

KANSAS STATEWIDE STRATEGY FOR COVID-19 SPECIMEN COLLECTION AND TESTING

INTRODUCTION

To facilitate a rapid increase in statewide testing for COVID-19, the Kansas Department of Health and Environment (KDHE) has developed a set of priorities and recommendations outlined below. Included are implementation guidelines, as well as a set of hierarchical priorities for various types of facilities to assist with the management of collection of diagnostic specimens and subsequent testing. Because facilities of diverse scopes and sizes will have distinct technical capabilities and infrastructure, this document will clarify a hierarchy of priorities for each type of facility. If a facility is not specifically described in this document, priorities can be extrapolated based on their capabilities and infrastructure.

GOAL/PURPOSE

The goal of this strategy is to facilitate a rapid increase in statewide testing for COVID-19 utilizing all testing sites and platforms available. KDHE will work with vendors, laboratories and local sampling sites to help ensure that testing supplies and platforms are in place or easily mobilized to support communities, Kansas local health departments and to support the early detection of outbreaks in congregate settings.

DEFINITIONS

Sampling: The collection of specimens (e.g. nasopharyngeal swabs, serum) from individuals suspected of having COVID-19 disease and submitted for diagnostic testing.

Molecular Testing: A procedure performed on a collected specimen to confirm the presence or absence of the virus that causes COVID-19 disease.

Serological Testing: A procedure performed on a collected specimen to confirm the presence or absence of antibodies produced by the body in response to a COVID-19 infection.

IMPLEMENTATION STRATEGIES

KDHE is striving to identify and monitor the statewide daily testing capacity by identifying available platforms and supplies across the state. Part of this strategy includes supporting overflow testing for facilities by accepting samples that exceed their capacity. While the daily monitoring of supplies and capacity is the responsibility of each facility, KDHE will assist with allocating resources in the event of supply shortages, coordinating overflow testing facilities and receiving samples for testing from those facilities that lack the ability to conduct in-house testing or contract with a reference laboratory.

- For most testing through the state laboratory, persons must meet the PUI criteria promulgated by the State Epidemiologist. Currently, this is symptomatic persons with at least two symptoms from the PUI criteria. Providers testing through a reference lab may choose to test symptomatic patients with fewer or different symptoms and the state laboratory may test persons that do not meet PUI criteria based on epidemiological need.

- In some situations, such as outbreaks at congregate living facilities, both symptomatic and asymptomatic persons may be recommended for testing either at the state laboratory or at a private laboratory.
- The initial testing target is to conduct diagnostic tests for approximately 2% of the Kansas population (60,000 tests) by the end of 2020. KDHE will continue to pursue a testing rate of 200 tests per 1,000 population (20%).
- To meet the 2% testing goal, the U.S. Health and Human Services (HHS) has started sending large quantities of nasopharyngeal swabs and viral transport media to support the increased demand for testing.
- Where possible, sampling and testing should be kept as localized as possible (i.e. avoid shipping samples to outside labs if possible). This will help minimize turnaround times, mishandling of samples, misplacement of samples and reduce testing burden on outside laboratories.
- KDHE has created a real-time map of all testing locations, their capacities, and available testing platforms. This includes laboratories that currently have the technical capabilities and testing platforms but are not conducting testing. As demand for testing increases, if statewide deficiencies become apparent, KDHE can “stand-up” these laboratories with the necessary supplies to ensure testing coverage remains at appropriate levels.
- Many facilities across the state have been identified that have access to point of care platforms such as the Abbott and Cepheid instruments. However, HHS has advised KDHE to de-prioritize the Cepheid and Abbott testing platforms as primary mechanisms for reaching the testing goals. These companies are currently at their maximum manufacturing capacity for the necessary kits and are shipping their products to regions of high infection rates. Therefore, it may be necessary to allocate resources for these platforms depending on specific geographical needs.
- KDHE will support and assist with the early detection of outbreaks in congregate settings. Congregate settings include, but are not limited to, long-term care facilities, skilled nursing, and homeless shelters. Residents and staff of these facilities should be monitored regularly for symptoms of COVID-19 disease. Symptomatic patients and staff should continue to be tested through existing arrangements with local healthcare providers and/or the local health departments. Once a case is identified in a congregate setting, in consultation with the local health department and KDHE Epidemiology, a facility can request testing support through the state laboratory. KDHE will support the testing of all asymptomatic and symptomatic residents and staff. This aggressive testing strategy allows for the timely identification of cases and improves the likelihood of successfully cohorting residents and staff.
- KDHE will support and assist with local health department coordinated “drive through” testing sites to provide the most efficient testing strategy for these needs.

