Use of BinaxNOW COVID-19 Antigen (Ag) Test Training for Long Term Care Facilities

Kentucky Department for Public Health and Abbott Laboratories

December 14, 2020

1:00 - 2:15 P.M. (EST)

Kentucky Public Health

Prevent. Promote. Protect.

Abbott BinaxNOW™ COVID-19 Antigen (Ag) Cards

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Abbott

BinaxNOW™
COVID-19 Ag Card
Overview

Emergency Use Authorization Granted by FDA

Intended Use: Key Points

- The BinaxNOW™ COVID-19 Ag Card is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasal swabs from **individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.**

- Antigen is generally detectable in nasal swabs during the **acute phase of infection**.

- Negative results from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay if necessary, for patient management, may be performed.

BinaxNOW™ COVID-19 Ag Card
Emergency Use Authorization

The BinaxNOW™ COVID-19 Ag Card is only for use under the Food and Drug Administration's Emergency Use Authorization

What is Emergency Use Authorization (EUA)?

- FDA emergency access mechanism
- Health & Human Services declare when circumstances exist to justify use of diagnostics under EUA for the diagnosis of COVID-19
- It is not full FDA clearance or approval and is temporary, until the declaration is terminated or revoked.

BinaxNOW™ COVID-19 Ag Card
Emergency Use Authorization

Test Site Obligations:

- Notify relevant public health authorities on intent to run test
- Report all results to healthcare providers and include the Healthcare Provider Fact Sheet. Healthcare providers to include Patient Fact Sheet with results
- Utilize product as outlined in the BinaxNOW COVID-19 Ag Card Instructions for Use
- Ensure all operators are trained to perform and interpret the test
- Have process in place for reporting test result to Healthcare Providers & relevant public health authorities
- Per Product Insert: Collect performance data and report any significant deviations from the product performance characteristics via email to FDA/HHS and to Abbott Technical Support
- Retain all records associated with EUA until otherwise directed by FDA

BinaxNOW™ COVID-19 Ag Card
Technical Overview

BinaxNOW™ COVID-19 Ag Card
Product Overview

Test Summary	Rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2
Testing Environment	Point of Care settings with a CLIA Certificate of Waiver, Compliance or Accreditation
Specimen Type	Direct nasal swab
Time to Result	Results visually read at 15 minutes *Results should not be read after 30 minutes
Waste Disposal	All components should be discarded as Biohazard Waste
PPE for Specimen Collection & Handling	Refer to CDC Guidelines for collecting, handling and testing clinical specimens (link in Product Insert)

Reagent and Materials

Materials Provided:

- 40 Test Cards
- Extraction Reagent
- Patient Collection Nasal Swabs
- Positive Control Swab
- Blank Nasal Swab for Negative Control
- Product Insert
- Procedure Card
- Healthcare Provider & Patient COVID-19 Fact Sheets

Materials Required but not Provided:

- Clock, timer or stopwatch

Optional Materials:

- Plastic Transport Tube

Storage & Stability:

- Store kit at 2-30°C
- Ensure all test components are at room temperature before use
- Stable until the expiration date marked on the outer packaging

Quality Control

Internal Procedural Controls:

- BinaxNOW™ COVID-19 Ag Card has built-in procedural controls
- In an untested card there will be a blue line at the Control Line position
- In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working

Note: If the blue line is not present at the Control Line position prior to running the test, do not use and discard

When is Quality Control Required?

- External Positive & Negative Controls:
  - Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working properly and that the test is correctly performed
  - BinaxNOW™ COVID-19 Ag Card kits contain a positive control swab and sterile swabs that can be used as a negative control

