



K-12 Testing Program
Resource Manual
March 2021

Points of contact & overview of K-12 testing program

KDHE Points of Contact

Lacey Kennett

- Preparedness Public Information Officer at KDHE
- Lacey.Kennett@ks.gov
- (785) 296-1984

Maria O' Sullivan

- School Health Clinical Consultant at KDHE
- BSN, RN
- Maria.Osullivan@ks.gov

Overview of K-12 Testing Program

In order to **promote the safe re-opening of K-12 schools in-person**, KDHE has worked to set up and manage a K-12 testing program. This **program offers testing resources and support to all schools interested in participating in screening or diagnostic testing.**

Program features:



- Step-by-step instructions & guidelines on how to get set up for testing



- Interactive webinars to inform on latest testing updates & cross-share success stories



- Overall program support with any questions/obstacles in testing

Five simple steps required to perform BinaxNOW Antigen testing



Obtain CLIA certification

- Process generally takes 1-2 weeks and requires \$180 fee
- Fill out and submit Form CMS-116 outlined [here](#)
- Organizations may be able to partner with LHDs to operate under their Certificate of Waiver



Design program

- Decisions include:
 - Who are you testing?
 - How often is testing taking place?
 - Who is collecting samples?
 - How are results reported?



Order test kits

- Identify & contact the Emergency Manager in your county to order test kits
- Emergency Manager contact information can be found [here](#)
- Connect with your region's lab vendor for confirmatory PCR tests (*slide 15*)



Perform testing

- Watch the Abbott [\(here\)](#) and KDHE BinaxNOW training videos [\(here\)](#)
- Refer to information in this packet [\(here\)](#) for further testing directions guidance



Report results

- **All** results will need to be submitted within 24 hours to KDHE through LabXchange, an electronic resulting system that helps automate the process
- Refer to information in this packet for further guidance



Obtain CLIA certification



Overview of the CLIA Certificate of Waiver FAQs

- 1 What is a CLIA certificate of waiver?

 - Clinical Laboratory Improvement Amendments (CLIA) regulates the quality and safety of labs to ensure accuracy, reliability, and timeliness of patient test results
 - A certification of waiver allows an organization to performed "waived tests," which are simple tests that have an insignificant risk of an erroneous result
 - Abbott BinaxNOW is a waived test under CLIA
- 2 Is my organization eligible?
What are the requirements?

 - Any organization can apply for a CLIA certificate of waiver
 - As part of the application, the organization must complete an CMS-116 form and pay a \$180 fee for a waiver that is valid for 2 years
 - There is no physical inspection as part of the approval process and organizations are not routinely surveyed
- 3 How long will it take to receive a CLIA certificate of waiver?

 - A certificate of waiver can typically be granted in 1-2 weeks
 - In some instances, applications can be prioritized if a faster turn around time is required
- 4 Can I operate under the CLIA certificate of my LHD?

 - Yes, an organization can perform tests under the CLIA waiver of their LHDs
 - The LHD must be informed and agree to allow the organization to operate under their waiver
- 5 Do I need to wait to have a CLIA certificate before ordering tests?

 - No, the CLIA certificate of waiver process and the ordering process can work in parallel. However, testing cannot begin until the waiver is approved

*The CLIA Certificate of Waiver application can be found on the KDHE website [HERE](#).
Please email KDHE.CLIA2@ks.gov to ask any clarifying questions*



Design program

Two types of COVID-19 tests used as part of the K-12 testing program: PCR & Antigen tests



On-site antigen testing



Lab-based PCR test

Description

- KDHE provides BinaxNOW kits with necessary supplies and instruments
- Results in **15-30 minutes**
- **Potentially less accurate** than PCR; potential for false-negative results

- State-contracted labs provide variety of PCR based kits
- Lab equipment/ processing needed, resulting in **longer processing times (~48-96 hours)**
- PCR tests are the **gold-standard for accuracy**

Use case for K-12 districts

- To be used as primary test for diagnostic/ screening at K-12 schools

- To be used as a confirmatory test in response to specific antigen test scenarios

Sampling method

- Nasal

- May be nasopharyngeal, mid-nasal, oropharyngeal, or saliva based

Detailed on pages 9-10

Detailed on page 11



Backup: Detailed information on best use for PCR v. Antigen tests

Purpose	PCR	Antigen
Regular and repeated screening of unexposed and asymptomatic people	Preferable	Acceptable
Diagnostic testing in symptomatic people	Preferable	Preferable within the first 5-7 days from symptom onset
Diagnostic testing in asymptomatic people	Preferable	Acceptable in people with known exposure
Diagnostic testing in previously COVID-19 positive patients with new exposure and symptomatic (potential re-infection)	X	Preferable within the first 5-7 days from symptom onset

Additional information can be found on the KDHE website [here](#)



Rapid Antigen Testing: Screening testing guidance

Sample: Who can be tested?

