TESTING GUIDANCE

Abbott BinaxNOW™ COVID-19 Antigen Card

State Allocation

Kentucky Public Health
Prevent. Promote. Protect.

PURPOSE

The purpose of this fact sheet is to provide guidance for the allocation, distribution, use and reporting of Abbott BinaxNOW™ COVID-19 Antigen (Ag) Card tests in the Commonwealth of Kentucky. The Kentucky Department for Public Health (KDPH) may modify this guidance based upon availability, outbreak surges or other factors during the response to COVID-19.

BACKGROUND

Through December 2020, the federal government will provide Kentucky with BinaxNOW™ COVID-19 Ag Cards. These test cards will be distributed to designated facilities with high-risk, vulnerable populations through coordination with federal, state and local agencies.

The BinaxNOW™ COVID-19 Ag Card is a rapid antigen test with a nasal swab that provides results in as little as 15 minutes. It is intended for use in individuals suspected of COVID-19 by their healthcare provider within the first seven (7) days of symptom onset. This test is a screening tool used in conjunction with established mitigation procedures and does not replace any prevention measures.

ALLOCATION STRATEGY

Allocations will be based upon expected usage of the BinaxNOW™ COVID-19 Ag Cards including, but not limited to:

- Clinical Settings for Symptomatic Patients
- Outbreak Scenarios
- Surveillance Testing in Settings with Confined Populations

The following types of facilities have been prioritized to receive allocations:

- Acute Care Adult Psychiatric Facilities
- Correctional Facilities
- Federally Qualified Health Centers (FQHC)
- Local Health Departments (LHD)
- Residential Substance Use Treatment Centers
- Rural and Critical Access Hospitals
- Rural Health Clinics (RHC)
- University/College Health Centers

November 4, 2020

FACILITY REQUIREMENTS

Use of this authorized test is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests and Point of Care (POC) settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

Each facility requesting BinaxNOW™ COVID-19 Ag Cards must meet the following requirements and agree to follow KDPH's policies for use and reporting results:

- Develop a process/plan for using the cards, to include follow up PCR testing as required by KDPH's Antigen Test Result Guidance at:
  - https://govstatus.egov.com/ky-healthcare-guidance
- Train staff to administer the BinaxNOW™ COVID-19 Ag Card test and document this training per agency protocols.
- Report all positive and negative results through established reporting processes.

TRAINING RESOURCES

BinaxNOW™ COVID-19 Ag Card

- Train-the-Trainer: KDPH will coordinate with Abbott to schedule virtual train-the-trainer courses. Persons will be invited to scheduled classes via established distribution lists.
- Training: Abbott has developed videos, modules, guidance documents and FAQs for the BinaxNOW™ COVID-19 Ag test that can be accessed at:
  - https://www.globalpointofcare.abbott/en/support/productinstallation-training/navica-brand/navica-binaxnow-ag-training.html

Kentucky Health Information Exchange (KHIE)

- Training on how to register for an account and submit test reports electronically is available through live trainings, printed materials or online at:
  - https://khie.ky.gov/COVID-19/Pages/Direct-Lab.aspx

QUESTIONS

- CLIA: Contact Truman Taylor, OIG, at truman.taylor@ky.gov
- BinaxNOW™: 1-800-257-9525 or ts.scr@abbott.com
- KHIE Portal: KHIElabs@ky.gov
- Allocation/Distribution: DPH.SEOC@ky.gov
- Aggregate Reporting System: COVIDKYLAB@ky.gov

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REQUESTS & DISTRIBUTION

Facilities can submit requests for the BinaxNOW™ COVID-19 Ag Card tests by completing a Resource Request Form at:

- https://ky.readyop.com/fs/4iR3/11ea

KDPH staff will review resource requests daily and notify the requestor of the request status and further actions.

KDPH will distribute tests through UPS to facilities who have been approved through the state's Resource Request Process. Shipments will continue until further notice. LHDs are encouraged to distribute tests throughout their respective jurisdictions in accordance with KDPH guidance.

STORAGE REQUIREMENTS

Facilities must store test cards between 35.6°F - 86°F. The test cards are stable until the expiration date marked on the outer packaging and containers. All test components must be prepared at room temperature before use.

SPECIMEN COLLECTION & TESTING

Testing personnel must have a high school diploma, at minimum, and be trained with periodic assessment on their ability to perform quality testing. Due to health and safety concerns, it is recommended that all non-healthcare persons administer the test under the direction of a trained health care professional of the CLIA home office.

Specimens should be tested immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/ storage/transport may yield erroneous results. Refer to the Centers for Disease Control and Prevention (CDC) for PPE guidance and Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) at:

- https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

DISPOSAL

ALL components of this COVID-19 antigen test should be discarded as biohazard waste according to federal, state and local regulatory requirements.

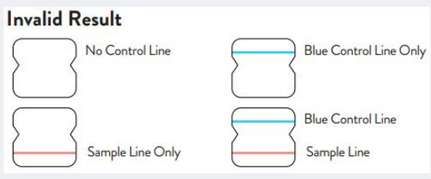
November 4, 2020

RESULT INTERPRETATION

- Antigen Guidance: Refer to KDPH's Antigen Test Results Guidance "Response to Point-of-Care Antigen Test Results" at:
  - https://govstatus.egov.com/ky-healthcare-guidance
- Negative Result: 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 performed correctly, but no COVID-19 antigen was detected.

- Positive Result: 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 *Sample Line*. Any visible pink/purple colored *Sample Line* designates a positive result.

- Invalid Result: If no control and no sample lines are seen, if just the sample line is seen, or the *Blue Control Line* remains blue, the assay is invalid. Invalid tests should be repeated.



REPORTING REQUIREMENTS

All states and laboratories must report COVID-19 results to the appropriate federal, state or local public health agency within 24 hours of each individual being tested. ALL positive results must be reported daily into KHIE at:

- https://khie.ky.gov/COVID-19/Pages/Direct-Lab.aspx

ALL positive and negative aggregate results must be reported daily to KDPH through the COVID-19 KY Aggregate Daily Lab Report system.

Entities reporting aggregate results will need to register for access to submit data. The access request link can be found at:

- https://tinyurl.com/KyLabCovidAggRpt

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