2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Washington
Population Size:	7614893

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

The State of Washington has approximately 7.6M residents. The priorities for testing are tiered and range from testing persons who are symptomatic, contacts of persons testing positive, persons in congregate settings where there has been one or more positive cases, testing of asymptomatic groups at highest risk of severe illness (e.g. those in long term care settings), and essential workers, including: first responders, health care workers, agricultural workers, and grocery store workers. It is also a priority for the state to work with stakeholders and community members to effectively outreach to and test traditionally marginalized groups, including but not limited to: people experiencing homelessness, people of color, members of tribal nations, Latinx people and those with disabilities.

To meet a minimum of testing 2% of the population monthly, 5,000 persons need to be tested daily. Testing numbers in Washington have slowly increased as specimen collection supplies and PPE have become more available. For the week of May 12-18, approximately 5,100 persons were tested daily. Recognizing the need for testing will likely exceed this number as fall approaches, Washington State has developed a near-term model for predicting testing needs that includes the following considerations: estimates of disease prevalence, estimates of symptomatic persons presenting for testing and their contacts, and the number of daily tests needed to proportionally sample asymptomatic populations at high risk of community spread. Included in this model, assuming a sustained and reliable supply of specimen collection and processing supplies become available, is monthly testing for persons and staff living in nursing facilities and memory care units as well as monthly testing of 10% of the asymptomatic persons who are in groups with a high risk of community spread. The numbers put forth in this model reflect our testing plan, in terms of capacity needs, for the upcoming 90 days. At the time of this plan's submission, we do not feel we have enough epidemiologic information to estimate with moderate certainty our testing needs as flu season arrives. We are hopeful that information obtained from some of the surveillance testing we have planned, along with the information gained from the testing of asymptomatic persons at high risk of community spread, will improve our ability to more accurately model capacity needs beyond the upcoming 90 days. We also recognize that the science around testing is rapidly evolving and that new tests may come on line that will further limit the need for PPE and allow us to rethink our approaches.

Current in-state laboratory capacity to test for COVID-19 is significant. If our federal partners can help assure adequate and ongoing laboratory supply chain needs, including sample preparation, extraction, and reagent, using 13 of the state's labs currently able to process more than 400 samples per day, Washington has the capacity to analyze close to 22,000 specimens daily. These numbers do not include the processing capabilities of the national commercial labs who may be receiving specimens from private business or health care related entities or most of the hospital or clinic based labs also providing

and processing testing in Washington. These 13 labs have the ability to increase their throughput and by working with additional labs who have expressed an interest in expanding their capacity, we can reach the ability to process 44,000 tests per day by August. Many of the labs can further scale up testing capacity with only a few weeks' notice if necessary.

The target of 44,000 reflects an increase in the expected number of contacts an infected person will have as social distancing measures are relaxed over the next three months and accounts for a graded increase in the number of asymptomatic high risk groups who will be added to routine testing efforts over time. This number is based on our need for testing to control community spread and assumes that supply chain issues for both specimen collection kits and test processing supplies will continue to improve. Without the assistance of our Federal partners in assuring that these supply chains remain steady and that states are supported through continued delivery of Federal supplies to augment state purchasing, to include processing extraction kits and reagents, it will not be possible to perform the necessary number of tests.

Most of the labs mentioned above are using high throughput instruments/processes like the TaqPath assay, Cobas 6800/8800, Abbott m2000, Panther Fusion or other lab developed tests. These laboratories have increased their own capacity using existing instrumentation and have added testing capability based on their institution's or business needs. This has led to a diverse set of testing capabilities which will be helpful as supply chain issues may persist for some time. We also anticipate that additional testing capabilities will emerge over the course of the response. We will continue to evaluate the performance characteristics of newly developed lab tests as they become available. While these testing methods/sites may provide additional testing capacity, it is unclear how reliable new test methods are or will prove to be. As such, Washington's testing strategy relies on testing performed by established laboratories running more robust and sensitive/specific tests.

In response to the increased need for testing as a result of outbreaks among agricultural and other essential workers who may be uninsured, the State Public Health Lab has added capacity. There has also been capacity added to a mobile Community Supported Testing site run by the National Guard. In addition, strike teams supported by personnel from the State Department of Health have been deployed to help assist local health jurisdictions in responding to outbreaks. The testing supplies needed for these outbreaks have been provided by the state and the bulk of processing has been performed at the State Public Health Lab. As the size of outbreaks have expanded with the seasonal increase in agricultural workers, some of the specimens are being directed to additional labs. To assure there are not barriers to testing for persons who are uninsured, the state is assuming the costs of providing and processing these tests.

