

ELC ENHANCING DETECTION: KENTUCKY TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Kentucky
Population Size:	4.5 million

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 or approximately 3,000 tests/day will need to be performed in Kentucky. Through a contract with Gravity Diagnostics alone, Kentucky has the capacity to perform 125,000 tests/month or 5,000 tests/day (Monday-Saturday), exceeding the monthly minimum. Additionally, the Division of Laboratory Services (DLS) has recently expanded its testing capacity to approximately 1,300 specimens/day (Monday-Saturday).

In addition to current capacity, the Kentucky Department for Public Health (DPH) must continue to increase availability and accessibility of testing. To stop transmission of COVID-19, the primary goals are to identify as close to 100% of people who are infected as quickly as possible after they are infected, to isolate cases immediately, to identify and quarantine their close contacts, and monitor close contacts for symptoms. A critical component of this plan is to increase testing capacity in Kentucky, which will require a multi-pronged approach. Five primary public health objectives need to be met:

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.)
- Workers in critical infrastructure jobs (including healthcare, food manufacturing, processing and distribution, education, childcare providers, first responders, agriculture, etc.)
- Vulnerable, underserved, uninsured, underinsured populations
- Those living in rural communities
- Minorities, refugees, immigrants and other populations with limited English speaking proficiency
- Individuals with substance-use disorder (SUD)

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- Persons experiencing homelessness
- Elderly, immunocompromised, and those with pre-existing medical conditions

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

First, DLS will enhance capacity to perform COVID-19 testing. Using CARES funding, DLS purchased new extraction platforms and instrumentation to expand COVID-19 testing. Full implementation of CDC, Cepheid, and Hologic assays provides DLS with the capacity to test approximately 1,300 specimens/day. Further, DLS will use Enhancing Detection funds to purchase the Abbott Alinity m for high-throughput testing, allowing for an additional 300 specimens tested in one shift. Testing capacity can be scaled as needed on the Alinity m by hiring additional staff for second shift coverage. DLS will validate the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex assay, as well as similar assays, as they become available from vendors. These assays will streamline testing procedures, conserve testing supplies, and aid surveillance efforts. DLS recently began amplicon sequencing of SARS-CoV-2 using ARCTIC protocol and Swift BioAssay version 2 on the Illumina Miseq and Nanopore MinION. Sequencing data will be used for surveillance, tracing transmission routes, and new mutation detections. In the next year DLS will explore implementation of enrichment and metagenomics protocols with inclusion of SARS-CoV-2. With Enhancing Detection funds, DLS will purchase a NextSeq 2000 sequencing system to provide scalability as specimen volume increases, improve cost efficiency, and accommodate addition of new protocols.

Second, DPH will quantify the current and projected capacity of Kentucky laboratories performing COVID-19 testing, as well as conduct outreach to any new onboarded laboratories. DPH will distribute a survey that queries current and future testing capacity of all sentinel clinical labs, commercial labs, and university labs performing COVID-19 testing. Specifically, the survey will query: type of testing performed at the laboratory (PCR, antibody, antigen), instrument(s) and assay(s) used to perform testing, average turnaround time, current and future daily testing capacity by test type, current and future barriers to testing, and planned COVID-19 testing expansion. Survey data will identify testing gaps, as well as the quantity and geographic distribution of point-of-care and high-throughput instrumentation. Survey data will also identify any overreliance of a particular instrument/assay, which will be problematic in the event of supply chain disruptions. With these data, DPH will implement mitigation strategies for identified gaps. Laboratories that fail to respond to the survey will be contacted by phone for follow-up. The survey will be administered electronically via REDCap on a quarterly basis within the first year (June 2020, September 2020, December 2020, March 2021), then biannually for the remainder of the project period.