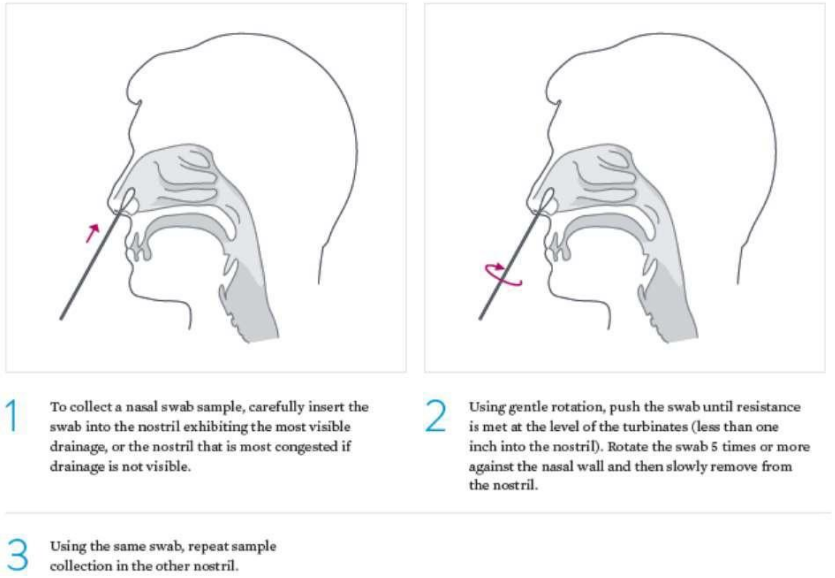
Note: *If correct results are not obtained, contact the Abbott Technical Services Team at 1-800-257-9525 between 8 a.m. and 8 p.m. EST Monday-Friday before testing patient specimens*

- Required Frequency:
  - New shipments received
  - Untrained operators
  - Conforming with local, state, and/or federal regulations, accrediting groups, or lab's standard QC procedures.

