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KDHE PLAYBOOK FOR EMPLOYER-FUNDED TESTING PROGRAMS

With the wide availability of free, safe, and effective vaccines for COVID-19, the role of testing has begun to change. Many private employers are encouraging their employees to get vaccinated and offering testing to their unvaccinated employees to quickly identify individuals with COVID-19 infection so they can reduce ongoing transmission of the virus at the workplace. The Occupational Safety and Health Administration (OSHA) issued a federal rule will require large employers (a 100 or more employees) to test their unvaccinated employees on a weekly basis. KDHE has drafted this Playbook to assist employers in testing their workforce and will update this playbook as federal and state regulations are updated.

The Playbook is intended to support all businesses that wish to offer employee testing to prevent COVID-19 outbreaks in their workplace and help keep their businesses open. Just as schools in Kansas are successfully keeping schools open safely by identifying cases and stopping outbreaks, employers can use testing to screen against SARS-CoV-2 - the virus that causes COVID-19 – to protect their employees.

The Playbook will be incorporated to the state's unified testing strategy that Governor Laura Kelly introduced a year ago. That strategy helped ensure COVID-19 testing was available across the state by coordinating public and private COVID-19 testing efforts and encouraging routine screening in places like schools and nursing homes, to stop the spread of COVID-19 before it starts. In addition, KDHE has a COVID-19 Testing Map which directs Kansans to locations across the state where they can get free testing. The availability of these testing sites is dependent upon need, as well as federal funding.

Even with widespread vaccination against COVID-19, the virus is not expected to entirely go away. Scientists expect SARS-CoV2 to continue circulating in the population, not unlike the flu. Moving forward, COVID-19 testing will increasingly become a shared responsibility for both the public and private sector ensuring Kansans across the state have adequate access to testing. Although the OSHA regulations are not final and thus subject to change, employers are expected to be responsible for the costs of their employee testing programs.

OVERVIEW: The KDHE Playbook for Employer Testing Programs is intended to support businesses that wish to offer employee testing by providing:

Introduction

The purpose of this document is to provide employers with strategies to consider for incorporating testing for SARS-CoV-2, the virus that causes COVID-19, into the workplace. Much of this information comes from the Centers for Disease Control (CDC) ([link](#)) which updates its guidance as new information becomes available[1]. Employer testing strategies should protect employee privacy and confidentiality, consistent with federal guidance ([link](#)). In addition, employers providing testing of employees should put procedures in place for timely notification of results and establish appropriate measures to keep workers safe based on their testing results. This includes guidance on self-isolation ([link](#)) and restrictions on workplace access. New federal regulations requiring COVID-19 vaccination or weekly testing ([link](#)) have been recently released, but are already tied up in the courts.

Overview of testing scenarios

Diagnostic testing is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19 or has been exposed to someone who is suspected to have COVID-19.

Examples of diagnostic testing include:

- Testing people who have symptoms consistent with COVID-19 and who present to their healthcare provider
- Testing people as a result of contact tracing efforts
- Testing people who indicate that they were exposed to someone with a confirmed or suspected case of COVID-19.
- Testing people who attended an event where another attendee was later confirmed to have COVID-19

Screening tests are intended to identify infected people who have no symptoms and no known exposure. Screening helps to identify unknown cases so that measures can be taken to prevent further transmission.

Examples of screening testing include:

- Testing unvaccinated employees in a workplace setting
- Testing unvaccinated students, faculty, and staff in a K-12 school or institute of higher education setting
- Testing an unvaccinated person before or after travel
- Testing at home for someone who does not have symptoms associated with COVID-19 and no known exposures to someone with COVID-19

Test types: PCR and other NAATs and antigen diagnostic and screening testing for SARS-CoV-2 (COVID-19)

Viral tests can be used for diagnostic testing and screening testing. Nucleic acid amplification tests (NAATs) like PCR tests, and antigen tests are two common types of viral tests. Both can be used in employee testing programs.

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[1] Health care workplaces follow different requirements, which are listed [here](#)

PCR and other NAATs are the most accurate option to determine whether an individual is infected with COVID-19. Antigen tests are effective at determining whether an individual is currently infectious and can transmit COVID-19 to others. Currently, there are various manufacturers and platforms for PCR and antigen tests (see Menu of vendors section). There are some PCR and antigen tests that need to be processed in a laboratory, while others are point-of-care tests (see definition below).

