## 2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Kentucky
Population Size:	4,500,000

#### 1. Describe the overarching testing strategy in your state or jurisdiction.

Kentucky's estimated population is 4.5 million residents. To reach the monthly 2% minimum testing target, 90,000 tests/month (3,000 tests/day) will need to be performed within the commonwealth. Through the Gravity Diagnostics contract, Kentucky has the capacity to perform 125,000 tests/month or 5,000 tests/day (Monday-Saturday), exceeding the monthly minimum. The Division of Laboratory Services (DLS) has recently expanded its testing capacity to approximately 240 specimens/day (Monday-Sunday).

In addition to the current capacity, DPH must continue to increase the availability and accessibility of testing. To stop transmission of COVID-19, the primary goals are to identify as close to 100% of infected persons as quickly as possible and isolate cases immediately, as well as identify and quarantine their close contacts and monitor for symptoms. A critical component of this plan is to increase testing capacity, which will require a multi-pronged approach with five primary public health objectives:

- 1. Increase access and availability of testing to all who need or desire testing
- 2. Reduce barriers to accessing testing
- 3. Facilitate testing that has a short turn-around time from specimen collection to results
- 4. Collect accurate data on those tested and their results

5. Have flexibility to rapidly increase testing in particular geographic regions, congregate care settings, businesses, or other areas of need

Special consideration is warranted for at-risk populations:

- Those living and working in congregate settings (long-term care, corrections, in-patient behavioral health, homeless shelters, facilities that care for individuals with intellectual and developmental disabilities, rehab centers, etc.)

- Vulnerable, underserved, uninsured, underinsured populations
- Populations with limited English speaking proficiency
- Critical infrastructure workers (including grocery store and meat processing facilities)
- Individuals with substance-use disorder (SUD)
- Persons experiencing homelessness
- Elderly and immunocompromised individuals and those with pre-existing medical conditions

To accomplish the above objectives, a multi-pronged approach to increase laboratory-testing capacity is needed, consisting of the following:

First, the Division of Laboratory Services (DLS) will enhance its capacity to perform COVID-19 testing. Using CARES funds, DLS purchased new extraction platforms (2 Qiagen EZ1 Advanced XL and 2 QIAcube Connect) and instrumentation (2 new 7500 Fast Dx), which was essential for DLS to increase PCR testing capacity using the CDC 2019-nCOV real-time PCR assay from 80 specimens/day to 240 specimens/day. Also using CARES funds, DLS purchased four additional modules to expand the capacity of its existing Cepheid GeneXpert Dx instrument using Cepheid Xpert Xpress SARS-CoV-2 real-time RT-PCR testing kits. The Xpert Xpress kits provide an additional capacity of 80-100 specimens per day and rapid turn-around of results, particularly for specimens of public health significance. To provide high-throughput testing, DLS purchased Hologic Aptima SARS-CoV-2 testing kits to complement the two existing Hologic Panther systems. Once the Hologic testing is in place, DLS will have the capacity to test an additional 1000 specimens/day. Full implementation of the CDC, Cepheid, and Hologic assays will enable DLS to test approximately 1300 specimens/day. DLS will use Enhancing Detection funds to purchase an instrument, such as the Abbott Alinity m, for high-throughput testing.

Second, DPH will quantify the current and projected testing capacity of Kentucky laboratories performing COVID-19 testing. DPH staff is finalizing a survey via SurveyMonkey that will query current and future planned capacity of all sentinel clinical labs, commercial labs and university labs performing COVID-19 testing to address: type of testing performed (PCR, antibody, antigen); instrument(s) and assay(s); average turnaround time; current and future daily testing capacity by test type; current and future barriers; and planned COVID-19 testing expansion. Survey data will identify testing gaps throughout the commonwealth, as well as the quantity and geographic distribution of point-of-care and high-throughput instruments being used. Survey data will identify whether or not there is an overreliance on a particular instrument/assay, which will be problematic in the event of supply chain disruptions. With these data, DPH will be able to implement mitigation strategies for identified gaps. Laboratories that fail to respond to the survey will be contacted by phone for completion. The survey will be repeated quarterly for the first year of the project period (June 2020, September 2020, December 2020, March 2021) and then biannually for the remainder of the project period.

