

ELC ENHANCING DETECTION: MONTANA TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Montana
Population Size:	1,000,000

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

The state of Montana has developed a COVID-19 Testing Plan designed to expand current testing capacity beyond symptomatic individuals. Identifying COVID infections as early as possible will allow for public health contact tracing and implementation of interventions to prevent and respond to outbreaks. The expansion of testing in asymptomatic, at-risk populations such as long-term care and clinical settings serving underserved populations, include our tribes, is a component of state and national strategies to better detect and understand transmission of the virus responsible for COVID-19. Sentinel testing may allow us to detect and respond to the transmission of the virus in high-risk settings at an earlier stage and improve containment efforts. In addition to providing useful information in key populations and helping guide response efforts, surveillance testing may help us assess our efforts to protect essential and frontline workers who interface with others in the community who may be at a higher risk for exposure.

Montana has established priority COVID testing areas, categorized in five tiers: 1) symptomatic individuals, 2) long-term care and assisted living facilities, 3) tribal populations, 4) community testing, and 5) correctional institutions, mental health facilities, treatment centers and facilities for those with developmental needs. There are 15 Abbott ID Now instruments place around the state to aid in point of care testing. The MPHL and PHEP programs are working closely together to distribute the necessary supplies for the ID Now's. Also, 5 of the Abbott ID Now's are "mobile". They are moved to hot spots around the state as deemed necessary by the Governors Coronavirus task force. MPHL is utilizing multiple COVID-19 extraction and testing platforms in order to increase testing capacity and reduce reliance on any single supplier. The MPHL currently utilizes 1 Magnapure LC, 2 EasyMags, 1 EMag, 2 KingFisher extraction systems to prepare patient specimens for PCR testing and use the CDC 2019-nCoV Real Time PCR diagnostic Panel and the ThermoFisher TaqPath COVID-19 Combo test kits both of which can be analyzed on 7 available ABI Real Time PCR instruments to increase throughput. Additional PCR systems are also available. The lab has also implemented the Hologic Aptima SARS CoV-2 Panel which increased our testing capacity and throughput and allowed additional laboratory scientists to perform testing due to its onboard automation. Furthermore, a DiaSorin XL Immunoassy analyzer is being implemented for high-throughput COVID-19 serological studies. This is a chemiluminescent assay system and is EUA approved and is consistent with the most recent sensitivity and specificity CDC guidelines for COVID-19 serological assays. The MPHL anticipates completing validation during the first two weeks of July 2020. The viral and serological testing methods will be used to enhance the detection and prevalence of COVID-19 in Montana.

The Communicable Disease Epidemiology Section (CDEpi) at the State of Montana is working with a variety of partners in coordination with the Governor's Coronavirus Task Force. Montana signed a

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contract with Quest Diagnostics to provide testing supplies, transportation of inoculated tests from Montana to the Quest lab in Kansas, perform the SARS-CoV-2 PCR tests, and supply test results. The state of Montana is also partnering with the Montana Primary Care Association, which has a network of community health centers across the state, to provide testing to assisted living facilities and communities (including drive-thru testing events). CDEpi is working closely with each tribal jurisdiction in the state to roll out large, multi-day testing events at every tribe in the state. Montana is also working with the Montana Hospital Association and Montana Dental Association to develop testing capacity in every community in the state. CDEpi is coordinating testing at long-term care facilities and some assisted living facilities, as well as correctional institutions, mental health facilities, treatment centers and facilities for those with developmental needs.

CDEpi is hiring a COVID-19 epidemiologist to coordinate our sentinel surveillance testing, assist counties with case and outbreak investigations, and work with the Governor's Coronavirus Task Force to promote and develop community mitigation practices, such as the Governor's stay at home directive, the Montana University Systems #maskupMT campaign, and working with schools and business to promote practices that reduce transmission among employees and the public to maintain a healthy work environment.