Testing Groups / Scenarios	Sample frequency	Target Population(s)
Screening: School Staff	x2/ week	Including, but not limited to: <ul style="list-style-type: none"> • Teachers • Administrative staff • Coaches • Lunch staff
Screening: Students participating in high-risk activities	x2/ week	Students participating in: <ul style="list-style-type: none"> • Contact or indoor sports • Choir, Cheer, Band, Orchestra
Screening: Students working in high-risk settings or with vulnerable populations	x1/ week	Students working in (self-select): <ul style="list-style-type: none"> • Settings with face-to-face interaction (e.g. grocery stores, food services, retail, etc.) • Settings with vulnerable populations (e.g. nursing home, hospitals, etc.)



Rapid Antigen Testing: Diagnostic testing guidance

Who should be tested?

- **Students/ staff who become symptomatic** with COVID-10 symptoms during the school day, including:
 - Fever (>100.4 degrees Fahrenheit)
 - Chills
 - Rigors
 - Myalgia
 - Malaise
 - Headache
 - Sore throat
 - Lower respiratory illness
 - Olfactory and taste disorders
 - Congestion/ runny nose
 - Nausea or vomiting
 - Diarrhea
- **Students/ staff who have been identified as close contacts** with someone who has tested positive for COVID-19
- **Students/ staff who have participated in high-risk activities**
- **Students/ staff who request to be tested**



PCR Testing: Use for confirmation

When should a confirmatory PCR test be used?

- **Symptomatic individual:**
 - Positive antigen test is a positive – follow recommended quarantine/isolation guidelines
 - Negative antigen test should be confirmed by PCR test in most cases

- **Testing an asymptomatic close contact:**
 - Confirm a positive antigen test with a PCR test in most cases
 - If there is community spread or the person has ongoing close contact to an infected person or persons, then the clinician can decide not to confirm via PCR
 - KDHE guidance: Confirmatory test not be needed in this scenario above
 - Negative antigen test is a negative – individual should finish required quarantine regardless of negative test result

- **Screening asymptomatic and unexposed individual:**
 - Positive antigen test should be confirmed by PCR test
 - Negative antigen test is a negative

Kansas K-12 school options for confirmation PCR testing

- **Coordinate with KDHE Unified Testing Strategy allocated lab vendors** to establish a working agreement
- Use local health department
- Require staff / students to coordinate with their own test providers



What to do when an individual tests positive/comes in close contact

Isolation of a Case

- A symptomatic case should stay home for whichever of the below cases is longer:
 - 10 days from the onset of symptoms **OR**
 - 72 hours after fever is gone without the use of fever reducing medication **AND** there has been a significant improvement in symptoms

****Isolation for confirmed cases is a minimum of 10 days*

Quarantine of Close Contacts

- Close contacts of a confirmed case should ideally quarantine for 14 days after their last contact with a case
- If they do not develop symptoms during the quarantine period, then they are released from quarantine at the end of the 14 days
- Those who are under a 14-day home quarantine should not attend school, work or any other setting where they are not able to maintain a 6-foot distance from other people.
- They can attend settings where they can maintain a 6-foot distance from other people as long as they remain asymptomatic

Testing out of quarantine

KDHE recently adopted guidelines that allow for testing out of quarantine after day 7, or a shortened quarantine period of 10 days instead of 14. However, the decision of whether to allow this rests with each county health department. Contact your county health department about whether or not this is an option in your school

- KDHE guidance on shortened quarantine can be found [here](#).