Third, DPH will implement or enhance COVID-19 testing capacity at the local health departments (LHDs). There are 120 counties in Kentucky, served by 61 local and district health departments. A few LHDs already offer COVID-19 testing to their residents. To enhance testing capacity at the local level, DPH will publish a request for proposal (RFP) to the LHDs in early June, which will be due June 18. DPH will review the proposals, select awardees, and notify applicants by June 30, 2020. To be selected, LHDs must address several items in their proposals, including: estimated number of tests per month; proposed testing platform; outreach to at-risk populations; ability to deploy mobile specimen collection and testing units; and data collection and electronic reporting method. DPH will select a minimum of 16 LHDs to bring point-of-care testing in-house. This will allow DPH to fund a minimum of one LHD in each of the 14 regions and 2 largest metro areas.

Fourth, in addition to the mobile specimen collection and testing units that will be operated by LHDs, DPH plans to establish a minimum of 2 units, which will offer point-of-care testing for smaller events and will offer specimen collection only (testing at DLS within 24 hours of collection) for larger testing events. These units each will be staffed by 1 person to do intake, data collection, and reporting, 2 people to collect swabs, and 2 people to run the tests, as needed. Units will be used to target at-risk populations mentioned previously. The mobile units will be used to assist with specimen collection during facility, worksite, and community outbreaks. Units will also be deployed when syndromic surveillance data indicate a spike in influenza-like illness or COVID-like illness occurring in a county or community, particularly if the spike is in an underserved area or in an at-risk population. Finally, units will be deployed during community-based events. During all mobile events, staff will provide community education and prevention information, as well as specimen collection and testing services. The target deployment of units from the identification of need is within 48 hours.

Fifth, DPH will continue to support the contract with Gravity Diagnostics, which enables the testing of up to 5,000 specimens/day and will expire at the end of July. Through this contract, Gravity Diagnostics provides testing services to LHDs, healthcare facilities, and community-based drive-thru testing sites. DPH will maintain this contract through July. To date, those testing partners include 34 LHDs, 42 healthcare facilities (hospitals, clinics, Federally Qualified Health Centers (FQHCs), Urgent Treatment Centers, etc.), 2 corrections facilities, and 315 long-term care facilities (LTCFs) who are conducting facility-wide testing of every resident and employee. Additionally, Gravity Diagnostics provides the testing services for Kroger drive-thru clinics. To date, 16 cities have hosted drive-thru testing events through Kroger and Gravity Diagnostics.

Sixth, DPH will work with the Federally Qualified Health Centers (FQHCs) in Kentucky to identify current COVID-19 testing capacity, access to COVID-19 testing, and any gaps in testing coverage and barriers to accessing testing.

Seventh, DPH will continue to support community-based drive-thru testing and continue to partner with the entities who offer such testing. Community partners providing testing in Kentucky include Walmart, Walgreens, and Kroger. Walmart and Walgreens are providing testing independently of DPH and will continue to do so. DPH will work to obtain lab results from both entities electronically, so that all results (positive, negative and indeterminate) are captured. As mentioned previously, testing through Kroger is provided by Gravity Diagnostics, whose contract will expire at the end of July. DPH will issue a new, more limited RFP in June to select the lab who will provide community-based drive-thru testing services through May 2020. Through this contract, the selected lab will be able to test up to 2,000 specimens/day during each testing event. Drive-thru testing will be provided as needed in communities with an increase in case counts, as well as in communities that show a spike in syndromic surveillance data for influenza-like illness and COVID-like illness. Drive-thru testing will also be targeted to communities with at-risk populations, including those identified to have limited access to COVID-19 testing. In addition to the drive-thru testing support, the contracted lab will be able to provide surge capacity to DLS as needed, especially before DLS testing reaches full capacity.