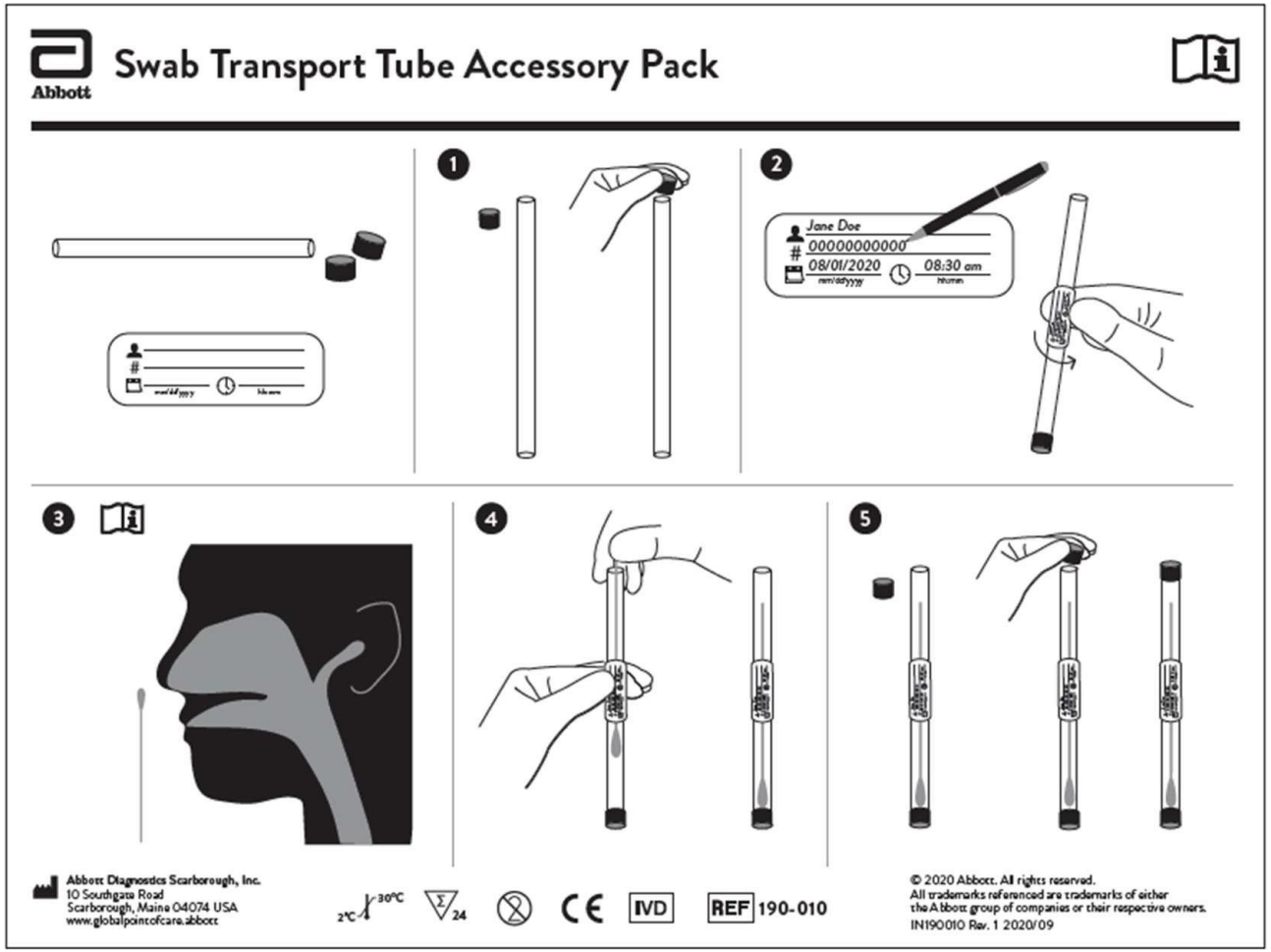
Nasal Swab Sample Collection

Only the swab provided in the kit is to be used for nasal swab collection

- Insert the nasal swab into the nostril exhibiting the most drainage or congestion
- Using gentle rotation, push the swab until resistance is met
  - At the level of the nasal turbinates
  - Less than one inch into nostril
- Rotate the swab 5 times or more against the nasal wall
- Slowly remove the swab
- Using the same swab, repeat sample collection in the other nostril



Specimen Transport & Storage



Specimen Transport & Storage

For best performance, direct nasal swabs should be tested as soon as possible after collection.

If immediate testing is not possible:

- **Do not return the nasal swab to the original paper packaging**
- To avoid contamination and preserve sample integrity, place the nasal swab in a clean, unused, tightly capped plastic tube & label with the patient information
- The sample is stable in the plastic tube at room temperature (15-30°C) for up to one (1) hour prior to testing
- If greater than one (1) hour delay occurs, dispose of sample & collect new sample

BinaxNOW™ COVID-19 Ag Card Procedure

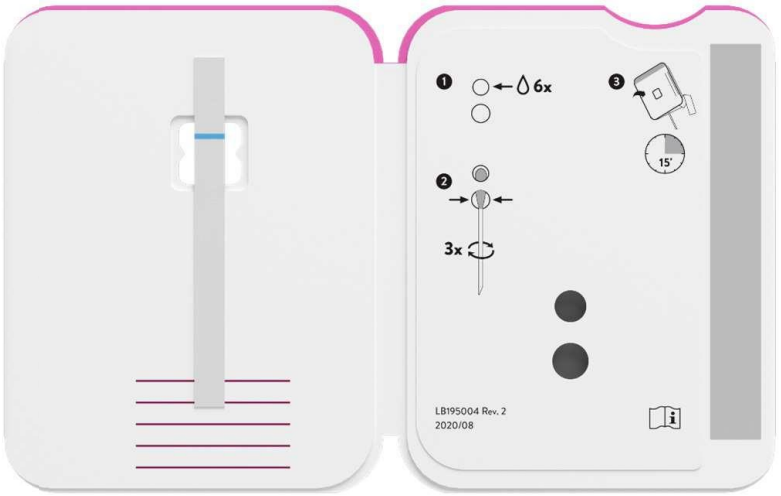
Key Points

Prior to Beginning a Test Remember to:

- Ensure all components are at room temperature
- Open test card <u>just prior</u> to use
- Lay test card flat for use
- Ensure Blue Control Line is present

BinaxNOW™ COVID-19 Ag Card Overview

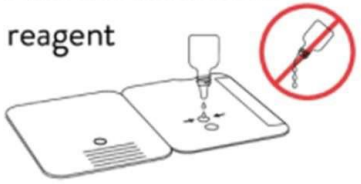
Exterior View



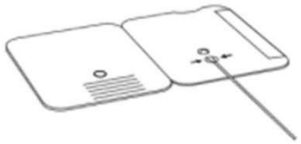
Interior View

BinaxNOW™ COVID-19 Ag Card Test Procedure Overview

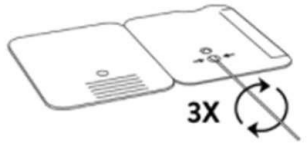
1. Add the extraction reagent



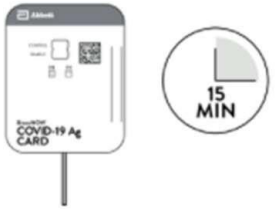
2. Insert the sample nasal swab



3. Rotate the nasal swab shaft three times



4. Close the test card; wait 15 minutes



5. Results are read visually

BinaxNOW™ COVID-19 Ag Card Procedure

Key Points

Step 1:

