

# ELC ENHANCING DETECTION: VIRGINIA TESTING PLAN

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

Jurisdiction:	Virginia
Population Size:	8536000

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

VDH's overarching strategy will include setting goals for testing, establishing testing targets, identifying private sector barriers, and initiating testing priorities and strategies to enhance detection of COVID-19 across Virginia. Primary goals of the VDH testing strategy include: increase containment activities as a result of reopening, expand testing to support identification of cases and contacts including those with mild and asymptomatic presentations, and testing more aggressively where increased burden or high risk of transmission exist (e.g. LTCFs, congregate settings, jails, schools).

#### Maximize Use of Testing Platforms

VDH will maximize a variety of testing platforms to include expansion at the Division of Consolidated Laboratory Services (DCLS), Virginia's state lab. DCLS is currently validating the TaqPath COVID-19 Combo Multiplex real-time reverse transcriptase PCR assay and will be implementing high-throughput automated instrumentation for SARS-CoV-2, including two NeuMoDx instruments (capacity of 288 tests in 8 hours/instrument) and Hologic platforms (capacity of 275 – 300 tests in 8 hours/instrument), provided that sufficient reagents are available to support testing. These additional assays and platforms are anticipated to increase the daily testing capacity at the public health laboratory to 3,500 per day by November 2020. DCLS is additionally adding staffing to support a second 8 hour work shift for SARS-CoV-2 diagnostic testing, which is anticipated to be fully operational in July 2020. The instruments, and testing workforce when operated at full capacity, will have the ability to process up to 4,000 per day by the end of 2020. DCLS is additionally implementing serology testing for SARS-CoV-2 to meet the expanded surveillance needs for the commonwealth. In the short-term, DCLS will use the Autobio Lateral Flow Device for an estimated throughput of 160 tests per day in June 2020. DCLS is investing in the higher-throughput Siemens Atellica system for total antibody testing, and IgG testing. It is anticipated that the Siemens system can support serologic testing of up to 3,520 specimens per day. Virginia will further expand testing through partnerships with the Fairfax County Health Department Laboratory and academic institutions, including the University of Virginia Medical Laboratories, Virginia Commonwealth University Medical Center laboratories, and Virginia Tech. Expanded capacity through the Fairfax County Health Department will include procurement of a Panther Fusion System (Hologic), to complement the Panther System that is currently in place at that laboratory. Several contractual laboratories have additionally been identified to support large testing events that exceed the capacity of the public health laboratory and academic partner network.

To ensure barriers to access to kits and tests are removed, DCLS is coordinating the distribution of FEMA supplies, including specimen collection kits, and Abbott ID Now test supplies to Virginia clinical partners to ensure continued capacity for diagnostic testing on a needs basis. Existing sentinel laboratory network and outreach responsibilities at DCLS have been capitalized to gauge and assist with clinical laboratory needs. VDH is additionally surveying private, academic and public health laboratories

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approximately once per month to determine platforms in use and estimated testing capacity. This information can be used to assess continuity in testing services for Virginians.

## Approach to Non-Traditional Testing Sites

VDH plans to partner with Federally Qualified Health Centers (FQHCs) and Free Clinics throughout the state as another method to increase testing for under and uninsured, regardless of their ability to pay. Not only does this increase access to testing, but it also provides persons that may not have a provider with a medical home in case there is any medical follow-up needed. As a component of this partnership, VDH will provide testing kits, PPE, and lab testing capacity for FQHCs and Free Clinics that conduct COVID-19 testing on behalf of public health.

In addition, various pharmacies have begun testing throughout Virginia by utilizing nasal swabs via a drive-thru testing model. Two pharmacy chains, Walmart and Rite Aid, have received funding from Health and Human Services to begin providing COVID-19 testing at six locations throughout the state. Both of these pharmacies provide specimen collection and send specimens to a laboratory for testing. As a result of high demand, these locations have expanded their daily testing capacity. As of May 29, CVS will begin COVID-19 testing in 39 locations. CVS will utilize their Minute Clinic to not only provide covid testing, but will be the first pharmacy utilizing a clinic/provider model in Virginia.