Eighth, DLS will implement serology testing. A very low percentage of the population in Kentucky is estimated to have been infected by COVID-19, which makes population-based serology testing of limited utility at the moment. DPH will prioritize serology testing in congregate living facilities (LTCF and corrections facilities) that have experienced outbreaks of COVID-19. DPH also will provide serology testing to healthcare workers, LTCF staff, and corrections staff.

Finally, to ensure that the data obtained through the enhanced testing efforts are captured, DPH will work with the laboratories performing testing, the Kentucky Health Information Exchange (KHIE), the Commonwealth Office of Technology (COT) and the Office of Application and Technology Services (OATs) to increase the number of lab reports (positive, negative and indeterminate) received electronically (either through electronic lab report or via flat file). This has been an ongoing challenge throughout this response, as DPH only routinely receives all laboratory results (positive, negative, and indeterminates) from a small subset of testing facilities. This has limited the response, as the true scope of testing in Kentucky is an underestimate of the accurate number.

Through all of the previously mentioned efforts, DPH will partner with local public health and community agencies to ensure testing is available and accessible to the at-risk populations within the commonwealth. DPH will support LHD testing efforts that target these populations, including implementing COVID-19 testing in-house at selected LHDs and testing by DLS for those LHDs who are not able to implement in-house COVID-19 testing. Many LHDs already are reaching these populations through existing programs, including harm reduction and syringe exchange.

DPH will develop a lab-testing subject matter expert team, with individuals from multiple Divisions and Departments responsible for overseeing testing efforts at DLS, local health departments, commercial and university labs, community drive-thru testing events. This team also will be responsible for ensuring that at-risk populations are being identified and targeted for testing. This team will be added to the existing incident command structure.

DLS has intentionally diversified the instruments and extractors used for COVID-19 testing to help mitigate against future disruptions to the COVID-19 testing supply chain. The external lab survey will identify any potential weaknesses in capacity external to DPH.

#### Table #1a: Number of individuals planned to be tested, by month

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Diagnostics*	147,301	154,667							301,968
Serology	19,910	24,888							44,798
TOTAL	167,211	179,555	0	0	0	0	0	0	

#### Table #1b: Planned expansion of testing jurisdiction-wide

Name of testing entity	<b>Testing</b> <b>venue</b> (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through- put	Daily serologic through- put	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Division of Laboratory Services	Public health lab		200	0		LTCF residents and staff, corrections inmates and staff, healthcare workers, persons experiencing homelessness, the most acutely ill those with chronic health conditions, first responders
Gravity Diagnostics	Commercial or private lab		5,000	0		LTCF residents and staff, corrections inmates and staff, healthcare workers, persons experiencing homelessness, the most acutely ill those with chronic health conditions, first responders

Name of testing entity	<b>Testing</b> <b>venue</b> (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through- put	Daily serologic through- put	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Appalachian Regional Hospital	Hospitals or clinical facility		25			
Baptist Health Corbin	Hospitals or clinical facility		10			
Baptist Health Lexington	Hospitals or clinical facility		25			
BioTapMedical	Commercial or private lab		100			
Bluewater Diagnostics (Bluewater Toxicology)	Commercial or private lab		1,000			
Lexar	Commercial or private lab		100			
Louisville Metro Public Health Lab	Public health lab		60			

Name of testing entity	<b>Testing</b> <b>venue</b> (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through- put	Daily serologic through- put	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Onsite Health Solutions	Other			100		Prepared to screen workers
Owensboro Health	Hospitals or clinical facility		575			
Solaris	Commercial or private lab		6,500			

Name of testing entity	<b>Testing</b> <b>venue</b> (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through- put	Daily serologic through- put	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
TEC Biosciences Inc	Commercial or private lab		190			
University of Louisville	Other		1,200			
University of Louisville Infectious Disease Laboratory	Other		500			