- KDHE may further develop specific strategies around the placement of rapid testing platforms or mobile lab units in key locations to address issues related to vulnerable populations. Based on emerging evidence, vulnerable populations include, but are not limited to, the elderly, people with underlying health conditions, certain minority groups, and people living in congregate settings.
- Months of testing supply shortages and prolonged media coverage of the shortages has led many to believe that testing is not available. Therefore, many symptomatic persons may avoid coming to a testing center and providers may be reluctant to order testing. A comprehensive messaging strategy including social media, news outlets, radio and television advertisements should be implemented to increase awareness of the availability of testing.
- Sample-pooling for testing should be avoided due to uncertainties about limits of detection leading to false negative test results. If supplies become scarce, sample-pooling may be considered if proper validation is incorporated.

SEROLOGICAL SURVEILLANCE

Although serological or antibody testing should not be considered as a diagnostic tool for individual patients, nor is it considered as part of the initial testing capacity targets for the state, it does have potential benefits. Any serological or antibody testing should be evaluated to ensure that it is specific to the SARS-CoV-2 virus to avoid false positives due to other similar viruses. Investigations using serology testing are called seroprevalence surveys. From seroprevalence surveys, Kansas can potentially learn more about how common the infection is in the population, and whether there are different characteristics or risk factors associated with infection and use this information to guide control measures including social distancing recommendations. Knowing what proportion of the population has not been infected also helps to plan for future demands on the healthcare and public health systems.

Additionally, seroprevalence surveys that are conducted repeatedly over time in the same population can potentially be useful to monitor the prevalence of infection in the population compared to the incidence of new cases in the same population. It should be noted that current World Health Organization (WHO) and United States Centers for Disease Control and Prevention (CDC) guidance advises against using antibody detection as a means for diagnosing patients with COVID-19. It can take one to two weeks after symptoms appear for antibodies to develop in the body, and on average it takes about a week for symptoms to appear after exposure. Therefore, antibodies should develop about two to three weeks after exposure, which is why antibody testing is not recommended for diagnosing patients with current infection and is not useful for timely public health response like isolation of cases, contact tracing and quarantine of close contacts. The WHO and CDC also advise against using antibody testing to determine immunity from future reinfections as research is still emerging on how the presence of antibodies may or may not protect an individual from reinfection.

- Counties and facilities considering a seroprevalence survey should determine the objectives of the survey and decide on the appropriate survey design (large-scale geographic, community level or special population) that will address the objectives.

Consideration should be given to the sampling strategy that will ultimately allow the results of the survey to be generalizable. Finally, the protocol should detail how results will be interpreted and what, if any, actions will be taken based on the results. Per K.A.R 28-1-18, all results (reactive AND non-reactive) will be sent to KDHE; however, KDHE Epidemiology may not recommend case investigation based on results of seroprevalence surveys.

- KDHE, in collaboration with partners, will pursue plans for either a large-scale geographic seroprevalence survey which may use blood samples already drawn for other purposes with no personal identifying information attached to the sample or a community-level seroprevalence survey that samples from select counties.
- To obtain maximum coverage, testing all asymptomatic persons at the following locations should be prioritized:
 - Long-term care facilities
 - Prisons
 - Dormitories and school health clinics
 - Other places of congregant living
 - Factories
 - Military bases
 - Primary physician offices
 - Tribal clinics
 - Hospitals: patients and staff
 - Mobile settings: Drive-throughs, Tents at large venues (Walmart, Home Depot)

FACILITY SPECIFIC STRATEGY

Facilities should determine how their unique infrastructure and technical capabilities align with the facility categories below. Sampling and testing should be conducted within the hierarchy of priorities as closely as possible.

Large healthcare facilities (e.g. hospitals)

These facilities generally have the technical capabilities (i.e. doctors, nurses) to collect samples from patients and staff, as well as conduct in-house testing.