In terms of added testing capability, there are several pharmacies and private businesses that are bringing on point-of-care testing capabilities which has increased access to testing. To date, drive through testing sites have been set up and supported with the help of FEMA, individual cities, counties,

local health jurisdictions, healthcare centers and first responders. As the availability of PPE and specimen collection supplies increase, outpatient health care providers will be able to incorporate testing for COVID-19 into their routine work flows, adding substantially to current access points for testing.

Currently, Washington State is working to develop a strategy for the use of serological testing as a proxy for disease prevalence rather than as a clinical tool given the uncertainty around whether or not the presence of antibodies reflects immunity to future infection. There is current capacity within the State to perform serologic testing as referenced in the table below, however it is unclear how this technology may best be used beyond prevalence surveys at this time.

A key component of Washington's approach to testing is the development of a statewide testing network across laboratories. The network will accept universal requisition forms. The labs will bill patient insurance whenever possible and seek reimbursement from the State when a patient doesn't have insurance or is otherwise ineligible. The State will develop an electronic test ordering portal that will collect all required demographic information to facilitate rapid contact tracing. The labs will be required to report results electronically to the State Department of Health. Each laboratory will provide daily updates on available capacity such that the ordering portal can route samples to labs that can accept samples. This will maximize testing efficiency, minimize sample TAT and reduce specimen backlog. We will hold regular conversations with a variety of institutions involved in sample collection, including healthcare systems, clinics, local health jurisdictions and community-based testing sites, as well as with labs.

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*	434,000	600,000	930,000	1,364,000	1,320,000	1,364,000	1,364,000	1,364,000	8,740,000
Serology	0	0	0	0	0	0	0	0	0
TOTAL	434,000	600,000	930,000	1,364,000	1,320,000	1,364,000	1,364,000	1,364,000	

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**	**Platforms or devices used** (list all)	**Specific at-risk populations targeted** (list all)
Northwest Pathology & Northwest Laboratory	Commercial or private lab		8,000			Nursing homes and long term cart facilities (Patients and staff)
UW Lab Medicine Virology (UW) MOLECULAR	Hospitals or clinical facility		6,000			Nursing homes and long term cart facilities (Patients and staff)
Polyclinic Madison Center 2nd Floor Lab SEROLOGY	Hospitals or clinical facility		0	3,000		Nursing homes and long term cart facilities (Patients and staff)

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**	**Platforms or devices used** (list all)	**Specific at-risk populations targeted** (list all)
UW Lab Medicine Virology (UW) SEROLOGY	Hospitals or clinical facility		0	3,000		Nursing homes and long term cart facilities (Patients and staff)
Altius Institute for biomedical science	Commercial or private lab		1,728			Nursing homes and long term cart facilities (Patients and staff)
Pacific Northwest National Laboratory - already live but wish to be underwater	Other		1,300			Nursing homes and long term cart facilities (Patients and staff)
Molecular Epidemiology Inc	Commercial or private lab		1,000			Nursing homes and long term cart facilities (Patients and staff)
WA PHL	Public health lab		1,000	1,000		Nursing homes and long term cart facilities (Patients and staff)
FIDA lab	Commercial or private lab		700			Nursing homes and long term cart facilities (Patients and staff)

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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**	**Platforms or devices used** (list all)	**Specific at-risk populations targeted** (list all)
Everett Clinic	Hospitals or clinical facility		450			Nursing homes and long term cart facilities (Patients and staff)
The Brotman Baty Institute at the University of Washington (aka, Seattle Flu Study Lab)	Hospitals or clinical facility		600			Nursing homes and long term cart facilities (Patients and staff)
Molecular Testing Labs	Commercial or private lab		500			Nursing homes and long term cart facilities (Patients and staff)
US Biotek Laboratories LLC	Commercial or private lab		500			Nursing homes and long term cart facilities (Patients and staff)

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.

The State of Washington currently has labs with the capacity to assess close to 22,000 specimens per day, if they are kept fully supplied, or 9% of the State's population every month. As we are able to establish a secure and continuing supply chain of specimen collection and test processing materials, and expand testing to asymptomatic persons at high risk of community spread, we plan to increase our testing capacity to 44,000 tests per day by August, ahead of respiratory virus season.