Name of testing entity	<b>Testing</b> <b>venue</b> (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through- put	Daily serologic through- put	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
University of Kentucky Health Center/Systems	Hospitals or clinical facility		400			

Name of testing entity	<b>Testing</b> <b>venue</b> (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through- put	Daily serologic through- put	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
VA Lexington Micro Biology (LEXINGTON VA HEALTH CARE)	Hospitals or clinical facility		300			Veterans
VA Medical Center Lexington (Special Reference Laboratory Lexington VAMC)	Hospitals or clinical facility		300			Veterans
VA Medical Center Louisville (Robley Rex)	Hospitals or clinical facility		50			Veterans
LabCorps	Commercial or private lab		2,000			
Quest	Commercial or private lab		500			

# 2020 Direct Expansion of SARS-COV-2 Testing by Health Departments

#### 2. Describe your public health department's direct impact on testing expansion in your jurisdiction.

DPH will expand internal public health lab COVID-19 testing capacity and enhance external testing capacity by contracting with private labs, augmenting local health departments (LHDs), improving healthcare system capacity, and fostering public-private partnerships through a variety of community-based programs (e.g., hospital-based, clinic-based, community drive-thru, mobile testing units, employer-supported workplace screening, etc.). The Division of Laboratory Services (DLS) recently expanded COVID-19 testing. Using CARES funding, DLS purchased new extraction platforms (2 Qiagen EZ1 Advanced XL and 2 QIAcube Connect) and instrumentation (2 new 7500 Fast Dx). This additional instrumentation increased PCR testing capacity using the CDC 2019-nCOV real-time PCR assay from 80 specimens/day to 240 specimens/day. In late May, DLS also acquired four additional modules to expand the capacity of its existing Cepheid GeneXpert Dx instrument using Cepheid Xpert Xpress SARS-COV-2 real-time RT-PCR testing kits. The Xpert Xpress kits provide an additional capacity of 80-100 specimens per day and rapid turn-around of results, particularly for specimens of public health significance. DLS has four scientists trained in the CDC assay and three additional scientists trained in the Cepheid assay.

For high-throughput testing, DLS purchased Hologic Aptima SARS-CoV-2 testing kits for use with its two Hologic Panther systems. Validation studies and scientist training will be completed by mid-June 2020. Once Hologic testing is available, DLS will have the capacity to test an additional 500 specimens/day per instrument (1000/day total). Full implementation of the CDC, Cepheid, and Hologic assays will enable DLS to test approximately 1300 specimens/day. In addition to four existing laboratory scientists trained to perform this testing, DLS has hired 1 additional laboratory scientist and is researching further options for high-throughput testing, particularly the Abbott Alinity m platform.

DLS intends to begin sequencing positive SARS-CoV-2 specimens to enhance surveillance and monitor the viral evolvement in local populations. DLS has three Illumina Miseqs in the Microbiology Branch and has recently purchased an Oxford Nanopore MinION sequencing device. DLS is investigating various protocols for sequencing and staff have joined the CDC SPHERES consortium to gain insight into sequencing activities occurring at other laboratories across the country.

DPH has also contracted with Gravity Diagnostics, a commercial molecular diagnostic laboratory in Northern Kentucky. The initial contract supported 2,000 COVID-19 PCR tests per day, Monday through Saturday, using Thermofisher high-throughput machines, but has been expanded to 5,000 specimens/day or >120,000 specimens/month (approximately 2.7% of Kentucky's population/month). Using this testing capacity, DPH supports three unique programs: 1) approximately 34 LHDs and 42 healthcare facilities (hospitals, clinics, Federally Qualified Health Centers (FQHCs), Urgent Treatment Centers, etc.) throughout the state; 2) Kroger and other community-based drive-thru testing sites, and

3) a congregate setting (e.g., long-term care (LTC) facilities, behavioral health hospitals, prisons) testing program. DPH will maintain this contract through July, with an option to extend.