## Approach to Serologic Testing

Diagnostic testing methods have been the primary focus in Virginia and across the United States as we have entered the pandemic. As we move through the pandemic and serology platforms have improved, VDH has developed a serologic testing strategy to better characterize the extent of transmission of COVID-19 in the Commonwealth. VDH plans to sponsor and fund several seroprevalence studies throughout Virginia. The objectives of this project are to: (1) determine the extent of infection in communities as determined by COVID-19 seroprevalence; and (2) determine factors associated with COVID-19 seropositivity. This will be a point prevalence study at multiple outpatient sites across the Commonwealth and will be targeted at adults and pediatric patients. Participants will be surveyed using a standardized questionnaire. Blood samples will be collected from all participants and tested for antibodies to COVID-19, with results reported back to the individual. In addition to these defined seroprevalence studies, VDH will partner with the local health departments to sponsor community testing events for serology particularly to assess vulnerable communities. VDH will continue to evaluate the role of serology in public health practice to ensure that we are capitalizing on this testing capacity and using this information to inform on the immunity status of many of vulnerable populations, including those in long-term care facilities and other congregate settings.

## Communication and Coordination with Broad Testing Community

Virginia created a Testing Advisory Council. The charge to the Advisory Council is to collaborate across key private and public stakeholders to assist the Commonwealth in fulfilling the testing requirements for effectively addressing the COVID-19 pandemic and supporting the Governor's Forward Virginia Blueprint. The Advisory Council consists of representatives from the Virginia Department of Health,

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Virginia Hospital and Healthcare Association, the Governor's Office, the state laboratory, commercial laboratories, private providers, long-term care, pharmacies, urgent care centers, dental, the Department of Medicaid and Medicare Services, private insurance, safety net providers, public safety, and health equity. The Advisory Council meets weekly and contains five subcommittees for more targeted discussions, which also meet weekly.

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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*	200,000	300,000							500,000
Serology	0	2,800							2,800
TOTAL	200,000	302,800	0	0	0	0	0	0	

**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 throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Division of Consolidated Laboratory Services (DCLS)	Public health lab		600	0		outbreak investigations, un/underinsured, vulnerable populations, healthcare workers and first responders, sentinel surveillance
University of Virginia	Hospitals or clinical facility		1,500			Clinical/Diagnostic Lab. Public Health surge lab

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Virginia Commonwealth University	Hospitals or clinical facility		400			Clinical/Diagnostic Lab. Public Health surge lab
Virginia Tech	Other		150			Clinical/Diagnostic Lab. Public Health surge lab
Fairfax Co. HD Lab	Public health lab		100			Public Health Lab

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Inova Health System (Alexandria, Fairfax, Fair Oaks, Mt Vernon & Loudoun)	Hospitals or clinical facility		500			Clinical/Diagnostic Lab
Sentara Reference Lab	Hospitals or clinical facility		700	350		Clinical/Diagnostic Lab

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
HCA SW VA Market (Lewis Gale Salem testing for Lewis Gale Salem, Montgomery Regional, Alleghany & Pulaski)	Hospitals or clinical facility		100			Clinical/Diagnostic Lab
HCA Richmond Market (testing for Chipp, JW, HDH Forest/Retreat/Parham, John Randolph & Spotsylvania Reg MC)	Hospitals or clinical facility		288			Clinical/Diagnostic Lab
HCA-Reston Hospital Center; performs for HCA Stone Springs & Dominion Hosp also	Hospitals or clinical facility		15			Clinical/Diagnostic Lab
LifePoint Sovah-Danville; will be performing testing for Martinsville Hosp as well	Hospitals or clinical facility		0			Clinical/Diagnostic Lab

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LifePoint Sovah-Martinsville	Hospitals or clinical facility		0			Clinical/Diagnostic Lab
Mary Washington & Stafford Hosps-MWH is performing all Stafford Hospital testing for the Cepheid. Each hospital is performing their own Abbott ID Now testing	Hospitals or clinical facility		450			Clinical/Diagnostic Lab
LifePoint-Clinch Valley Med Ctr	Hospitals or clinical facility		20			Clinical/Diagnostic Lab
Virginia Hospital Center Arlington	Hospitals or clinical facility		190			Clinical/Diagnostic Lab
VAMC (Veterans Admin Med Ctr)-Durham NC	Hospitals or clinical facility		188			Clinical/Diagnostic Lab