To automate and improve our communication with our partners, healthcare facilities and laboratory information systems (LIMS) Montana is going to hire a dedicated CDEpi/Lab Systems Integration manager. This employee will focus on updating our NEDSS Base System (NBS) to receive and manage electronic lab reports within our NBS and train local health jurisdiction users how to manage these feeds. Data management of the test results from our sentinel surveillance project is also a major task, requiring a SAS programmer to download, merge, sort, and export lab results that can be shared with facilities. Additionally, the LIMS system manager will support additional interface development with our clinical partners. This interface development allows for Electronic Test Ordering and Reporting (ETOR), which would eliminate the need for manual processes in order to capture patient information and test requests in our LIMS. ETOR should improve accuracy by eliminating manual entry errors, improve timeliness by reporting directly back to the submitting facility's LIMS, and improve overall efficiency.

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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*	60,000	60,000	60,000	60,000	60,000	60,000	60,000	60,000	480,000
Serology			5,000	5,000	5,000	5,000	5,000	5,000	30,000
TOTAL	60,000	60,000	65,000	65,000	65,000	65,000	65,000	65,000	

*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)
MTPHL	Public health lab		1,000		Montana has established priority COVID testing areas, categorized in 5 tiers 1) symptomatic individuals, 2) long-term care and assisted living facilities, 3) tribal populations, 4) community testing, and 5) correctional institutions, mental health facilities, treatment centers and facilities for those with developmental needs
MTPHL	Public health lab			167	Testign offered to patients receiving a COVID-19 PCR screen.

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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)
Quest Lab	Commercial or private lab		1,000		2) long-term care and assisted living facilities, 3) tribal populations, 4) community testing, and 5) correctional institutions, mental health facilities, treatment centers and facilities for those with developmental needs
Bozeman Health	Hospitals or clinical facility		100		1) symptomatic individuals within region 4
Billings Clinic	Hospitals or clinical facility		100		1) symptomatic individuals within region 3 & 1
Kalispell Regional Medical Center	Hospitals or clinical facility		100		1) symptomatic individuals within region 5

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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.

In an effort to expand testing capacity throughout Montana, the MPHL surveyed clinical laboratories throughout the State to understand their testing capabilities, needs, constraints and desires to increase their COVID-19 testing abilities. This information was used to work with laboratory partners throughout the state. In this survey we requested an instrumentation listing. From that listing we were able to assess each laboratory's ability to perform COVID-19 PCR testing. MPHL is finalizing contracts with 3 Montana Clinical Laboratory partners to perform symptomatic COVID-19 PCR testing within their region of the state. MPHL is actively working on contracting with 2 additional Montana Clinical Laboratory partners to develop or increase COVID-19 testing capacity outside of the public health laboratory for each of the remaining regions. Grant funding will be utilized to support these regional laboratories with laboratory staffing, training, testing platforms, service contracts as well as testing kits and supplies.

The Montana Department of Health, MPHL and CDEpi have contracted with out of state commercial and private laboratories to complement testing performed at the MPHL and other Montana clinical laboratories to further enhance detection and testing capacity for Montana. At this time contracts have been completed with both Quest and National Jewish Health clinical laboratories. Additional testing has been initiated at both Quest and National Jewish Health.

The state of Montana is currently in the process of ramping up testing capacity that includes asymptomatic individuals who fall into various demographic/risk categories as well as continued testing of symptomatic individuals. In July, the MPHL will begin offering COVID-19 antibody testing on all symptomatic and asymptomatic individuals being tested for COVID-19 virus. The data collected will be able to be correlated with presence or absence of COVID-19 virus and into the various risk categories being used for asymptomatic surveillance testing. In this manner, the state hopes to gain valuable information regarding the generation of the antibody response in COVID-19 positive individuals and the prevalence of COVID-19 IgG and IgM in high and low risk asymptomatic populations.