Hierarchy of Priorities

- Facility should manage their own supply procurement for sampling AND testing (e.g. PPE, reagents, kits)
 - ↳ If a facility begins to experience shortages in sampling and testing supplies or supply chain disruptions, contact local emergency managers or KDHE to identify solutions or request supplemental supplies.
- Facility should collect samples from staff and patients that are suspected of having COVID-19
 - ↳ Facility should conduct all diagnostic testing in-house

- ↳ If facility cannot meet sampling and testing demands due to lack of required supplies then a contract testing laboratory should be considered (e.g. Quest, LabCorp)
 - ↳ If facility is unable to negotiate suitable costs or delivery schemes with a contract testing laboratory, then facility should coordinate with KDHE to send samples for testing.

- *If local venues with large groups of essential workers cannot conduct their own sampling and testing, then the facility should consider sending sampling teams to increase testing coverage or request support from the local emergency manager.*
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Small healthcare facilities (e.g. long-term care facilities, small hospitals, primary doctors)
These facilities generally have the technical capabilities (i.e. doctors, nurses) to collect samples from patients and staff but lack the ability to conduct in-house testing.

Hierarchy of Priorities

- Facility should manage their own supply procurement for sampling (e.g. PPE, nasopharyngeal swabs)
 - ↳ If a facility begins to experience shortages in sampling and testing supplies or supply chain disruptions, contact local emergency managers or KDHE to identify solutions or request supplemental supplies.
 - Facility should collect samples from staff and patients that are suspected of having COVID-19
 - ↳ Facility should consider using a contract testing laboratory for all diagnostic testing
 - ↳ If facility is unable to negotiate suitable costs or delivery schemes with a contract testing laboratory, then facility should coordinate with KDHE to send samples for testing.
 - *Due to the size and vulnerability of populations in the larger long-term care facilities, KDHE may consider installing a testing platform to allow for in-house testing.*
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Correctional Facilities

These facilities generally have the technical capabilities (i.e. doctors, nurses, medics) to collect samples from inmates and staff but lack the ability to conduct in-house testing.

Hierarchy of Priorities

- Facility should manage their own supply procurement for sampling (e.g. PPE, nasopharyngeal swabs)
 - ↳ If a facility begins to experience shortages in sampling and testing supplies or supply chain disruptions, contact local emergency managers or KDHE to identify solutions or request supplemental supplies.

- Facility should collect samples from staff and prisoners that are suspected of having COVID-19
 - ↳ Facility should consider using a contract testing laboratory for all diagnostic testing
 - ↳ If facility is unable to negotiate suitable costs or delivery schemes with a contract testing laboratory, then facility should coordinate with KDHE to send samples for testing.
 - *KDHE may consider installing a testing platform in the larger correctional facilities to allow for in-house testing.*
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Factories and larger organizations with essential workers (e.g. meat packing plants)

These facilities generally have the technical capabilities (i.e. doctors, nurses, medics) to collect samples from staff but lack the ability to conduct in-house testing.

Hierarchy of Priorities

- Facility should manage their own supply procurement for sampling (e.g. PPE, nasopharyngeal swabs)
 - ↳ If a facility begins to experience shortages in sampling and testing supplies or supply chain disruptions, contact local emergency managers or KDHE to identify solutions or request supplemental supplies.
 - Facility should collect samples from staff that are suspected of having COVID-19
 - ↳ Facility should consider using a contract testing laboratory for all diagnostic testing
 - ↳ If facility is unable to negotiate suitable costs or delivery schemes with a contract testing laboratory, then facility should coordinate with the local health department who will coordinate with the state laboratory to send samples for testing.
 - *If a facility does not have the technical capability to conduct sampling, requests to local hospitals to deploy a testing team should be considered.*
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Universities

These facilities generally have the technical capabilities (i.e. doctors, nurses) to collect samples from students and staff and may or may not be capable of conducting in-house testing.

Hierarchy of Priorities

- Facility should manage their own supply procurement for sampling AND testing (e.g. PPE, reagents, kits)
 - ↳ If a facility begins to experience shortages in sampling and testing supplies or supply chain disruptions, contact local emergency managers or KDHE to identify solutions or request supplemental supplies.
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- Facility should collect samples from students and staff that are suspected of having COVID-19
 - ↳ Facility should conduct all diagnostic testing in-house (if capable)
 - ↳ If facility cannot meet sampling and testing demands due to lack of required supplies, then a contract testing laboratory should be considered (e.g. Quest, LabCorp)
 - ↳ If facility is unable to negotiate suitable costs or delivery schemes with a contract testing laboratory, then facility should coordinate with KDHE to send samples for testing.
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Military Bases

These facilities generally have the technical capabilities (i.e. doctors, nurses, medics) to collect samples from their members, as well as conduct in-house testing.