DPH will work with LHDs to implement or enhance in-house COVID-19 testing at a minimum of 16 LHDs. Funds will be through an LHD allocation and allow for expenses related to testing equipment, supplies and personnel. DLS will support larger testing events with high-throughput capacity, but priority will be given to LHDs who plan to implement point-of-care testing using DLS-recommended platforms to increase access to vulnerable populations and provide on-site, real-time surveillance capacity throughout the state. In order to obtain feedback and determine the best course of action for local planning efforts, DPH met with LHDs on May 29. DPH will publish a request for proposal (RFP) to the LHDs in early June, which will be due June 18. DPH will review the proposals, select LHDs awardees, and notify applicants by June 30, 2020. To be selected, LHDs must address several items in their proposals, including: estimated number of tests per month; proposed testing platform; outreach to at-risk populations; ability to deploy mobile testing units; and data collection and electronic reporting method.

For the duration of this response, both through DLS and Gravity Diagnostics, DPH prioritized testing specimens from at-risk populations, including those with occupational exposure, such as healthcare workers, first responders, employees of congregate settings (e.g., LTCFs, behavioral health hospitals, prisons, etc.), and other critical infrastructure workers (such as employees of meat processing facilities). DPH also prioritized testing of other at-risk populations, including residents of congregate settings, persons experiencing homelessness, those most acutely ill, and those with pre-existing medical conditions.

The Cabinet for Health and Family Services (CHFS) established a LTC Task Force that includes a multifaceted assessment, consultation, and support program, as well as targeted, facility-wide (residents and staff) molecular diagnostic testing at all Kentucky LTCFs from May through July 2020. DPH works collaboratively with the Department of Corrections to provide consultative and testing services to correction centers. When necessary, DPH has facilitated facility-wide (inmates and staff) testing. In partnership with some LHDs, DPH has provided testing resources for homeless populations. Peer–topeer sharing is occurring among the LHDs via a monthly webinar to discuss challenges, barriers, and solutions. DPH supports LHD efforts to reach underserved persons through LHD in-house and drivethrough testing, as well as partnerships with local healthcare providers and community partners. Several LHDs have worked collaboratively to target at-risk community members through explorative means, such as food banks, syringe exchange programs, military families, and utilization of mobile units. DPH supports a variety of testing sites at community-based locations throughout the commonwealth through the contract with Gravity Diagnostics, which is available to any Kentucky resident, regardless of symptom presence, illness severity, or health insurance status.

DPH partnered with over 40 Kentucky hospitals and 34 LHDs to make testing capacity available, particularly in rural communities, early in the response when testing was scarce. DPH supports local communities for COVID-19 related response and for resumption of elective healthcare services.

DPH is in regular, ongoing communication with hospital, LHD, medical, and laboratory communities across the state to identify and address testing-related barriers. The governor's office has engaged the business community to facilitate workplace testing, safety, and mitigation of the spread of COVID-19. DPH is flow-mapping the entire testing process in Kentucky, from the supply chain to reporting to streamline the process, eliminate barriers, promote electronic data submission, and reduce errors.

DPH has developed ArcGIS 1,2,3 surveys that integrate with WebEOC, through which DPH staff reviews applications from providers wishing to become Gravity testing partners. Within this system, staff are able to review and approve test kit orders for testing partners.

Finally, obtaining collection kit materials has been a statewide obstacle. Thankfully, Gravity Diagnostics has been able to obtain all the testing materials to support its contractual obligations. To support other testing needs across the state, swabs have been procured through Emergency Management and the International Reagent Resource (IRR). DLS purchased supplies to make viral transport media in-house and to create collection kits. To aid specimen collection and delivery, DLS provides collection kits to facilities statewide free of charge by overnight delivery. DLS has intentionally diversified the instruments and extractors used for testing to help mitigate against future disruptions to the testing supply chain. Initially, extraction kits were in short supply and DLS validated three different extraction platforms, in addition to manual extraction. DLS has further expanded options for PCR testing by researching additional high-throughput and serology platforms to help prevent testing shortages due to lack of testing supplies. Additionally, DLS has identified specimen accessioning and test resulting as process bottlenecks. DLS supports the Outreach online portal for creation of specimen requisitions and real-time results reporting. In collaboration with the Healthcare Association Infection Prevention Antibiotic Resistance (HAI/AR) Prevention Program, DLS has significantly increased the number of Outreach users, and created several custom user groups for users who oversee multiple facilities. DLS educates new and existing submitters regarding creating test requisitions to aid in more rapid accessioning once specimens arrive in the lab.