Lab-based tests: Tests that need to be processed in a laboratory require transporting the specimen that is collected from the individual (e.g., a swab from the nose or a sample of saliva) to an off-site commercial laboratory. It typically takes 1-3 days to receive the result. Employers that choose to use tests that are processed in a laboratory need to contract with a lab company or commercial entity to determine how a specimen will be collected and transported. There are some tests that allow the individual to self-collect a specimen at-home and ship the specimen to the lab directly.

Pooled testing: PCR and other NAATs that are processed in a laboratory can also be "pooled." Pooling is the process of combining specimens from several people and conducting one laboratory test on the "pool" of specimens. If the pool is negative, the individuals whose specimens were in the pool are considered negative for COVID-19. If the pool is positive, each specimen is re-tested individually to determine which individual(s) are infected with COVID-19. Given that fewer testing materials are required for testing, pooling can reduce the overall cost of the testing program.

Point of Care: Point of care tests do not require transporting the specimen to a laboratory. Results are available on-site within 15-45 minutes of collecting a specimen. All PCR and other NAAT point-of-care tests require an instrument or a dock to process the specimen and provide a result. Antigen point-of-care tests may or may not require an instrument or dock to process the sample and provide a result. Employers can contract with a commercial vendor to offer point-of-care testing or purchase point-of-care tests directly from the manufacturer.

Most employers will contract with a lab company, university, or other commercial entity to perform SARS-CoV-2 tests. The vendor used by the employer should provide the technical and clinical details about their testing services and equipment. The type of test selected for an employee testing program will depend on multiple factors, including cost, the number of employees who need to be tested, testing frequency, availability of staff to perform on-site testing, and access to testing supplies**.**

 The table below summarizes the types of testing available:

	PCR and other NAATs	**Antigen tests**
Overview	Most accurate option to identify if an individual is infected with COVID-19	Most effective option for real-time identification of an individual who is currently infectious and can spread COVID-19 to others
Specimen type	Self-collected nasal swab or saliva sample *(At-home or on-site)*	Self-collected nasal swab *(At-home or on-site)*
Time to results	**Lab based:** 24-72 hours **Point-of-care**: 15-30 minutes	**Lab-based**: 24-72 hours **Point-of-care**: 15-30 minutes

Price per test *(Estimates, prices may vary by vendor and manufacturer)*	Lab-based (Individual sample): ~$75+ Lab-based (pooled samples): ~$50+ Point-of-care: ~$800+ (instrument); $40+ (test)	Point-of-care (No instrument): $5+ Point of care (Instrument required): ~$2K+ (instrument); $40+ (cartridge)
Limitations	PCR tests processed at commercial laboratories typically require 24-48 hours or longer to provide results. An employee with undiagnosed COVID-19 infection may be present at the workplace while waiting for the test to be resulted. Higher cost per test relative to antigen.	Detection of virus depends on higher viral loads (when people are most likely to spread virus to others). Therefore, people with early infection may test negative and therefore be present in the workplace until the next test cycle. Serial use of antigen tests with weekly testing will help identify people with COVID-19 who had a false-negative test previously. Confirmatory testing is recommended for some antigen test results (*CDC guidance*)

Considerations to support standing up an employee testing program

To stand up a successful testing program, employers will need to define who they want to test, how tests will be administered, policies for managing employees who test positive, a process for tracking compliance and policies for enforcing compliance with testing.

Who will be tested?

Employers will need to define which employees will be tested as part of their program.

Employers may choose to have voluntary or mandatory **diagnostic testing** available for employees that have COVID-19 symptoms or have a recent exposure to COVID-19. Diagnostic testing can enable employees to know their status and either seek care or isolate to prevent the spread of COVID-19 in the workplace. These tests are reimbursable by health insurance.