CDEpi has contacted every long-term care facility (n=71) and assisted living facility (n=211) in the state to offer testing to every resident and staff member of these facilities (estimated at nearly 20,000 individuals, 2% of MT population). Some facilities have decided not to participate, but every long-term care facility that wanted to participate has already completed their testing by the end of June. We have tested 7170 staff and residents at assisted living and long-term care facilities. 67/73 (92%) of all LTCF are participating in surveillance testing, 64/67 (96%) have completed their testing. 177/216 (82) ALF are testing or have participated in surveillance testing. Due to an outbreak in a Nursing Home that initially refused testing, Governor Steve Bullock has now ordered all assisted living and nursing home facilities in the state to test all employees and residents before allowing any visitors. This testing is expected to be completed by the end of July 2020. The Public Health Emergency Preparedness (PHEP) program and

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MPHL is leading the procurement of specimen collection supplies, including test kits supplied by Quest, and PHEP is assisting assembly of testing supplies under the direction of the MPHL and other partners. Supplies include viral transport media, sterile tubes and nasopharyngeal swabs used for collection and transport of specimens from clinical laboratories to MPHL for COVID-19 PCR testing necessary for the project. Necessary supplies are being delivered through mail or direct transfer to participating sites, sometimes in coordination with the laboratory courier service and the Montana National Guard.

State public health staff, contractors and partners, working with the Governor's Coronavirus Task Force, have been working to coordinate with tribal health authorities and partners in the Indian Health Service (IHS) to identify key facilities in tribal areas and devise sampling protocols. The goal is to establish a long-term testing approach that can support up to 16,000 tests per month from sources serving tribal members. To date, approximately 12,500 tribal sentinel surveillance tests have been performed, with testing events occurring at every single tribal jurisdiction in the state.

State public health staff, contractors and partners, working with the Governor's Coronavirus Task Force, will also work to coordinate with the DPHHS facilities and the Department of Corrections (DOC) to devise sampling protocols and targets for the testing of residents and staff at State Institutions. The goal is to establish a long-term testing approach that can support up to 1,000 tests per month among staff and residents in approximately 15 congregate settings. Asymptomatic residents and staff will be offered testing. Basic demographics on each individual and their history of COVID-19 symptoms and any underlying medical conditions of interest will be collected.

To overcome barriers to testing, MPHL has expanded our same-day-courier service, added new staff for CDEpi and MPHL, partnered with other laboratories (clinical labs within Montana and commercial laboratories outside of Montana) and worked with FEMA and the Governors Coronavirus Task Force to obtain necessary collection and testing supplies. Montana is the fourth largest state with diverse topography. Mail delivery service of specimens in Montana can range from 2-7 days. The 7-day same-day-delivery courier service for MPHL provides the daily pick-up of laboratory specimens from over 40 locations throughout the state, resulting in improved turn-around time. MPHL also seeks to renovate our current space. MPHL has been occupying the same area for nearly 20 years and has serious space constraints that limits front end processing of COVID-19 specimens. MPHL renovations and construction will include additional laboratory space and infrastructure needs such as BSL2 work areas, benches and biological hoods to support current and future increases in testing capacity and additional instrumentation.

As stated previously, the MPHL has contracted with 3 Montana clinical laboratory partners and is actively working on contracting with 2 additional Montana Clinical Laboratory partners to develop or increase COVID-19 testing capacity outside of the public health laboratory. MPHL has contracted with National Jewish Health and CDEpi has contracted with out of state commercial laboratories to complement testing performed at the MPHL and throughout Montana. The Montana Governors coronavirus task force has established a close working relationship with FEMA and have aided in MPHL