Order test kits



Orders for antigen tests need to be submitted through Emergency Managers (EM)

Process for ordering antigen tests

Determine quantity to request

- No set order sizes for BinaxNOW tests¹. It is **up to the organization to determine the volume** requested
- It is highly encouraged that organizations place orders based on **planned usage for the next 4-6 weeks**

Connect with county EM

- All orders need to be **made through the county's EM**
- In order to expedite the process, make sure you can provide the following information to your EM—***District/school name, address, order size, number of tests on-hand***

Reorder supply as needed

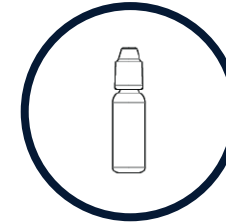
- Your district/school must **proactively place an order** through your county EM **to replenish supplies of tests**
- Currently, KHEL is unable to provide recurring shipments and can only send tests on an as-requested basis

Organizations can find their county EM [here](#).
For more detailed ordering instructions, please refer to this [form](#)

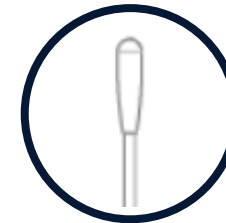
Materials included in kit



Test Cards: A cardboard, book-shaped hinged test card containing the test strip



Extraction Reagent: Bottle containing <1 mL of extraction reagent



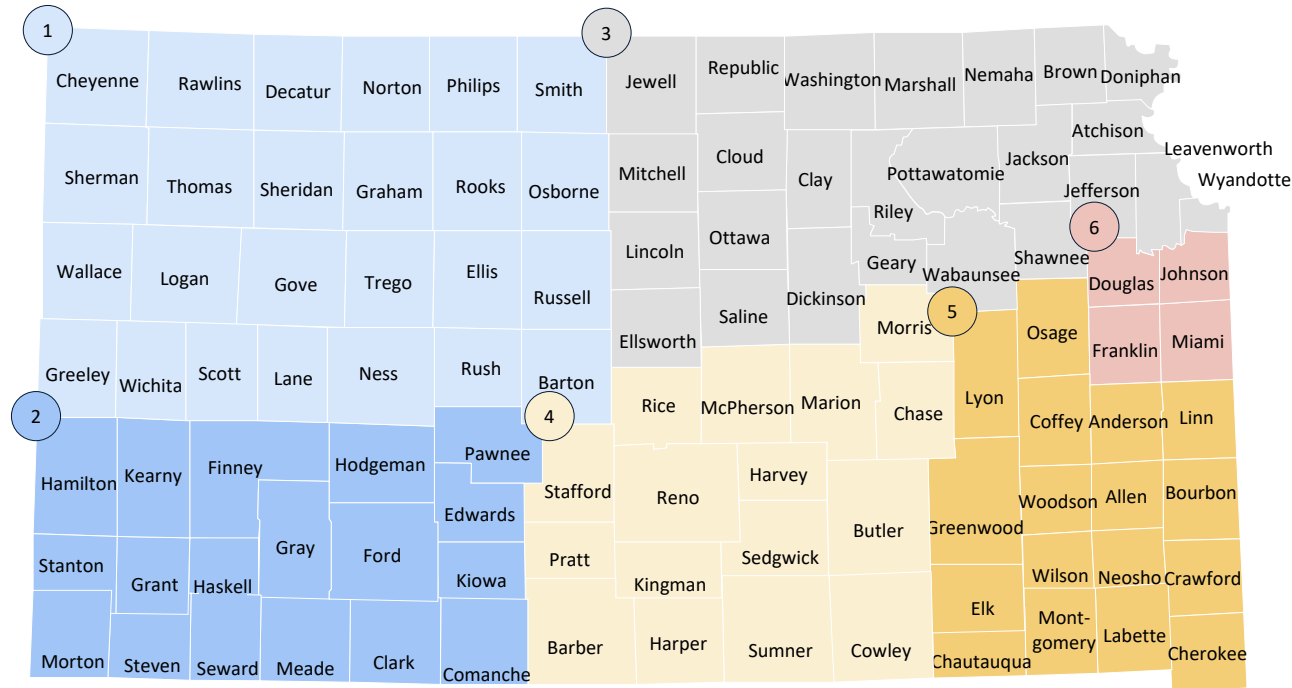
Nasal Swabs: Sterile swab for use with BinaxNOW COVID-19 Ag Card Home test

Timer not included. Test should be read at 15 minutes for an accurate result.

1. KDHE may recommend upper bound for order based on historical usage pattern

Geographic coverage of lab vendors for PCR tests

Counties have been grouped into the following six regions to balance vendor testing capacity. See the table on the right to find the vendor for your region.



Instructions for finding your vendor

Please contact vendor assigned to your region as below. Use the accompanying contact information on the following page for each vendor to get started.

Region	Vendor
1	KHEL
2	KHEL
3	Clinical Reference Lab
4	WSU
5	MAWD
6	MAWD

If you have a pre-existing vendor relationship with any of the vendors above, or the three vendors not assigned to regions (listed below), you may continue testing through them instead and testing will be reimbursed by KDHE. However, please ensure during your 1:1 call that they are aware of the KDHE initiative and able to provide kits, transportation and receipts as needed.