Third, DPH will work to implement or enhance COVID-19 testing capacity within Kentucky local health departments (LHDs). There are 120 counties in Kentucky, served by 61 local and district health departments. DPH will provide a base allocation to each LHD using a 30% base/70% population formula. Those funds may be used to increase specimen collection at the LHD and LHD-run mobile collection sites with testing performed by DLS. To further enhance testing by LHDs, DPH will issue a mini-grant application to select a minimum of 16 LHDs for in-house point-of-care testing. This will allow DPH to

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fund a minimum of one LHD in each of the 14 regions, as well as 2 largest metro areas. To be selected, LHDs must the following in their proposals: estimated number of tests to be performed per month, proposed testing platform , outreach to at-risk populations, ability to deploy mobile specimen collection and testing units to reach those at-risk populations, data collection, and electronic reporting method. DPH met virtually with the Kentucky Health Department Association (KHDA) May 29 to discuss the mini grant application, which was then sent to the LHDs June 12 with a due date of July 6. A committee at DPH is reviewing and scoring the proposals, with notification to awardees July 14.

Fourth , in addition to the mobile specimen collection and testing units that will be run by LHDs, DPH plans to establish a minimum of two, one that will offer point-of-care testing for smaller mobile testing events and a second for larger testing events that will offer specimen collection only (testing at DLS within 24 hours of collection). These units will be staffed by one person to do intake, data collection, and reporting; two persons to collect swabs; and two persons to run the tests, as needed. Units will be used to target at-risk populations mentioned previously. The mobile testing 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 testing events, staff will provide community education and prevention information, as well as testing services. The target deployment of units from the identification of need is within 48 hours.

Fifth, DPH will continue to support the Gravity Diagnostics contract, which enables testing of up to 5,000 specimens/day, through the end of July, with the option to extend if needed. Through this contract, Gravity Diagnostics provides testing services to LHDs, healthcare facilities, and community-based drive-thru testing sites. To date, those testing partners include 34 LHDs, 42 healthcare facilities (hospitals, clinics, Federally Qualified Health Centers (FQHCs), Urgent Treatment Centers, etc.), 13 corrections facilities, and 315 long-term care facilities (LTCFs) who are conducting facility-wide testing of every resident and employee. Additionally, Gravity Diagnostics provides testing services for Kroger drive-thru clinics. To date, 16 cities have hosted drive-thru testing events through Kroger and Gravity Diagnostics. A future determination will be made whether to extend the Gravity Diagnostics contract or if DLS will provide all testing for LHDs. DPH is working with other entities currently using Gravity Diagnostics through this state-executed program to ensure that their testing needs will be covered once the contract expires.

Sixth, DPH is working with FQHCs and Rural Health clinics (RHCs) in Kentucky to identify current COVID-19 testing capacity, access to COVID-19 testing, gaps in testing coverage, and barriers to accessing testing. There are over 90 FQHCs and RHCs covering Kentucky counties. DPH met virtually on July 1 with the Kentucky Primary Care Association (KPCA) who oversees the FQHCs and RHCs to discuss coordination of current testing efforts at the state and local level and minimize duplication of efforts.

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Seventh, DPH will continue to support community-based drive-thru testing and partner with the entities who offer such testing, including Walmart, Walgreens, and Kroger. Walmart and Walgreens are providing testing independently of DPH and will continue to do so. DPH will work to obtain electronic lab results from both entities, 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 is assessing the need to extend this contract for wide-scale community-based testing beyond July. DPH will support LHD-run drive-thru, pop-up, and community-based testing through the LHD allocations and mini-grant awards. During these events, DLS will provide specimen collection kits, packaging and shipping materials, support for shipping costs, and service as the reference laboratory. 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 as limited access to COVID-19 testing.