Another option is that employers may choose to implement voluntary or mandatory **screening testing programs** in the workplace. Screening can help prevent further transmission by identifying individuals who may have a COVID-19 infection but have no symptoms. In the context of the COVID-19 pandemic, the U.S. Equal Employment Opportunity Commission notes that testing to determine if an employee has SARS-CoV-2 infection is permissible as a condition to enter the workplace because an employee with the virus will pose a direct threat to the health of others (link). Additionally, the Occupational Safety and Health Administration (OSHA) has recently issued a federal rule that will require large employers (a 100 or more employees) to test their unvaccinated employees on a weekly basis. This rule is

scheduled to go into effect on Jan 4, 2022, however, it is currently tied up in the courts. Based on the regulations as written ([link](#)), employers are not mandated to cover the costs of these screening tests; this provision is controversial.

Implementing a program that mandates testing for unvaccinated workers will require identifying those individuals that have not been vaccinated. Employers should work with their legal and/or human resource (HR) professionals to design a process for determining the employees who have not been vaccinated. The process should also allow workers to update their vaccination status, so they may be removed from the testing requirement.

Employers may benefit from including even vaccinated employees in testing programs because, although not common, COVID-19 variants have been found to cause infection and transmission in some vaccinated individuals.

How will employees be tested?

Employers could pursue various testing strategies each with their own set of considerations. Broadly, employers can implement and manage a testing program completely in-house, contract with a lab or commercial entity to administer and process tests, or request that workers find testing options off-site.

Employer run testing program: Employers who wish to implement and manage a testing program completely in-house can procure point-of-care tests directly from manufacturers. The employers conducting point-of-care tests will require CLIA Certificate of Waiver for the program (See appendix for additional information on CLIA Certificate of Waiver). Additionally, employers would need to onboard and train staff to administer tests and submit test results KDHE. KDHE requires that all results—positive and negative-- be submitted to the Kansas Reportable Disease Portal within 24 hours. KDHE offers two options for reporting testing results, directly through the Kansas Reportable Disease Portal or using a software call LabXchange (additional in the appendix).

Alternatively, employers managing their own testing program can procure over-the-counter tests from manufacturers. These tests can be self-administered and processed by employees at-home. Over-the-counter tests would reduce the need for staff to administer tests and report test results. However, some over-the-counter tests do not have a reporting mechanism. This means that determining whether a test was conducted or identifying positives cases may rely solely on the self-reported results of the worker. Of note, these at-home tests would not meet the new federal OSHA standards for weekly testing.

Managing the testing program in-house could reduce the cost of testing relative to contracting a vendor. However, employers must account for the operational complexity of onboarding staff and managing reporting without third party tools.

Vendor administered testing: Many employers contract with a lab company, university, or other commercial entity to perform SARS-CoV-2 tests. Testing vendors offer a range of services to meet the testing needs of employees. Some vendors offer "end-to-end" services that include program design and implementation, specimen collection, test processing, result reporting, and digital dashboards to track results and compliance. Other vendors offer services a la carte. For example, a commercial lab may handle the shipping, processing, and reporting of tests, but leave the specimen collecting to the employers. That said, all lab vendors should be able to offer the reporting of results to KDHE and the digital tools to track result and compliance of testing. Vendors can reduce the administrative complexity of standing up a testing program and can significantly reduce the burden for an organization. However, vendors may be more expensive than low-cost point of care antigen tests that may be purchased from manufacturers.

Testing through off-site options: Employers may wish to require workers to seek testing options outside of the workplace. If the employer does not offer testing or work with a vendor, then the responsibility for testing falls solely on the individual. Employees could seek tests at physicians' offices, pharmacies, or clinics or purchase over-the-counter tests at retailers and share results with employers.

Although this approach could present the lowest cost option for employers, employers should consider the impact on workers and the complexity of tracking results and compliance. Workers may be less willing to pay for tests out-of-pocket for screening programs or take time outside of the work schedule to find testing options to meet the testing requirement. Employers may also struggle to track results and compliance for the program, given that workers will be pursuing testing at different locations with different reporting platforms. Employers will need to consult their legal/HR professional to determine whether this approach aligns with the OSHA testing requirements and whether time spent outside of work to get a COVID-19 is compensable (for example, if the employee gets a COVID-19 on their day off).

How should employers manage employees who test positive?