Hierarchy of Priorities

- Facility should manage their own supply procurement for sampling AND testing (e.g. PPE, reagents, kits)
 - ↳ If a facility begins to experience shortages in sampling and testing supplies or supply chain disruptions, contact local emergency managers or KDHE to identify solutions or request supplemental supplies.
 - Facility should collect samples from patients and staff that are suspected of having COVID-19
 - ↳ Facility should conduct all diagnostic testing in-house
 - ↳ If facility cannot meet sampling and testing demands due to lack of required supplies then a contract testing laboratory should be considered (e.g. Quest, LabCorp)
 - ↳ If facility is unable to negotiate suitable costs or delivery schemes with a contract testing laboratory, then facility should coordinate with KDHE to send samples for testing.
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Local Health Departments

Most of the counties in Kansas have active local health departments; however, the services offered and expertise available can vary widely. Most often, these would be facilities that could provide or coordinate collection of samples and only occasionally would they be able to perform testing directly. For those that do not test, they may use either commercial reference laboratories for testing or the KDHE state laboratory.

Hierarchy of Priorities

- Facility should manage their own supply procurement for testing (e.g. PPE, reagents, kits)
 - ↳ If a facility begins to experience shortages in sampling and testing supplies or supply chain disruptions, contact local emergency managers or KDHE to identify solutions or request supplemental supplies.
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- Facility should collect samples from patients that are suspected of having COVID-19
 - ↳ Facility may use a contract testing laboratory for all diagnostic testing
 - ↳ If facility is unable to negotiate suitable costs or delivery schemes with a contract testing laboratory, then facility should coordinate with KDHE to send samples for testing.

Federally Qualified Health Centers

These facilities most often have the expertise and experience to support collection of specimens to be tested for SARS-CoV-2. Some of these centers also have point of care testing available. Some have mobile units that can be used for collections and most of them have the capacity to reach vulnerable and underserved populations.

Hierarchy of Priorities

- Facility should manage their own supply procurement for testing (e.g. PPE, reagents, kits)
 - ↳ If a facility begins to experience shortages in sampling and testing supplies or supply chain disruptions, contact local emergency managers or KDHE to identify solutions or request supplemental supplies.

- Facility should collect samples from patients that are suspected of having COVID-19
 - ↳ Facility may use a contract testing laboratory for all diagnostic testing
 - ↳ If facility is unable to negotiate suitable costs or delivery schemes with a contract testing laboratory, then facility should coordinate with KDHE to send samples for testing.

TESTING FACILITIES:

There are four significant testing facility types operational in Kansas for COVID19 testing.

1. **Kansas Health and Environmental Laboratories:** The state testing laboratory in Topeka managed the first wave of testing during the COVID-19 pandemic and currently primarily supports outbreak investigations and local health department testing. They currently have the capacity to test over 1,000 samples per day, 6 days/week.
2. **Mobile Laboratories or Collection Teams:** KDHE and KHEL will develop mobile testing units that can be used for rapid testing at the point of care. This type of mobile laboratory could be used to support homeless shelters, congregate living facilities and underserved Kansans such as minority populations by setting up locally to these populations. Likewise, a mobile collection team/vehicle can support drive through or walk up testing for these same populations in coordination with local health departments, community health centers, local religious or community organizations. Mobile collection vehicles/teams could also be used to collect serum specimens for serological (antibody) testing for seroprevalence surveys.
3. **Major commercial reference laboratories:** These facilities have daily capacity exceeding 2,000 samples locally, as well as larger network testing capacity. They also often have logistics capabilities to ensure sample pickup and delivery of specimens to the laboratory for testing. At least four such testing operations have been identified as serving Kansas with a capacity exceeding 10,000 samples per day.
4. **Local reference laboratories and captive laboratories:** Local reference labs may still receive samples from multiple areas of the state but have a daily capacity less than

2,000 samples. This group also includes those facilities such as hospitals and clinics that have the capability to perform testing for their facility and may or may not be able to receive and test samples from other facilities. Currently, nearly 30 laboratories in Kansas fall into this category with a combined testing capacity in excess of 2,500 samples per day. Additional testing could be performed in Kansas should more testing kits be available to the rural facilities in Kansas that have instruments such as Cepheid and Abbott IDNow.