DLS purchased the Bio-rad SARS-CoV-2 Total Ab assay to use with the existing EVOLIS systems. The Biorad SARS-CoV-2 Total Ab assay enables DLS to implement serology testing of patients, with a very high (99.5%) specificity. In June, DLS will finalize validation and write a new standard operating procedure, with intended July 1 implementation date. A minimum of three scientists will be trained on this assay to achieve a two-day turn-around time from specimen receipt to result reporting. DLS hired one new laboratory scientist to assist with this testing. Serology testing will target vulnerable populations, including healthcare workers, residents and staff in congregate care settings (LTCF's, prisons), and critical infrastructure workers. DLS plans to target facilities or communities with an expected minimum

seroprevalence of >5% in order to maximize positive predictive value. DLS is researching options to bring another serology assay in-house, likely IgG only. Ideally, this second assay will have a different antigenic target and could be used for an orthogonal testing algorithm.

DPH had an initial conversation with a commercial lab about providing sustained state-wide serology testing, however, a targeted approach for serology is still being planned.

Early in the response, lack of testing options and scarcity of resources limited necessary testing in Kentucky. To address this, DPH developed in-house resources, identified a laboratory partner (Gravity Diagnostics), contracted with a logistics company (UPS), and built a de novo hub-and-spoke fulfillment system that now services 34 LHDs, 42 healthcare facilities, supports 4 drive-through testing sites (Kroger) moving weekly throughout the state, and a comprehensive LTCF testing program up to a maximum 5,000 tests per day, 6 days per week, giving Kentucky testing capacity of approximately 2.7% of all Kentuckians on a monthly basis; this does not include the myriad other and still expanding clinical and laboratory service providers.

In mid-May, DPH contracted with Deloitte to evaluate the entire testing process. DPH is exploring options to enhance electronic lab reporting and to better integrate data into sentinel surveillance systems that could support vulnerable populations. An efficient and reliable testing and data reporting process will be foundational to targeted testing and contact tracing.

Through a master agreement with Medasource, DPH is able to rapidly hire and on-board new staff (within two weeks), which has enabled sharply increased staffing capacity. DLS will not hire additional laboratory staff in May and June and will reevaluate staffing as testing capacity and demand increases. Collection materials and testing supplies/reagents have been procured through the IRR and outside vendors in adequate volumes to meet the testing demand through the end of June.

DPH will continue the Gravity contract through the end of July, to support the testing programs described above. Concurrently, DLS is expanding its testing capacity to support LHDs and other public health testing efforts. Looking to mid-summer and beyond, DPH will continue to assess the testing capacity of the regular healthcare system and academic and commercial laboratory community. Where gaps are identified, DPH will work with existing partners to mitigate against those gaps.

#### Table #2: Planned expansion of testing driven by public health departments

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Number of additional* staff to meet planned testing levels	0	0							0
		FOR DIA	AGNOSTIC TE	STING					
How many additional* testing equipment/devices are needed to meet planned testing levels? (provide an estimated number, and include platform details in narrative above)	0	0							0
Volume of additional swabs needed to meet planned testing levels <sup>++</sup>	0	0							0
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels <sup>++</sup>	0	0							0
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	0	0							0
		FOR SE	ROLOGIC TE	STING					
Number of additional* equipment and devices to meet planned testing levels	0	0							0

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	0	0							0

\* Report new monthly additions only, not cumulative levels

++ For May and June, only include needs beyond the supplies provided by FEMA. Report new monthly additions only, not cumulative levels.