Additional vendors not assigned to regions: 4M, KU, Quest.

If you do not have an existing relationship with a vendor, please use the vendor assigned to your region.

PCR Lab Contact Information

Lab	Contact Name	Contact Email	Contact Number
Clinical Reference Lab	James Sotos	james.sotos@crlcorp.com	913-693-5499
MAWD	Cory Morgan	cmorgan@mawdpathology.com	913.339.8575
WSU	Debra Franklin	Debra.Franklin@wichita.edu	O: 316-978-5209 C: 316-213-4238
Kansas Health & Environmental Labs (KHEL)	KHEL	kdhe.KHEL_HELP@ks.gov	Please contact using email.

Contact Lacey Kennett from KDHE if any questions at Lacey.Kennett@ks.gov.



Perform testing



Information on steps required prior to performing a BinaxNOW antigen test



Complete training

Watch required training videos on Abbott & KDHE websites

Modules 1-4 on Abbott website found [here](#)

KDHE training video found [here](#)



Obtain supplies

Required supplies include:

- BinaxNOW test kit provided by KHEL
- Biohazard bags (for disposal of supplies)
- PPE
- Timer
- Record keeping supplies
- An observer



Run quality control (QC)

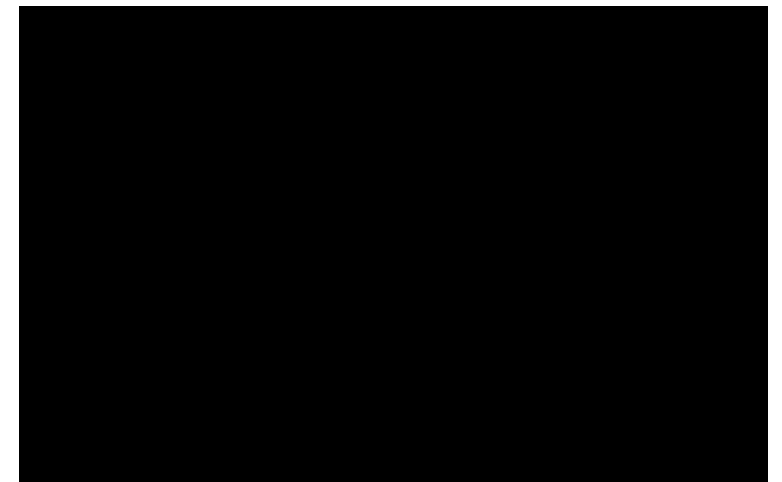
A negative QC (unused specimen swab) and a positive QC (only 1 provided in each box) needs to be done for each BinaxNOW test kit (box of 40 tests) and recorded before any specimen tests can be performed

Abbott video on how to run a QC can be found [here](#) in Module 2



Perform test

Follow the instructions in the video below to perform test



For additional information refer to the [KDHE Standard Operating Procedure](#) or the [Abbott instruction guide](#)