Managing ongoing exposure to an employee who tests positive is critical for reducing further spread of infection inside the workplace. If the employer is providing diagnostic testing to an employee that is [symptomatic](#) or has had a known exposure, then the employee should remain in isolation until test results are received. If the person is being tested for another purpose, such as routine work-based surveillance testing, they are not required to isolate while waiting for the results.

KDHE has developed a useful graphic about the [release from isolation and quarantine](#). Symptomatic cases should stay home for 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 WHICHEVER IS LONGER. Meaning, isolation for confirmed cases is a minimum of 10 days.

If the case is asymptomatic (the individual had no symptoms of COVID-19), then they should stay home for 10 days from the day their positive sample was taken. If they develop symptoms during this 10-day period, then they would begin a new isolation period as described above for symptomatic cases.

A "close contact" is defined as an employee who was near another person who tested positive for COVID-19, **even if that person did not have symptoms** based on the following criteria:

- o The employee was within 6 feet of the person with COVID-19 for 10 consecutive minutes or more, even if both persons wore masks,
- o The employee had contact with the person's respiratory secretions (for example, coughed or sneezed on; kissed; contact with a dirty tissue; shared a drinking glass, food, towels, or other personal items)
- o The employee lived with the person or stayed overnight for at least one night in a house with the person.

Employees who are close contacts should quarantine away from work. Workplace testing and monitoring of close contacts is beyond the scope of an employer-based testing program.

How will compliance be tracked and enforced?

Tracking compliance will require having visibility into which employees get tested week over week. Employers contracting with vendors will be able to leverage the reporting tools and resources of the vendor to track compliance. In conversations with vendors, employers are encouraged to confirm that the reporting capabilities offered by the vendor

meets the needs of the employer. Employers who choose not to work with vendors will need to define processes to track which employees test week over week.

Employers will want to consult their legal/HR professional to determine appropriate disciplinary actions to consider if employees do not adhere to the requirements of the testing program.

Guidance on billing for testing

Can private health insurance be billed for testing?

Two recent federal laws require group and individual health insurance plans to cover COVID-19 *diagnostic testing* without cost-sharing, co-pays, or deductibles. In other words, insurance will cover the costs of a COVID-19 test when it is provided to someone with COVID-19 symptoms or with a recent suspected exposure to someone with COVID-19 (or has otherwise been ordered by a medical professional.)

Employers in general cannot bill insurance for routine surveillance testing of their employees. The federal government has clarified that group health plans and individual health insurers are not required to reimburse testing costs for public health surveillance or for employment purposes.

If employers have on-site health care providers, they may be able to bill insurance for tests performed on individuals with symptoms or who are identified as close contacts to a person who has been diagnosed with COVID-19.

MENU of vendors offering COVID-19 testing equipment and services
KDHE has compiled a menu of vendors, including their contact information, to assist employers with identifying and procuring the appropriate tests and support for their employee testing program. The **menu of vendors** is posted online and will be updated regularly as new testing options become available. You can access the menu by clicking this link.

Below, KDHE has listed the various testing platforms and the companies that manufacture them.

Vendors* Manufacturing <u>Antigen</u> tests:
*List may not be comprehensive

Manufacturer	Test name	Type of Reader	Instructions for Use
Abbott	BinaxNOW COVID 19 Antigen Card	Visual read (No instrument; At-home test available)	BinaxNOW IFU
Access Bio	CareStart COVID-19	Visual read (No instrument; At-home test)	CareStart COVID-19
Becton-Dickinson (BD)	BD Veritor At-Home COVID-19 Test	App on Smart phone (No instrument; At-home test)	BD Veritor At-Home IFU
Celltrion USA	Celltrion DiaTrust COVID-19	Visual read (No instrument; Not an at-home test)	Celltrion DiaTrust