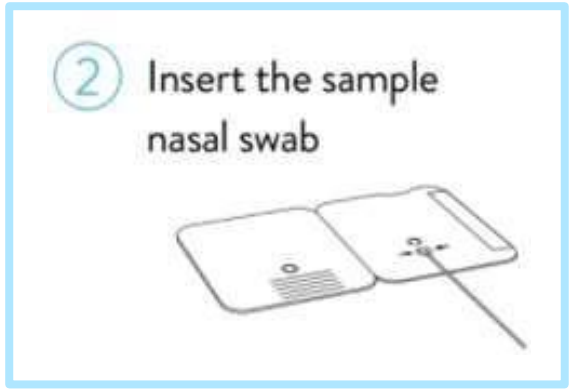
- Hold extraction reagent bottle **vertically** to ensure adequate volume
- Add 6 drops for a Patient test
- Add 8 drops for a Quality Control test

BinaxNOW™ COVID-19 Ag Card Procedure

Key Points

Step 2:

- Insert swab into the bottom hole of the test card
- Firmly push swab upwards until the swab tip is visible in the top hole

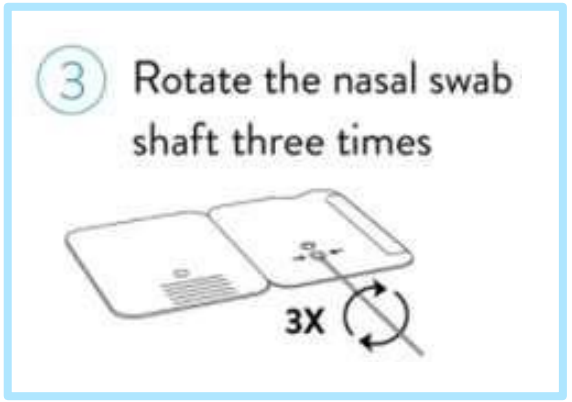


BinaxNOW™ COVID-19 Ag Card Procedure

Key Points

Step 3:

- Rotate swab shaft **3 times** CLOCKWISE (to the right).
- False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card

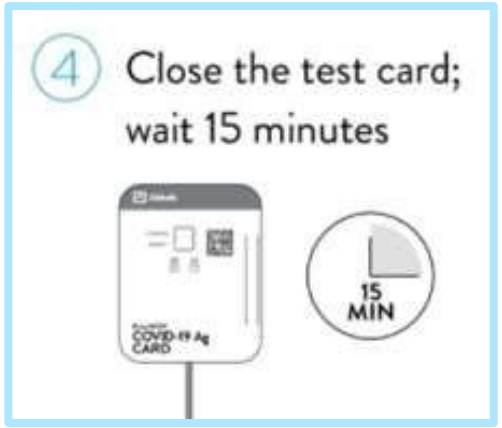


BinaxNOW™ COVID-19 Ag Card Procedure

Key Points

Step 4:

- Peel off adhesive liner from the right edge of the test card
- Close and securely seal the card
- To ensure proper test performance read results at **15 minutes** and not before
- Results should not be read after 30 minutes



Result Interpretation

Negative

- **One pink/purple colored line** in the top half of the window, in the Control Line position
- Indicates a negative result & no antigen detected

Positive

- **Two pink/purple colored lines** in both the Control & Sample Line position
- Indicates COVID-19 antigen was detected
- Any visible pink/purple line is positive

Result Interpretation

Invalid

The assay is invalid & should be repeated if:

- Only the Sample Line is present
- No lines are present
- Blue Control Line remains blue

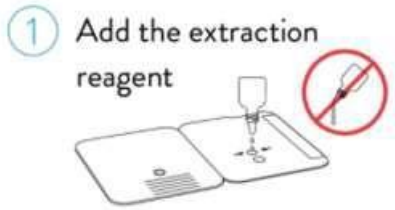
Test should be discarded as Biohazard waste

Near-Patient Workflow: No Swab Transport*

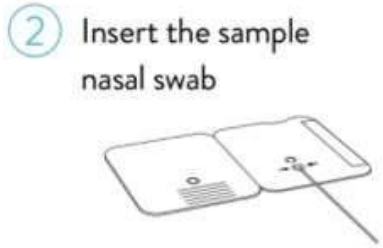
Option A (Collect Patient Swab First, Prior to Test Procedure)

Collect Nasal Swab

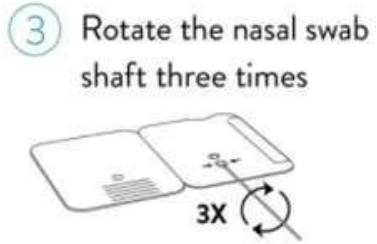
Step 1: Add the Extraction Reagent



Step 2: Insert sample into bottom hole and push firmly upwards so tip is visible in top hole