Biological Considerations

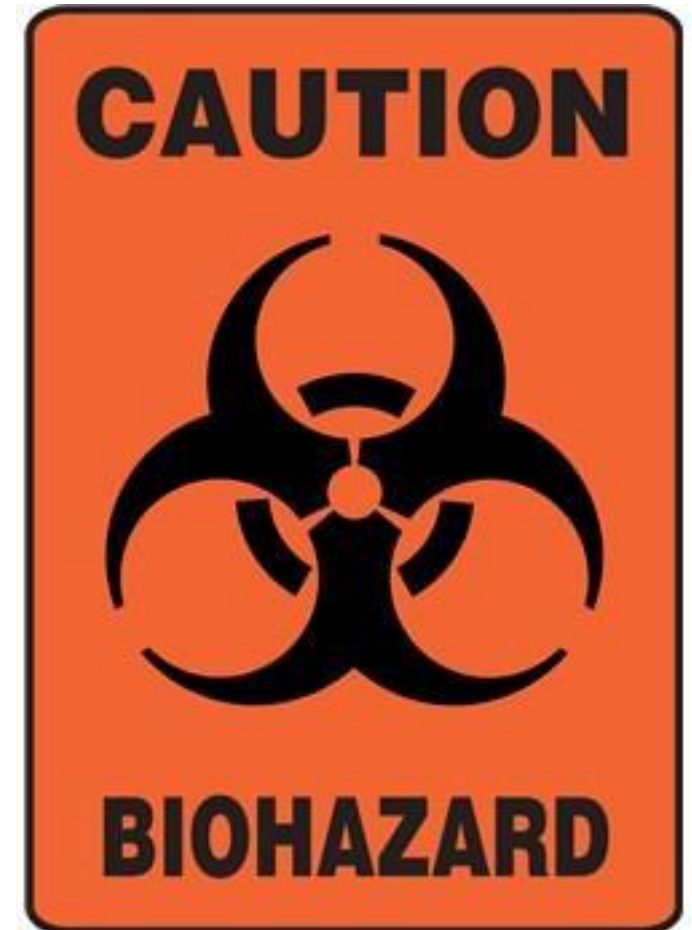
Biological substances

- A used swab is a biological substance
- Must be disposed of properly, usually through a third party
- Need a biological hazard bag
- Schedule a pickup for the bag once it gets full

<https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html>

“Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory.”

K.A.R. 28-29-7





Important Testing Reminders

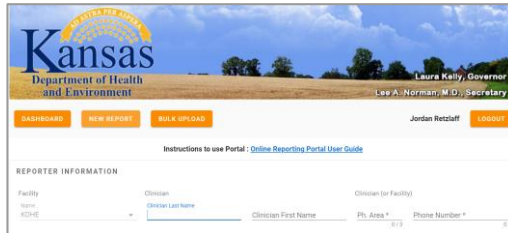
- Only use the swab that comes with the kit
- Test cannot be read after 30 minutes. You will need a timer
- Swab both nostrils for 5 seconds each
- Do NOT put swab back in original packaging after use
 - Test immediately
 - Can be placed in unused plastic tube, capped tightly at room temperature
 - Can be kept in tube for up to one hour. After that it is no longer viable



Report results



Two options for reporting antigen test results



OR

Kansas Disease Reporting Portal (page 23)

Online **COVID testing reporting portal** to submit patient information and corresponding test results

Kansas Disease Reporting Portal **does not have capability to inform users of their results**—additional processes required for notifications

LabXchange (page 24)

Electronic order entry system that helps to **automate the process of capturing patient information**—reducing time, errors, and paperwork

Offers reporting **capabilities to notify patients** of their results and allows org to **create a directory of patients to pre-populate data**



KDHE Disease Reporting Portal

AD ASTRA PER ASPERA
Kansas
Department of Health and Environment

Laura Kelly, Governor
Lee A. Norman, M.D., Secretary

DASHBOARD NEW REPORT BULK UPLOAD Jordan Retzlaff LOGOUT

Instructions to use Portal : [Online Reporting Portal User Guide](#)

REPORTER INFORMATION

Facility Name: KDHE

Clinician Name: Clinician Last Name, Clinician First Name, Ph. Area * (0/3), Phone Number * (0/7)

Kansas Disease Reporting Portal

- Option to input one at a time or via an Excel template for bulk reporting
- Can be used by one point-of-contact in each district, or each school testing can report individually
- All tests must be reported to KDHE, both positive and negative

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Facility	Patient_Last_Name	Patient_First_Name	Patient_DOB	Patient_Gender	Patient_Address_1	Patient_Address_2	Patient_City	Patient_State	Patient_Zip	Patient_Area_Code	Patient_Phone	Ordering_Facility
2													
3				Format MM/DD/YYYY (eg. 10/20/2020, 9/8/2020)									
4													
5													
6													



LabXchange

What is LabXchange: *LabXchange is an electronic order entry system that helps to automate the process of capturing patient information, reducing time, errors, and paperwork*

- 1 After logging into LabXchange and selecting Test Entry, **user must input Test Information** including **Test Location** (school site/ district), **Test Type** (rapid v. PCR), and **Test Result** (this can be added later if not resulted at time of input)
- 2 When entering Patient Information, the user has the **option scan a license which will pre-fill all required information**. They can also do a **Patient Lookup** which allows them to **type in the name of the patient and the corresponding Patient Information will auto populate**.
- 3 In order to use the Patient Lookup feature, the school must do a **one-time bulk upload of all their students/ staff utilizing a pre-set excel template**.

Patient First Name	Patient Middle Initial	Patient Date Of Birth	Patient Gender	Patient Address Line 1
JOHN		19980227	M	123 MAIN ST
JANE		19900101	F	234 SOUTH AVE

Live demo on LabXchange functionality and use can be found [here](#)

Questions? Contact Lacey Kennett

Lacey.Kennett@ks.gov