Ellume Lab	COVID Antigen test	Ellume reader (No instrument; At-home test)	Ellume IFU
GenBody	GenBody COVID-10	Visual read (No instrument; Not an at-home test)	GenBody IFU
InBios International	SCoV-2 Ag Detect Rapid Test	Visual read (No instrument; Not an at-home test)	SCoV-2 Ag Detect Rapid IFU
Luminostics	Clip COVID Rapid Antigen Test	Instrument read (Instrument required)	Clip COVID IFU
LumiraDX	LumiraDX SARS-CoV-2 Ag Test	Instrument read (Instrument required)	LumiraDX IFU
OraSure	InteliSwab COVID-19 Rapid Test	Visual read (No instrument; At-home test)	InteliSwab COVID-19
OraSure	InteliSwab COVID-19 Rapid Test Pro	Visual read (No instrument; Not an at-home test)	OraSure IFU
Phase Scientific	INDICAID COVID-19	Visual read (No instrument; Not an at-home test)	INDICAID COVID-19 IFU
Qiagen	QIAreach SARS-CoV-2	Instrument read (Instrument required)	QIAreach antigen IFU
Quidel	QuickVue SARS	Visual read (No instrument; At-home test)	QuickVue SARS
Quidel	Sofia SARS Antigen	Instrument read (Instrument required)	Sofia SARS Antigen IFU
Salofa Oy	Sienna-Clarity COVID-19	Visual read (No instrument; Not an at-home test)	Sienna-Clarity COVID-19

Vendors* Manufacturing Point of Care PCR and other NAATs:

*List may not be comprehensive

Manufacturer	Test name	Type of Reader	Instructions for Use
Abbott	ID NOW Covid-19	Instrument read (Instrument required; not an at-home test)	Abbott ID NOW IFU
Cepheid	GeneXpert SARs-CoV2	Instrument read (Instrument required; not an at-home test)	Cepheid SARs-CoV2 + Flu

CUE Health	Cue COVID-19 Test	Instrument read (Instrument required; not an at-home test)	[CUE Health IFU](#)
CUE Health	Cue COVID-19 OTC	Instrument read (Instrument required; At-home test)	[CUE Health OTC](#)
Lucira Health	Lucira COVID-19 All-In-One	Visual read (No instrument; At-home test)	[Lucira COVID-19 All-In-One](#)
Thermo Fischer Scientific / Mesa Biotech	Accula SARS CoV2	Instrument read (Instrument required; not an at-home test)	[Mesa Accula](#)
Visby Medical	Visby Medical COVID POC	Visual read (No instrument; Not an at-home test)	[Visby Medical POC](#)

Vendors* Manufacturing Multi-analyses tests:

*List may not be comprehensive

	Manufacturer	Kit name	Type of reader	Point-of-Care	Instructions for Use
Antigen	**Becton-Dickinson (BD)**	BD Veritor System for Rapid detection of SARs-CoV2 + Flu A/B	Instrument read (Instrument required; Not an at-home test)	Yes	[BD Veritor System for Rapid Detection](#)
	Quidel	Sofia 2 Flu + SARS Antigen F1A	Instrument read (Instrument required; Not an at-home test)	Yes	[Sofia 2 Flu + SARs AntigenIFU](#)
	Princeton BioMeditech	Status COVID-19/Flu	Visual read (No instrument; Not an at-home test)	Yes	[Status IFU](#)
NAAT/PCR	**Cepheid**	GeneXpert SARs-CoV2 + Flu A/B	Instrument read (Instrument required; Not an at-home test)	Yes	[Cepheid SARs-CoV2 + Flu](#)
	Exact Sciences	COVID - Flu Multiplex Assay	Lab-based test	No	[Exact Science Laboratories EUA summary](#)
	Everlywell	COVID-19 and Flu Test Home Collection kit	Lab-based test	No	[Everywell, Inc IFU](#)

Quest Diagnostics	RC COVID-19 + Flu Home Collection	Lab-based test	No	[Quest Diagnostics IFU](#)

Summary

This Employer Playbook is intended to support businesses that wish to offer COVID-19 testing to prevent COVID-19 outbreaks in their workplace and help keep their businesses open. As more businesses and employers are requiring proof of vaccination, or demonstration of a negative COVID-19 test, testing is become an increasingly important way for those who are unvaccinated to work, attend events, and travel. The Playbook will be incorporated to the state's unified testing strategy and will be updated to reflect federal and state law that applies to COVID-19 testing.