Step 3: Rotate (twirl) swab shaft 3 times clockwise (to the right)



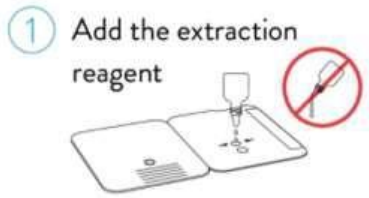
Step 4: Peel off adhesive liner, close and securely seal card. Read results in the window 15 minutes after closing the card

*Swab will not be moved from immediate testing area where sample collection is performed

Near-Patient Workflow: No Swab Transport*

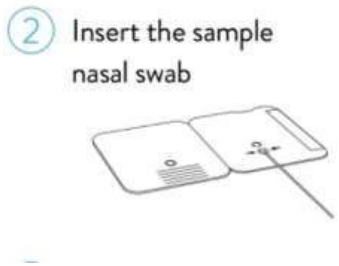
Option B (Begin Test Procedure, Then Collect Patient Swab)

Step 1: Add the Extraction Reagent



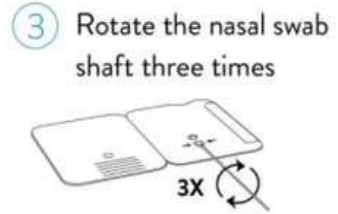
Collect Nasal Swab

Step 2: Insert sample into bottom hole and push firmly upwards so tip is visible in top hole



Within 3 minutes of adding extraction reagent drops, insert swab into test card

Step 3: Rotate (twirl) swab shaft 3 times clockwise (to the right)



Step 4: Peel off adhesive liner, close and securely seal card. Read results in the window 15 minutes after closing the card

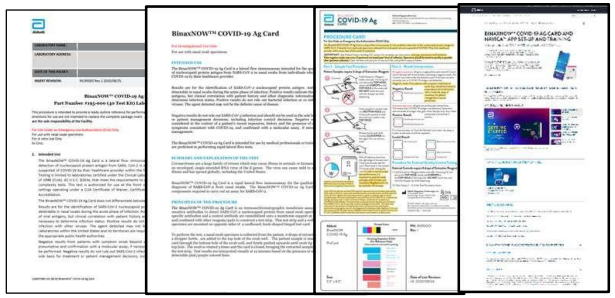
*Swab will not be moved from immediate testing area where sample collection is performed

Training Toolkit

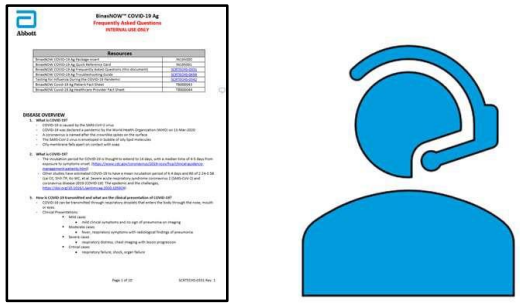
https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html

Six Detailed Training Videos

PowerPoint Training



Helpful Tools & Support Documents



FAQs and Technical Service Contacts
Monday-Friday 8am EST – 8pm EST
1-800-257-9525 or ts.scr@abbott.com

Additional Resources

Ordering Information

- 195-000: BinaxNOW™ COVID-19 Ag Card (40 Tests)
- 195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit (10 Positive Swabs)
- 190-010: Optional COVID-19 Swab Transport Tube Accessory Pack (24 Tubes)

Technical Support Line:

- US +1 800 257 9525, Option 2
  - 8am-8pm EST Monday-Friday
- ts.scr@abbott.com

The BinaxNOW™ COVID-19 Ag Test Card EUA has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories and patient care settings. The test has been authorized only for the detection of the presence of Antigen Protein from SARS-CoV-2, not for any other viruses or pathogens, and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Using the BinaxNOW™ COVID-19 Ag Cards

Doug Thoroughman, PhD, MS, State Epidemiologist (Acting)

CDC Career Epidemiology Field Officer, Kentucky Department for Public Health

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Use-Cases for BinaxNOW™ Ag Test Cards

- Three primary scenarios for effective use:
  - Outbreaks
  - Clinical settings
  - “Surveillance” testing
- Each requires different thought processes
  - How often they will be used
  - Who they will be used with
  - What kind of follow-up is needed

