who might introduce COVID-19 into other high-risk groups, such as inmates, or in-patient populations. DPH is partnering with the Kentucky Department of Corrections and the Behavioral Health Developmental and Intellectual Disabilities (BHDID) Division to offer BinaxNOW™ Ag test cards to state correctional and state behavioral health facilities. However, local, in-patient substance use treatment centers, local or county jails, other in-patient or residential facilities with limited outside contact, or other groups identified by the local health department might prevent introduction of COVID-19 into their confined populations by use of BinaxNOW™ Ag test cards.

LHD Response: Identify local facilities/agencies that might be appropriate for use of BinaxNOW™ Ag test cards. Oversee use of the cards directly or partner with facilities to distribute test cards to them for use if they are a CLIA-certified or waived facility (see Requirements below).

In order for this to be an effective strategy several points are critical:

- Regular testing must occur – 2 times/week is recommended, but at least weekly testing is needed due to the 2-14 day incubation period for COVID-19;
- Testing is targeted to those who might bring COVID-19 into the facility, including staff, vendors, visitors, and incoming inmates or patients (depending on the scenario), not to the full residential population;
- A plan for follow-up PCR testing for any positive result in an asymptomatic person must be in place: false positive results can occur with repeated testing in non-exposed, asymptomatic populations;
- Guidelines for isolation of positive individuals until f/u PCR testing is complete must be in place;
- Must be implemented directly by the LHD or arranged for distribution of these cards to facilities with CLIA-certification or waiver (see Requirements section below).

#### **Requirements for use of BinaxNOW™ Ag test cards by LHD's**

- All BinaxNOW™ Ag test cards must be used in the context of a CLIA-waived facility, either the LHD itself, or a partner organization with CLIA-certification or waiver;
- The CLIA-certified or waived facility using the cards is responsible for training staff to administer the test (online training is available); a high school diploma is a minimum requirement for those staff;
- The CLIA-certified or waived facility using the cards is responsible for reporting the results of testing;
  - All positive results must be reported electronically to the Kentucky Health Information Exchange (KHIE), either through a direct KHIE connection, or using a KHIE Portal for COVID-19 testing <https://khie.ky.gov/COVID-19/Pages/Direct-Lab.aspx>;
  - All aggregate test results (total number of positives and total tests administered) must be reported to KDPH via an online survey: <https://tinyurl.com/KyLabCovidAggRpt>;
- Interpretation of results using BinaxNOW™ Ag test cards should follow state guidance (attached).