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gaining access to much needed collection and testing supplies. With the help of PHEP, our courier system and the Montana National Guard, MPHL has been able to distribute COVID collection supplies to our healthcare facilities throughout Montana. Governor Steve Bullock has declared a state of emergency in Montana. This has allowed the Montana Health Department to quickly and efficiently hire new staff, procure new laboratory instrumentation, reagents, testing kits, consumables and all other necessary COVID-19 supplies. Governor Bullock has also assembled a coronavirus taskforce. The administrator of the Montana DPHHS Public Health and Safety Division (PHSD) is a member of this task force. PHSD is the division, within Montana DPHHS, that oversees the Laboratory Services Bureau and the Communicable Disease Bureau. Having the PHSD administrator on the task force allows for streamlined communication and approvals directly with Governor Bullock. CDEpi has hired two temporary workers to assist with the logistics and coordination of the testing at tribes and long-term care facilities. In addition to the COVID Epidemiologist being hired, we are working with CDC Foundation to hire 3 infection control specialists and a contact tracer for the state, and plan to transition these positions to funding through ELC after contracts with CDC Foundation end in March 2021. Contact tracing is performed by the local health jurisdictions who have already identified over 350 staff to assist in contact tracing across the state. Using ELC enhancement and infection prevention funding, the state contact tracer will provide training and coordination to the county contact tracing teams, already in place around the state. The infection control staff will be organized by CDEpi's Healthcare Associated Infections Epidemiologist to visit each nursing home in the state to assess and improve infection control practices. MPHL is in the process of hiring 4 clinical laboratory scientists (CLS) and 4 temporary administrative staff. The CLS's will cross train with existing clinical laboratory scientists to perform COVID-19 testing, as well as aid in the implementation and validation of the serological antibody testing that will begin in July 2020. The temporary administrative staff are to perform data entry associated with the increased laboratory testing and reporting required during the pandemic response effort. Additionally, The Montana National Guard has begun accessioning and sorting all symptomatic and asymptomatic specimens received.

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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	6	2		6					14
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)	King Fisher; 2 ABI 7500's; Emag (Issued PO. No Instrument yet); MagnaPure 96 (Issued PO. No Instrument yet); Hologic Fusion (Issued PO. No								0

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
	Instrument yet)								
Volume of additional swabs needed to meet planned testing levels ⁺⁺	5,000	20,000	20,000	20,000	20,000	20,000	20,000	20,000	145,000
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	5,000	20,000	20,000	20,000	20,000	20,000	20,000	20,000	145,000

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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)		10,000 tests - TaqPath COVID-19 Combo Kits; 30,000 tests - Aptima SARS-CoV-2 Assay; 5,000 tests to perform BioMerieux EasyMag and Emag extraction supplies; 5,000 tests to perform Roche Magna Pure LC extraction supplies	10,000 tests - TaqPath COVID-19 Combo Kits; 30,000 tests - Aptima SARS-CoV-2 Assay; 5,000 tests to perform BioMerieux EasyMag and Emag extraction supplies; 5,000 tests to perform Roche Magna Pure LC extraction supplies	10,000 tests - TaqPath COVID-19 Combo Kits; 30,000 tests - Aptima SARS-CoV-2 Assay; 5,000 tests to perform BioMerieux EasyMag and Emag extraction supplies; 5,000 tests to perform Roche Magna Pure LC extraction supplies	10,000 tests - TaqPath COVID-19 Combo Kits; 30,000 tests - Aptima SARS-CoV-2 Assay; 5,000 tests to perform BioMerieux EasyMag and Emag extraction supplies; 5,000 tests to perform Roche Magna Pure LC extraction supplies	10,000 tests - TaqPath COVID-19 Combo Kits; 30,000 tests - Aptima SARS-CoV-2 Assay; 5,000 tests to perform BioMerieux EasyMag and Emag extraction supplies; 5,000 tests to perform Roche Magna Pure LC extraction supplies	10,000 tests - TaqPath COVID-19 Combo Kits; 30,000 tests - Aptima SARS-CoV-2 Assay; 5,000 tests to perform BioMerieux EasyMag and Emag extraction supplies; 5,000 tests to perform Roche Magna Pure LC extraction supplies	10,000 tests - TaqPath COVID-19 Combo Kits; 30,000 tests - Aptima SARS-CoV-2 Assay; 5,000 tests to perform BioMerieux EasyMag and Emag extraction supplies; 5,000 tests to perform Roche Magna Pure LC extraction supplies	
FOR SEROLOGIC TESTING									
Number of additional* equipment		DiaSorin Liaison XL	2 ABI 7500x Real Time	1 BioMerieux Emag, 1					0

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
and devices to meet planned testing levels			PCR instruments	Roche Magna Pure 96					
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)		30,000 tests - Liaison SARS-CoV-2 S1/S2 IgG; 30,000 Serum Tubes							

* 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.