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DTHC-DiLorenzo Tricare Health Clinic/Pentagon DOD CLIP 2031001	Hospitals or clinical facility		8			Clinical/Diagnostic Lab
Military- Ft Lee Medical Center/Kenner Army Lab	Hospitals or clinical facility		56			Clinical/Diagnostic Lab
Bon Secours -Richmond Market (St Mary's, Community, Memorial & St. Francis); aka Bon Secours HealthPartners Lab	Hospitals or clinical facility		42			Clinical/Diagnostic Lab
Bon Secours-Hampton Rds (Maryview, Mary Immaculate, DePaul)	Hospitals or clinical facility		5			Clinical/Diagnostic Lab

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Riverside Health Systems (Shared lab performing for all Riverside locations); Riverside Med Grp Consolidate lab CLIA 49D0703050	Hospitals or clinical facility		1,096			Clinical/Diagnostic Lab
Valley Health Systems (Winchester Med Ctr); **Note: will also be testing for Warren Co Memorial Hospital once sufficient reagent supply is on hand	Hospitals or clinical facility		300			Clinical/Diagnostic Lab
Carilion Roanoke (Quest/Solstas)	Hospitals or clinical facility		300			Clinical/Diagnostic Lab
Augusta Health	Hospitals or clinical facility		32			Clinical/Diagnostic Lab

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Centra Health Systems- Lynchburg General & Southside Community-Farmville only	Hospitals or clinical facility		270			Clinical/Diagnostic Lab
Ballad Health Systems (Synergy Labs)- (Johnston Memorial/Abingdon; Smyth Co/Marion; Russell Co/Lebanon)	Hospitals or clinical facility		75			Clinical/Diagnostic Lab
Childrens Hospital of the Kings Daughters/Norfolk (CHKD)	Hospitals or clinical facility		96	2,000		Clinical/Diagnostic Lab

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University of Washington Medical Center/UWMC	Hospitals or clinical facility		5,000	3,000		Clinical/Diagnostic Lab

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Quest	Commercial or private lab		300			Clinical/Diagnostic Lab
LabCorp	Commercial or private lab		300			Clinical/Diagnostic Lab
Aperiomics_Howard Hughes Medical Institute	Commercial or private lab		1,000			Clinical/Diagnostic Lab
GENETWORx	Commercial or private lab		1,000			Clinical/Diagnostic Lab

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NEXT Bio-Research Services aka Next Molecular Analytics	Commercial or private lab		1,000			Clinical/Diagnostic Lab
Bode; Lorton, VA	Commercial or private lab		1,000			Clinical/Diagnostic Lab
ARUP/Salt Lake City UT	Commercial or private lab		168	500		Clinical/Diagnostic Lab

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Poplar Healthcare/Memphis TN	Commercial or private lab		60			Clinical/Diagnostic Lab
Kaiser Regional Lab, 6111 Executive Blvd, Rockville MD (will perform testing for all Kaiser VA locations)	Commercial or private lab		500			Clinical/Diagnostic Lab
Genetics & IVF/Fairfax	Commercial or private lab		110			Clinical/Diagnostic Lab
Excelsior Diagnostics-Houston, Texas	Commercial or private lab		400			Clinical/Diagnostic Lab

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Clinical Therapeutic Solutions/Bako Diagnostics-Alpharetta GA	Commercial or private lab		120			Clinical/Diagnostic Lab



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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
StageZero, COA/HC, CLIA# 49D2059683	Commercial or private lab		200			Clinical/Diagnostic Lab
Vista Clinical Diagnostics, Danville, VA	Commercial or private lab		150			Clinical/Diagnostic Lab

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Mira Scientific Labs /FFX	Commercial or private lab		1,152	1,500		Clinical/Diagnostic Lab
Mako Medical Labs, LLC (based in Raleigh & Henderson NC)	Commercial or private lab		500	300		Clinical/Diagnostic Lab

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Aegis Sciences Corp/Nashville TN CLIA 44D2062333	Commercial or private lab		2,000	3,000		Clinical/Diagnostic Lab
KBMO Diagnostics, Hopedale MA	Commercial or private lab			300		Clinical/Diagnostic Lab