Eighth, DPH will utilize serology test results from multiple sources to identify and monitor seroprevalence in the population. DPH will perform a seroprevalence survey using the Roche Total Antibody Test. During routine clinic visits, patients having blood drawn will have the option to consent to a COVID-19 antibody test. Aggregated test data will be reported monthly to DPH, which will be used to monitor seroprevalence. Further, DPH will receive de-identified antibody reports from Red Cross blood donors. Finally, DLS will bring serology testing in-house. Initial validations began in June with the Bio-rad Platelia SARS-CoV-2 Total Ab assay, which can be performed on existing EVOLIS systems, and will serve as the initial screening. A second assay, the EuroImmun SARS-CoV-2 ELISA (IgG), will be validated and used to test specimens initially positive from the first test. The EuroImmun assay has a differing antigenic target (Spike protein) as compared to the Bio-rad assay, which targets Nucleocapsid protein. Thus, the two assays can be used for an orthogonal testing algorithm, which will enhance DLS's ability to detect antibody response. Initial Red Cross data reveals <2% of Kentuckians are seropositive at present, making serology testing of most use to track disease evolution to guide future public health interventions and only of limited value at the individual patient level. DPH anticipates future use scenarios in which it may utilize serology testing for congregate living residents and staff (LTCF and corrections facilities) as well as healthcare workers where this information could help identify and cohort persons to reduce risk of disease transmission.

Finally, to ensure the data obtained through the enhanced testing efforts are captured, DPH is collaborating with the laboratories performing testing, Kentucky Health Information Exchange (KHIE), Commonwealth Office of Technology (COT), and 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 indeterminate) electronically from a subset of testing facilities. This data limitation prevents an accurate understanding of the true scope of testing in Kentucky.

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DPH will continue to partner with LHDs and community agencies to promote testing that is available and accessible to Kentucky at-risk populations. DPH will support LHD targeted testing efforts, including in-house at selected LHDs and testing by DLS for all LHDs able to collect specimens. Many LHDs are already reaching these populations through innovative and existing programs, including harm reduction and syringe services programs, as well as mobile outreach.

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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*	153,996	155,671	191,704	195,538	199,448	203,437	207,506	211,656	1,518,956
Serology	20,587	13,794	14,472	15,195	15,955	16,753	17,590	18,470	132,816
TOTAL	174,583	169,465	206,176	210,733	215,403	220,190	225,096	230,126	

*Each jurisdiction is expected to expand testing to reach a minimum of 2% of the jurisdictional population.

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

Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
Division of Laboratory Services	Public health lab		1,300	150	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

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
Appalachian Regional Hospital	Hospitals or clinical facility		170	0	Rural populations, uninsured, underinsured, those with chronic health conditions
Baptist Health Corbin	Hospitals or clinical facility		300	0	Rural populations, uninsured, underinsured, those with chronic health conditions
Baptist Health Lexington	Hospitals or clinical facility		50	0	
BioTapMedical	Commercial or private lab		500		
Bluewater Diagnostics (Bluewater Toxicology)	Commercial or private lab		1,000		
Lexar	Commercial or private lab		0		
Louisville Metro Public Health Lab	Public health lab		88	0	First Responders
Onsite Health Solutions	Other			100	Prepared to screen workers

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
Owensboro Health	Hospitals or clinical facility		160	10	
Solaris	Commercial or private lab		10,000	1,000	
TEC Biosciences Inc	Commercial or private lab		190		
University of Louisville	Other		1,200		
University of Louisville Infectious Disease Laboratory	Other		100		
University of Kentucky Health Center/Systems	Hospitals or clinical facility		800	1,000	
VA Lexington Micro Biology (LEXINGTON VA HEALTH CARE)	Hospitals or clinical facility		300		Veterans

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
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
LabCorp	Commercial or private lab		2,000		
Quest	Commercial or private lab		500		
AIT	Commercial or private lab		6,000	6,000	Info not available
Mako Medical Laboratories, LLC	Commercial or private lab		35,000	20,000	Info not available
Nulease Medical Solutions	Commercial or private lab		300	600	

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
Viracor Eurofins	Commercial or private lab		3,000	2,000	
eTrueNorth	Commercial or private lab		50,000	0	
Fulgent Genetics, Inc.	Commercial or private lab		20,000	0	
Acutis Diagnostics	Commercial or private lab		5,000	600	
X-gene Molecular Labs	Commercial or private lab		300		

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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.). As mentioned previously, the Division of Laboratory Services (DLS) recently expanded its COVID-19 testing capacity from 80 specimens/day to approximately 1,300 specimens/day using the CDC, Cepheid, and Hologic assays. DLS will utilize Enhancing Detection funds to purchase the Abbott Alinity m for high-throughput testing, allowing for testing of an additional 300 specimens in one shift. Testing capacity will be scaled as needed on Alinity m by hiring additional testing staff for second shift coverage. DLS will validate CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex assay and similar assays as they become available. These assays will streamline testing procedures, conserve testing supplies, and aid surveillance efforts. A minimum of four scientists will be trained on Hologic and Alinity platforms to ensure weekend and evening testing coverage.