As described in our overarching testing strategy, this expansion will build upon the capabilities of current high throughput labs and their expressed plans to further expand their capacity. A portion of the current capacity has been achieved by redirecting the efforts of our State's Public Health Lab. As of this writing, 80-90% of the work performed within the Lab's Microbiology Office is COVID-19 related. To meet this need, we have curtailed or eliminated many routine functions such as foodborne disease surveillance, flu surveillance, TB and STD testing. Part of our strategy is to leverage the use of additional funds to support and expand the ongoing COVID-19 testing at the Public Health Lab and allow all routine functions to resume. Our plans include the purchase of the Cobas 6800, 2 KingFisher Flex extraction platforms, one Thermo Fisher Q5 Real-Time PCR platform, one Panther Fusion platform and 1 Abbott Alinity serology platform. These platforms will improve labor efficiency and maintain rapid turn around time (TAT). To achieve this increase in capacity for the near term and what is likely to be a need for additional capacity come fall and winter, efficient use of the current laboratory system in Washington State and the creation of a laboratory network, will be needed.

To support an increase in efficiency, funds will also be used to improve or replace the Public Health Lab's LIMS system. Because there is not at present a state-wide laboratory network, we recognize the need to develop an infrastructure that will allow a real-time look at lab capacity across the network. This will assure samples can be routed to labs that have current capacity and not overwhelm them or slow down their TAT. We also plan to provide real time information that allows persons submitting specimens a view of a lab's current supplies of testing and processing materials to assure that capacity exists to meet their needs. As of this writing the Washington Department of Health has developed a contract with three of the largest COVID-19 testing labs in Washington to perform testing as a start to this network.

Additional labs will be added to reach the 44,000 test per day threshold. All labs participating in the network are required by contract to report results electronically to State and local stakeholders. We have already developed an electronic test ordering portal that is used by public health lab submitters. We plan to expand and enhance this portal for use by all network labs. The portal will be enhanced to capture information necessary to facilitate insurance billing, contact tracing and support QR code generation. In this way, each requisition printed from the portal will have all data elements coded for easy upload into the receiving lab's LIMS. The system will have an interface for network labs to update

their testing capacity on a daily basis. This will allow the system to route samples to labs with capacity. We expect that this system will ensure specimens are submitted and tested in an efficient manner. Submitters will only need to interface with one portal and by using a universal requisition form, specimens can be re-routed without the need for additional paperwork. The State will also establish a courier to pick up and deliver specimens as appropriate. Finally, the Washington Department of Health has developed a contract with a local VTM producer to help support the State's testing goals. Efforts to purchase sufficient swabs fit for clinical testing are ongoing. These collection kit materials are provided at no charge to local health jurisdictions and support the overall testing goals of the State.

Critical to achieving the capacity needed to effectively control the outbreak will be our ability to do two things. The first is to increase demand for the tests. We plan to work with our medical associations and our media partners to help encourage people with mild or any symptoms consistent with COVID-19 to seek testing. Due to supply limitations, we have previously recommended testing be prioritized for persons with moderate or severe symptoms or persons associated with an outbreak. As we are able to expand testing to persons with mild symptoms and begin routine surveillance of nursing facilities and memory care units, we will see demand increase. The second critical requirement will be to maintain an adequate supply of specimen collection and processing materials. As a state, we have been working to procure specimen collection supplies. As everyone in the world is competing for the same resources, we have been challenged in obtaining adequate supplies. In addition to shortages and delays, we have received large numbers of swabs and viral transport media that have failed quality control checks, some from international but also U.S. companies. This has led to our inability to adequately provide tests to all those who request them. More recently we have heard from a number of labs that they are unable to obtain the extraction kits and reagents they need to process specimens. While our Federal partners have helped to address our specimen collection needs in the last month, we are concerned that unless their plans to support states in procuring adequate swabs and VTM continue beyond June, we will not be able to keep up with our testing goals or have any chance of meeting surge needs come fall. We would also like to request assistance with processing supplies. We can collect all of the tests we have available, but if the labs are unable to process them in a very timely manner, we will miss our opportunity to effectively control community spread. We respectfully request our Federal partners' assistance in assuring state are able to maintain adequate supplies of specimen collection and laboratory processing materials.