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Clarity Labs/Somerset, NJ	Commercial or private lab		75			Clinical/Diagnostic Lab
AIT labs/Denton TX	Commercial or private lab		75			Clinical/Diagnostic Lab
p4Dx/NJ ; P4 Clinical Diagnostics	Commercial or private lab		48			Clinical/Diagnostic Lab
Granger Genetics	Commercial or private lab			1,000		Clinical/Diagnostic Lab

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ChemiSys Labs (NJ)	Commercial or private lab		90	5,000		Clinical/Diagnostic Lab
ResourcePath	Commercial or private lab		400			Clinical/Diagnostic Lab
Integrated Cellular and Molecular Diagnostics	Commercial or private lab		90			Clinical/Diagnostic Lab

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Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
AdvaGenix	Commercial or private lab		180			Clinical/Diagnostic Lab
KorvaLabs, Inc. [Curative Inc/Integrative PM (Los Angeles, CA)]	Commercial or private lab		30			Clinical/Diagnostic Lab

## 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.

#### Public Health Department Testing Expansion

VDH will maximize a variety of testing platforms and entities to achieve an estimated public health testing goal of approximately 84,000 tests in the month of June (3,000 tests per day), and additional tests in following months. This expansion will require investments in instrumentation and resources for the Division of Consolidated Laboratory Services (DCLS), Virginia's state lab. DCLS is currently validating the TaqPath COVID-19 Combo Multiplex real-time reverse transcriptase PCR assay for use on ABI 7500 Dx Instruments currently at the laboratory and will implement additional ABI instruments and high-throughput automated instrumentation, including two NeuMoDx instruments (capacity of 288 tests in 8 hours/instrument) and Hologic platforms (capacity of ~330 tests in 8 hours/instrument). These additional assays and platforms are anticipated to increase the daily testing capacity at the public health laboratory to an estimated 3,500 tests per day by November 2020. Additional assays and platforms will be incorporated progressively beginning in June 2020 for incremental increases in capacity through November 2020. DCLS is additionally adding staff to support a second 8-hour work shift for SARS-CoV-2 diagnostic testing, which is anticipated to be fully operational in July 2020. The instruments, and testing workforce when operated at full capacity, have the ability to process up to 4,000 tests per day by the end of 2020. DCLS is additionally implementing serology testing for SARS-CoV-2 to meet the expanded surveillance needs for the Commonwealth. In the short-term, DCLS will use the Autobio Lateral Flow Device for an estimated throughput of 160 tests per day in June 2020. DCLS is investing in the higher-throughput Siemens Atellica system for total antibody testing, and IgG testing. It is anticipated that the Siemens system can support serologic testing of up to 3,520 specimens per day. Virginia will further expand testing through partnerships with the Fairfax County Health Department Laboratory and academic institutions, including the University of Virginia Medical Laboratories, Virginia Commonwealth University Medical Center laboratories, Virginia Tech. Expanded capacity through the Fairfax County Health Department Laboratory will include procurement of a Panther Fusion System (Hologic), to complement the Panther System that is currently in place at that laboratory (estimated capacity of 600 samples per day for both instruments). At least two private laboratories have additionally been identified to support large testing events that exceed the capacity of the public health laboratory and academic partner network. These laboratories will be engaged to ensure testing is available for health department surveys, screenings and other needs.

VDH has also contracted with several private laboratories, FQHCs, and pharmacies across the commonwealth to increase access to testing. While DCLS will expand to support the majority of public health testing, VDH will identify continued partnerships with academic medical centers and private testing entities to ensure all Virginians have access to testing. Point of care testing options and mobile testing solutions are under review to ensure access to testing in some of Virginia's most rural communities.

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## Public Health Testing Prioritization

VDH will continue to prioritize outbreak investigations, selected contact investigations, particularly among vulnerable and at-risk populations, un- or under insured persons, and workers and residents in, or newly arriving to, congregate settings (e.g., long-term care facilities, prisons, jails, etc.). Additionally, public health prioritizes testing for those under public health monitoring, sentinel surveillance, and community testing clinics. Prioritization will occur at the local health department as those individuals or populations are identified that meet criteria for public health testing. Specimens collected will be submitted to the state public health laboratory for rapid turnaround testing.