Outbreak Scenarios

- Facilities may want to partner with local health department
  - To determine strategies for possible use
  - Coordinate procurement of cards
  - Assist with administration if needed
- Test symptomatic people to get early assessment
  - Speeds up isolation and quarantine decisions
- May test asymptomatic if indicated during outbreaks
  - High likelihood of exposure
  - At least two days have passed since exposure
  - May not have adequate supplies of cards to follow this strategy
  - Not highly recommended
    - Resource intensive
    - Interpretation of results questionable

Interpretation and F/U in Outbreak Settings

- If symptomatic
  - Tests positive: Initiate isolation and contact investigation
  - Tests negative: F/U PCR test to confirm negative
    - Isolate until results received
    - If still negative, quarantine if indicated by situation, consider testing for other illnesses
- If definite exposure but asymptomatic
  - Should be quarantined to start with
  - Positive result indicates infection – Isolate/contact trace - quarantine
  - Negative result – continue with quarantine
- If no exposure identified and asymptomatic
  - Recommend confirming positive result with PCR
  - Negative result taken at face value

Testing of Symptomatic Persons in Clinical Settings

- Can be used in healthcare settings for rapid assessment of COVID-19
  - Must have CLIA certification or waiver
  - FDA Emergency Use Authorization (EUA) approved for individuals suspected of COVID-19
  - Should be used within the first 7 days of symptom onset
- Consider Situation:
  - If NO (or very few) cases identified in community (not likely currently!)
    - Recommend F/U PCR test to confirm a positive test – Isolate until PCR results received
    - Negative result taken at face value – may want to test for Flu, other respiratory pathogens
  - If cases already prevalent in community
    - Positive result would be taken at face value
    - Negative results would be recommended for F/U PCR to confirm if there was a clear exposure UNLESS another etiology for symptoms is identified through testing
    - Negative results do not eliminate the need for quarantine if exposed

“Surveillance Testing” of Defined Populations

Goal is to prevent introduction into facility or patients

- Targeted testing
  - Recommended at least weekly (2X per week ideal)
  - Staff AND incoming inpatients
- If staff or incoming persons are asymptomatic
  - Positive results would recommend PCR confirmation (Isolate until results received)
  - Negative results taken at face value
- If symptomatic employee – shouldn’t be at work!
  - Get tested outside
  - Isolate until results received
  - Report results to workplace
- If symptomatic incoming inpatient
  - Positive results taken at face value – isolate and keep precautions in place
  - Negative results confirmed with PCR
- Must have strategy for follow-up PCR testing in place

Requesting BinaxNOW™ Ag Test Cards

- For additional test cards, complete and submit a BinaxNOW® Resource Request Form for Long Term Care Facilities (available at: https://ky.readyop.com/fs/4iY5/ac9d through 12/30/2020)
- KDPH staff will review and process resource requests daily
- KDPH will distribute test cards from the state warehouse and/or through UPS

KDPH Points of Contact

James R. House, Master Exercise Practitioner
State Health Operations Center Community Testing Operations Section Chief
Work Cell: (502) 330-5950
Email: jamesr.house@ky.gov

Robbie Hume
State Health Operations Center Logistics Section Chief
Work Cell: (502) 892-8899
Email: robbie.hume@ky.gov

Kentucky Health Information Exchange (KHIE) Portal

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

Charlese Blair, CRT, CMA, Project Coordinator, Office of Health Data and Analytics, Kentucky Health Information Exchange (KHIE)

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Reporting Requirements

Doug Thoroughman, PhD, MS, State Epidemiologist (Acting)

CDC Career Epidemiology Field Officer, Kentucky Department for Public Health

Kentucky Public Health

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Reporting Requirements

- All positive test results need to be reported
  - KHIE Portal or KHIE Electronic Lab Report feed
  - Clinical information reported separately if a clinical visit is involved
    - KDPH COVID-19 Case Investigation Form (Fillable)
    - https://khie.ky.gov/COVID-19/Pages/Direct-Lab.aspx
- All BinaxNOW Ag Test Cards utilized
  - Need to be reported in aggregate
    - Total tests performed each day
    - Total positive results each day
  - Online survey for this purpose
  - https://tinyurl.com/KyLabCovidAggRpt
- Who reports may vary depending on facility and scenario

Q/A and Points of Contact

Surveillance, Testing and Reporting

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Logistics and Request Process

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