Appendix A: Overview of CLIA Certificate of Waiver and application

Organizations that administer point of care tests are required to have a CLIA Certificate of Waiver. A certification of waiver allows an organization to perform simple tests that have an insignificant risk of an erroneous result. As part of the application process, an organization must complete a [CMS-116 form](#) and submit payment of $180 fee for 2-year waiver. The certificate of waiver is typically granted in 2 weeks. There is no required physical inspection of testing facility or routine surveillance visits. Additional information on the CLIA Certificate of Waiver process can be found on this [link](#). For questions about CLIA certification or to obtain a CLIA Certificate of Waiver, email request to [KDHE.clia2@ks.gov.](mailto:KDHE.clia2@ks.gov). CLIA waivers are NOT REQUIRED for entities using at-home tests that are self-administered, self-resulted, and self-reported by the individual being tested.

Appendix B: KDHE can provide free access to LabXchange, an order entry system that automates the process of capturing patient data

Benefits of the LabXchange order entry system

- **Streamlined input of patient info:** Several options available for automated patient info entry (e.g. bulk roster upload, license scan, historical input recognition)
- **Simplified consent collection process:** Allows each testing site to customize their consent checkbox/forms required and collect signatures before submitting tests
- **Automated results update to patient:** Offers the option to enter phone/email info to receive an update on test results (with recommended next steps for positive results)
- **Option for employers to manage compliance:** Employers can work with LabXchange administrators to create "groups" for your organization to track the employees who have received a test week over week.
- **Integrated upload straight to Epitrax:** After test results are entered and saved, they are automatically uploaded to Epitrax, eliminating the need for bulk uploads
- **Simple, user-friendly platform:** LabXchange can be accessed on any device (e.g. desktop, tablet, phone) and has a straightforward interface that can be navigated very easily

Instructional video for LabXchange: [Link](#)

Appendix C: Kansas Reportable Disease Portal

Overview:

The Kansas Reportable Disease Portal is an online COVID reporting portal to submit patient information and corresponding test results. The Kansas Reportable Disease Portal does not have capability to inform users of their results—additional processes are required for notification to patients.

Data entry process:

The Kansas Reportable Disease Portal offers **two methods for reporting**:

- **Individually input patient info and test result in online portal:** Create a unique report and fill-out required fields for each individual patient every time a test is performed.
- **Bulk upload results for multiple patients:** Use a template to collect the required information for all individuals tested and submit their test results in one upload. Note: A new template needs to be downloaded every time a bulk upload is completed.

For more detailed instructions on reporting to the Kansas Reportable Disease Portal, please view online instructions [here](#).

Appendix D: Detailed Discussion guide to facilitate internal planning or conversations with vendors

Employers can use the questions below to help guide them as they make decisions about their testing program. They may also be useful in discussions with vendors.

Pre-launch preparations:

1. How will the employer obtain vaccination status from their employees?
2. What type of testing platform will be used for the program?
3. How will testing supplies be delivered/stored?
4. How many tests will be needed, at what frequency?
5. Who will be responsible for collection of the samples (eg. swabs, saliva kits)?
6. How many staff will be needed and what kind of training is required for them?
7. What personal protective equipment (PPE) is required for those who assist with testing?
8. What will the testing schedule for employees be?
9. Based on the test type, will a CLIA waiver be required (see definition above)?

Testing Operations

1. Where will employee testing take place?
2. What is needed to set up the testing workflow (e.g., signs, tables, etc.)?
3. How will employees be registered as part of the testing process?
4. If using lab-based PCR, how will samples be transported/sent to the laboratory for processing?
5. What is the ideal time and frequency for courier collection/UPS dropoff? *Samples should be picked up ASAP. Test results must be returned within 24 hours of sample arrival to laboratory.*
6. Who will be the contact person for arranging the transportation of the samples?
7. Are there back-up transportation plans in case the initial transportation plan falls through?

Data management and tracking

1. What data reporting system will be used to register employees, collect individual information, report test results to KDHE, provide results to users, and track compliance of participants in testing program?
2. How will the list of unvaccinated employees be regularly updated to identify which employees need to be tested?
3. Does the software used for the data reporting meet the reporting requirements of the state?

Questions? Contact KDHE by email at covid-19@ks.gov or by phone at (866-KDHEINF)