## Overcoming Barriers to Ensure Efficient Testing

As we have identified solutions to expand testing, barriers have been identified. Primary barriers include: personal protective equipment (PPE), trained testing staff, and laboratory coordination with private entities. To address these barriers, VDH is increasing capacity at the state public health laboratory in order to streamline the coordination of testing. Using the already established laboratory infrastructure the localities are familiar with will streamline efficiency at our community testing events. Further, VDH will identify solutions to sample collection and administrative work to ensure that local health departments are not pulled away from their important work to ensure the logistics of sample collection are complete. DCLS is working to improve data acquisition for patients by developing an electronic test ordering system that will allow for transfer of patient information required for testing into DCLS' STARLIMS Laboratory Information Management System. This system will improve expediency in laboratory accessioning and reduce efforts to reconcile paper forms. DCLS has HL7 messaging in place for current molecular assay results to VDH and CDC, and will incorporate results messaging for additional molecular and serologic assays that come on line in 2020. There have been supply chain issues to assure laboratory testing during the COVID-19 pandemic response. DCLS has leveraged multiple partnerships to ensure test kit and test availability for the Commonwealth. DCLS has partnered with the Virginia agency procurement units and FEMA to obtain swabs for collection kits. DCLS has additionally taken on the role of distributing FEMA collection kits to Virginia hospitals for SARS-CoV-2 testing. DCLS has additionally scaled production of Viral Transport Media and collection kits to distribute approximately 10,000 kits per week; by preparing VTM onsite, DCLS has reduced dependency on commercial VTM manufacturers. This is critical as some of DCLS' media orders have gone unfulfilled since February 2020. DCLS also entered into a contract with a UVA current Good Manufacturing Practice laboratory preparing VTM. Due to constraints in receiving QIAGEN extraction kits, DCLS bridged the CDC EUA to include additional extraction platforms, including Roche systems, ThermoFisher King Fisher Flex systems, and the Perkin Elmer Chemagic 360 Instrument. DCLS is additionally acquiring and validating FDA EUA platforms and tests for SARS-CoV-2 expand capacity and build in redundancy, should testing reagents become limited for one system or test.

## Serology Testing at State Public Health Lab

DCLS is implementing serology testing for SARS-CoV-2 to meet the expanded surveillance needs for the Commonwealth. As an interim measure, DCLS will offer serology with Autobio Lateral Flow Devices



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during the month of June 2020; the estimated throughput is approximately 160 tests per day. DCLS is investing in a higher-throughput serologic testing platform, the Siemens Atellica System for total SARS-CoV-2 antibody testing, and IgG testing. It is anticipated that once validated, the Siemens system can support serologic testing of up to 3,520 specimens per day.

### Sentinel Surveillance Plan

VDH plans to enhance upon the already existing influenza surveillance network and partner with select outpatient, urgent care, student health, and emergency department providers to test specimens from patients with an coronavirus-like illness (CLI) for SARS-CoV-2 and other pathogens on the respiratory virus panel and further characterize the type and subtype of positive results. This surveillance effort allows VDH to determine what virus strains are circulating each week, monitor the community for any novel strains, and provide data for assessing trends in transmission. VDH intends to test approximately 300 specimens a week.

### Streamlined and Efficient Procurement of Goods and Services

VDH has established a streamlined process for expediting and streamlining procurement and onboarding of new staff. Programmatic leads of the response identify supply or personnel needs and work with the Shared Business Services, a business partner who provides client-centric solutions across the entire agency to ensure procurement and onboarding of staff can be operationalized in a rapid, timely, and standardized approach.

DCLS will continue to leverage the Virginia Emergency Declaration from March 12 to expedite the process for procuring high-throughput automated instrumentation. The Commonwealth has existing contracts with Hologic that will be utilized to purchase public health testing platforms. DCLS will additionally work with Health and Human Services partners, and Virginia agency procurement teams to obtain critical reagents and supplies for public health testing. Critically needed scientific and administrative staff will be hired as contractors to expedite the hiring process. DCLS has a well-established system for hiring and onboarding contractors with Athena and 21st Century Staffing, for temporary scientific and administrative services, respectively. These vendors are currently under state contract. DCLS has already initiated the approval process for hiring contractual employees.

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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	577	1,189							1,766
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	1							1
Volume of additional swabs needed to meet planned testing levels <sup>++</sup>	80,000	80,000							160,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels <sup>++</sup>	80,000	80,000							160,000
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	37,400	37,400							74,800
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	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	640							

\* 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.