DLS began amplicon sequencing of SARS-CoV-2 using ARCTIC protocol and Swift BioAssay version 2 on the Illumina Miseq and Nanopore MinION. Sequences will be analyzed using commercial software and publicly available pipelines. Sequencing data will be used for surveillance, tracing transmission routes, and detection of new mutations in local populations. DLS will explore implementation of enrichment and metagenomics protocols with inclusion of SARS-CoV-2. DLS will utilize Enhancing Detection funds to procure a NextSeq 2000 sequencing system to provide scalability as specimen volume increases, improve cost efficiency, and accommodate addition of new protocols.

DLS maintains a reference laboratory contract to perform testing for low volume tests and to send out testing temporarily due to unavailability of reagents or equipment malfunction. This agreement was renewed, effective 7/1/20, with Quest Diagnostics via competitive RFP for DLS testing surge capacity and increase in demand or supply chain difficulties.

DPH contracted with Gravity Diagnostics, a Northern Kentucky commercial molecular diagnostic laboratory, for testing of 5,000 specimens/day Monday through Saturday or >120,000 specimens/month (approximately 2.7% of Kentucky's population/month). Using this testing capacity, DPH supports three unique programs: 1) 34 local health departments (LHDs) and 42 healthcare facilities (hospitals, clinics, Federally Qualified Health Centers (FQHCs), Urgent Treatment Centers, etc.); 2) Kroger and other community-based drive-thru testing sites, and 3) congregate setting (e.g., long-term care (LTC) facilities, behavioral health hospitals, and prisons) testing program. DPH will maintain this contract through July, with option to extend.

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DPH will provide allocations to all 61 Kentucky LHDs, for target specimen collection and testing of at-risk populations. Either through DLS directly or ongoing support via Gravity Diagnostics, DPH will continue to support LHDs with testing access. For direct DLS support, DPH will enable LHDs to order specimen collection kits and packaging/shipping supplies free of charge through existing supply mechanisms. DLS will continue to support the FedEx account, which enables LHDs priority overnight submissions at no cost. LHDs will order tests and retrieve results through Outreach, an online portal for test ordering connected to the DLS Laboratory Information Management System (LIMS). DLS has online training available for Outreach and packaging and shipping of viral specimens on their website. Additionally, DLS will hire a Training and Outreach Coordinator to ensure that LHDs are able to successfully collect, store and ship specimens, as well as provide technical assistance when needed.

Additionally, DPH will collaborate with LHDs to implement or enhance in-house testing at a minimum of 16 LHDs through a mini-grant application process focused on testing equipment, supplies, and personnel. DPH through DLS or a contracted lab, will serve as the testing entity for 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. To be selected, LHDs must address: estimated number of tests per month; proposed testing platform; outreach to at-risk populations; ability to deploy mobile testing units; data collection and electronic reporting method and overall evaluation strategies and will be notified by July 14.

For the duration of this response, both through DLS and Gravity Diagnostics, DPH prioritized testing specimens from at-risk populations, including 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. DPH prioritized testing of other at-risk populations, including congregate settings residents, 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 multi-faceted assessment, consultation, and support program, as well as targeted, facility-wide (residents and staff) molecular diagnostic testing at all 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-to-peer sharing is occurring among the LHDs via a monthly webinar to discuss barriers and solutions. DPH supports LHD efforts to reach underserved persons through LHD in-house and drive-through testing, and partnerships with local healthcare providers and community organizations. Several LHDs have worked collaboratively to target at-risk populations through innovative means, such as food banks, syringe exchange programs, military families, and mobile units. DPH supports a variety of testing sites at community-based locations through

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the Gravity Diagnostics contract, 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 and LHDs are coordinating testing efforts with the FQHCs and RHCs to ensure that there is no duplication of efforts in the provision of clinic-based testing services. Through Enhancing Detection funds, DPH is enhancing the capacity of the LHDs to provide mobile, community-based, and pop-up testing sites to at risk populations. In the fall, DPH will work with an academic partner to provide additional non-clinic based testing in Appalachian counties, which we know are some of our most vulnerable populations with higher comorbidities and poor health outcomes.