Vulnerable populations are part of our third tier of testing after persons with symptoms and their contacts. Our plans include rapidly scaling physical access to testing and the development of culturally tailored and community-specific information about molecular testing for those in congregate settings with one or more active cases, such as nursing homes, assisted living, adult family homes, low-income housing/high risk housing, correctional settings, homeless shelters, farm worker housing, and worksites like meat-packing plants. To assure adequate testing and surveillance of our long term care facilities, the Secretary of Health issued a directive to test all residents and staff in nursing facilities by June 12, 2020. Testing in memory care units will be prioritized for asymptomatic testing subsequent to that. By the end of July, residents and staff of all Washington Department of Social and Health Services (DSHS) owned, operated or contracted facilities will be tested. Systems will be set up to implement and continue testing

the staff of these facilities at appropriate intervals. In response to an outbreak in a nursing facility or congregate setting, repeat testing will be based on the epidemiology of the outbreak and determined by local health officials. The state testing program includes staff whose focus is on equity. Dashboards are being developed that will reflect the rates of testing across the state. This dashboard will overlay variables associated with the social determinants of health to assure groups that may be under-represented in terms of access to testing are identified. The equity support team will also work with our tribal partners and the local health jurisdictions to help support their community outreach efforts to vulnerable and disproportionately affected populations, including efforts to address language barriers. We will work with our partners to help provide access points for testing that are low barrier and culturally appropriate to these less served communities. We will also look at how home testing can be used to support persons who are not able or who should not travel.

The state is continuing to look for ways to support local health jurisdictions and tribal nations to expand testing sites. Several local health jurisdictions have developed drive through testing sites with health care providers in their communities and some of the larger cities, Seattle and Tacoma, have developed drive through testing sites as part of public/private partnerships. Companies like Walmart, CVS and Bartell's have reached out to partner in these efforts and have been directed to the local health jurisdictions to determine how best to support their communities in terms of locating collection sites that are most accessible to the local population. The Department of Health will also continue to procure specimen collection kits to ensure local health jurisdictions are able to respond to outbreaks and to act as a backup source of supplies for health care systems and providers.

Currently, Washington State has not included the use serological testing as part of its testing strategy. There is some capacity within the State to perform these tests as referenced in the table below, however it is unclear how this technology may best be used at this point beyond prevalence surveys. To assure vulnerable populations are represented in these surveys they will be oversampled.

In terms of sentinel surveillance, the State of Washington will work with academic and philanthropic partners to conduct a statewide surveillance study with plans to oversample traditionally under represented populations. Ongoing surveillance will occur through the current statewide system in place. Results of molecular testing obtained from the Greater Seattle Coranavirus Assessment Network (SCAN), an outgrowth of the Seattle Flu Study, are and will continue to be used to develop a better understanding of disease transmission and manifestations as part of our surveillance efforts.

The Washington Department of Health has no current limitations regarding hiring of staff or purchasing of equipment in support of the COVID-19 response. All HR and procurement processes have been streamlined as the result of the activation of our State's Incident Response Framework. Our plan for hiring staff will be to simultaneously recruit for management positions and bench staff. We will shift current staffing to a 24 hour operation to accommodate additional staff and maintain appropriate social

distancing. Procurement of equipment and supplies will continue to occur through established relationships with vendors.

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	58	0	0	0	0	0	0	0	58
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)	4	0	1	0	0	0	0	0	5
Volume of additional swabs needed to meet planned testing levels++	150,000	150,000	660,000	660,000	660,000	660,000	660,000	660,000	4,260,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet	250,000	250,000	660,000	660,000	660,000	660,000	660,000	660,000	4,460,000

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
planned testing levels++									
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	TaqPath; 10700/day, Cobas; 6800/day, Unknown LDT; 3628/day, Abbott m2000; 450/day	TaqPath; 9900/day, Cobas; 7800/day, Unknown LDT; 3628/day, Abbott m2000; 450/day	TaqPath; 9900/day, Cobas; 7800/day, Unknown LDT; 3628/day, Abbott m2000; 450/day	TaqPath; 9900/day, Cobas; 7800/day, Unknown LDT; 3628/day, Abbott m2000; 450/day	TaqPath; 9900/day, Cobas; 7800/day, Unknown LDT; 3628/day, Abbott m2000; 450/day	TaqPath; 9900/day, Cobas; 7800/day, Unknown LDT; 3628/day, Abbott m2000; 450/day	TaqPath; 9900/day, Cobas; 7800/day, Unknown LDT; 3628/day, Abbott m2000; 450/day	TaqPath; 9900/day, Cobas; 7800/day, Unknown LDT; 3628/day, Abbott m2000; 450/day	
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	0	1 Alinity	0	0	0	0	0	0	0

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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)	Abbott; 3000/day, Unknown LDT; 3000/day	Abbott; 4000/day, Unknown LDT; 3000/day	Abbott; 4000/day, Unknown LDT; 3000/day	Abbott; 4000/day, Unknown LDT; 3000/day	Abbott; 4000/day, Unknown LDT; 3000/day	Abbott; 4000/day, Unknown LDT; 3000/day	Abbott; 4000/day, Unknown LDT; 3000/day	Abbott; 4000/day, Unknown LDT; 3000/day	

* 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.