Abbott BinaxNOW Antigen Tests for K-12 Schools

Departments of Health & Senior Services
and Elementary & Secondary Education

October 9, 2020
Federal government prioritized use in K-12 schools

Minimally invasive nasal swab that **must** be administered by a health professional

Yields results in 15 min. without additional equipment (uses a test card)

Missouri is expected to receive 1.84 million tests in incremental shipments in coming months
DHSS & DESE requires BinaxNOW tests be used among symptomatic school personnel & students

Available to any public or private K-12 school

Staff/students may still need to go home until they feel better, but test results help identify a course of action faster (excluded for 10 days or not)

Email questions during the webinar to Communications@dese.mo.gov
• Sensitivity & specificity
  - False positive rate = 1.5%
  - False negative rate = 2.9%
  - Based on tests administered within first 7 days of symptom onset

• Clarification re: use of tests among students

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Standing Order & CLIA Waiver

- State order allows school-based RNs/LPNs (or their designee) to administer BinaxNOW test onsite
- Statewide CLIA waiver gives all schools ability to administer laboratory tests onsite
  - Must submit test sites (building, address) & healthcare professional information (name, license number) on the application

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• Current max. allotment = 1 test/student and staff
  - May request fewer tests (i.e. only for staff)
• District’s/school’s portion of total number of tests requested becomes their “share”
• “Share” is then distributed to each district/school when the state receives a new shipment

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Shipping & Storing Test Kits

• 40 test kits per box
• Shipping all district tests to one central location
• Detail regarding how many tests will be shipped, and when, will be forthcoming, so adequate storage should be identified
• Application requests single point-of-contact for district/school – he/she will receive shipping alerts
  - First from DESE, then confirmation from SEMA

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Training to Administer Tests

- Adhere to Abbott’s written Instructions for Use (IFU)
- Abbott’s BinaxNOW test training video
  - Medical professionals administering tests must watch the overview video & modules 1-4
  - Provide documentation to DHSS to verify training

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Administering BinaxNOW Tests

- **Logistics**
  - Administer in a space other than the nurse’s office
  - Make hand hygiene products readily available
  - Have waste disposal arm’s length away
- **Medical-grade PPE is required** – state is providing & will ship along with test kits
  - Gown, surgical mask, eyewear & gloves

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Consent Required for Testing

- Receive consent from school staff members & parents/guardians for student testing
  - Sample provided in Appendix B in DHSS toolkit
- Direct consent-related to questions to school’s legal counsel
- Retain documents/records for at least two years

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• Required to report both positive & negative results within 24 hours
• State providing spreadsheet with required fields
• Spreadsheet will be submitted via secure FTP (contains PII & PHI, so do not email)
• Training session is forthcoming & further technical assistance will be provided

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BinaxNOW Test Disposal

- Test kit is the primary piece of infectious waste requiring appropriate disposal according to state regulations
  - Use infectious waste bags to discard used testing materials, gloves & grossly contaminated PPE
- Missouri Licensed Infectious Waste Transporters can help schools that don’t currently have an infectious waste plan (link/info in toolkit)

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If BinaxNOW Test is Negative...

- If showing COVID-19 symptoms, encourage to follow-up with health care provider
- Encourage symptomatic individuals to stay home until they feel better & follow the school’s policy for illness
- Consider the context of the patient’s recent exposures, medical history & COVID-like symptoms

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If BinaxNOW Test is Positive...

- Positive test is diagnostic for COVID-19
  - Create plan for where/how positive students should wait for parent/guardian pick-up
  - Send individual home to isolate
  - Contact LPHA to provide notification & begin case investigation ASAP

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# Antigen Testing Program Contacts

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>CONTACT PERSON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application, Test Allotment &amp; Shipments</td>
<td><a href="mailto:Communications@dese.mo.gov">Communications@dese.mo.gov</a></td>
</tr>
<tr>
<td>BinaxNOW Clinical Training</td>
<td><a href="mailto:Marjorie.Cole@health.mo.gov">Marjorie.Cole@health.mo.gov</a></td>
</tr>
<tr>
<td>CLIA Waiver to Perform Laboratory Testing</td>
<td><a href="mailto:Russ.Drury@health.mo.gov">Russ.Drury@health.mo.gov</a></td>
</tr>
<tr>
<td>Electronic Reporting of Test Results</td>
<td><a href="mailto:ELR@health.mo.gov">ELR@health.mo.gov</a></td>
</tr>
<tr>
<td>Infectious Waste Disposal</td>
<td><a href="mailto:Jonathan.Garoutte@health.mo.gov">Jonathan.Garoutte@health.mo.gov</a></td>
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Antigen Test Resources

- DHSS/DESE Guidance Document
- Abbott BinaxNOW Card Details
- Abbott BinaxNOW Card FAQs
- Abbott BinaxNOW Training Video
- FDA Emergency Use Authorization
- FDA Fact Sheet

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