DPH is in regular, ongoing communication with hospital, LHD, medical, and laboratory communities 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, from the supply chain to reporting in order to streamline the process, eliminate barriers, promote electronic data submission, and reduce errors.

Obtaining collection kit materials has been a statewide obstacle in March, April, and May. Gravity Diagnostics, however, has been able to obtain all the testing materials necessary 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) 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 Platelia SARS-CoV-2 Total Ab assay to use with the existing EVOLIS systems. Validation was started in June and the Bio-rad assay will serve as the initial screening test. A second assay, the EuroImmun SARS-CoV-2 ELISA (IgG), will be validated and used to test specimens initially

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positive from the first test. The EuroImmun assay has a differing antigenic target (Spike protein) as compared to the Bio-rad assay, which targets Nucleocapsid protein. Thus, the two assays can be used for an orthogonal testing algorithm, enhancing DLS's ability to detect antibody response. This algorithm will provide differentiation of antibody status (IgG or IgM) and with the diversification of the target antigens, should minimize the possibility of erroneous test results. A minimum of three scientists will be trained on each assay to achieve a two-day turn-around time from specimen receipt to result reporting. Additionally, DLS is evaluating the purchase of the Abbott Alinity I platform and associated IgG test as a higher throughput option, with the potential to replace other aging equipment. Serology testing will target at-risk and vulnerable populations, including healthcare workers, first responders, residents and staff in congregate care settings (LTCFs, prisons), and critical infrastructure workers.

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 and 42 healthcare facilities. It also supports 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 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 will improve sentinel surveillance and reporting throughout the commonwealth for both influenza and COVID-19. DPH will increase the number of ILINet providers and improve the timeliness and completeness of reported data. DPH plans to recruit several FQHCs to ILINet in the major metropolitan areas in KY (Louisville, Lexington, and Northern Kentucky) to better estimate ILI and COVID activity in the core-based statistical areas. DPH will encourage ILINet providers to submit COVID-19 specimens for confirmatory testing, following CDC guidelines. 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 plans to hire two additional testing scientists and a lab technician to assist with testing, specimen opening, and other needs as DLS expands testing capacity and begins testing for the LHDs. In addition, DLS will consider adding a second shift of testing scientists, a lab technician, and an administrative staff member to further increase testing capacity if deemed necessary to accommodate specimen volume. To date, collection materials and testing supplies/reagents have been procured through the IRR and outside vendors in adequate volumes to meet the testing demand. DLS collaborates with different vendors to ensure receipt of maximum allocations of testing kits and reagents every week for each assay performed at DLS in anticipation of increasing specimen volume.

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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.

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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	1	2	2	1	2	0	8
FOR DIAGNOSTIC TESTING									
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	0	1	0	0	0	1

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Volume of additional swabs needed to meet planned testing levels ⁺⁺	0	0	3,100	6,200	9,000	9,300	9,000	9,300	45,900
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	0	0	3,100	6,200	9,000	9,300	9,000	9,300	45,900

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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	100/d - Hologic	200/d - Hologic	300/d - Hologic 5/d - GX	300/d - Alinity m 5/d - GX	200/d - Alinity m 5/d - GX	100/d - Alinity m 5/d - GX	0
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	0	0	0	0	0	0	0	1	1

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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	50/d - Biorad	50/d - Biorad 10/d - EuroImmune	25/d - Biorad 10/d - EuroImmune	25/d - Biorad 10/d - EuroImmune	10/d - Alinity i	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.