2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	South Dakota
Population Size:	885000

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

(a) SDPHL performs the 2019-nCoV RT-PCR test designed to detect the SARS-CoV-2 virus from respiratory specimens such as nasopharyngeal (NP), oropharyngeal (OP), and sputum specimens. SDPHL performs nucleic acid extraction on three Roche LC2.0 extractors, three Qiagen EZ-1 Advanced, and one Kingfisher instruments. SDPHL performs real-time reverse transcriptase polymerase chain reaction (RT-PCR) on three Thermo Fisher ABI 7500 Fast DX and two QuantStudio instruments. SDPHL will add one additional Kingfisher and one Thermo Fisher ABI 7500 Fast DX to the state COVID-19 testing infrastructure. The current RT-PCR infrastructure at SDPHL can perform over 300 specimens in a conventional workday. Proposed RT-PCR infrastructure expansion will increase that throughput to almost 500 specimens each day. SDPHL also performs SARS-CoV-2 testing on the Cepheid GeneXpert which can test approximately 128 specimens each day, as well as the Hologic Panther, a high-throughput platform capable of testing as many as 1000 specimens each day. Clinical reference laboratories with the Avera and Sanford healthcare systems currently perform SARS-CoV-2 testing at facilities in Sioux Falls, South Dakota. These tests include a laboratory developed medium-throughput RT-PCR test performed by the Avera Institute for Human Genetics (AIHG) on an Applied Biosystems Quant Studio 7 Flex instrument capable of testing approximately 300 specimens each day, and a commercially available high-throughput test at Sanford Health performed on the Abbott m2000 instrument capable of testing approximately 500 specimens each day. Sanford, Avera, and Monument healthcare systems also perform SARS-CoV-2 testing on the low-throughput Cepheid GeneXpert line of instruments. Additionally, Sanford and Avera reference laboratories in Sioux Falls perform low to medium throughput SARS-CoV-2 testing on the Diasorin Liaison line of instruments. In support of rural and at-risk communities in South Dakota, SDDOH placed fifteen Abbott ID Now instruments throughout the state to improve access to SARS-CoV-2 testing. Communities that received ID Now instruments and test kits from SDDOH include Pierre, Mobridge, Watertown, Redfield, Huron, Sioux Falls, Yankton, Springfield, Martin, Hot Springs, Rapid City, and Spearfish. Indian Health Services (IHS) also deployed eleven Abbott ID Now instruments to nine locations in South Dakota; communities that received IHS ID Now instruments and test kits include Sisseton, Flandreau, Wagner, Fort Thompson, Lower Brule, Rosebud, Pine Ridge, Rapid City, and Eagle Butte. SDPHL continues to support diversification of SARS-CoV-2 testing capabilities in South Dakota. SDPHL is currently working with Avera Health and Physicians Laboratory in Sioux Falls, SD to implement SARS-CoV-2 testing on two high-throughput Hologic Panther instruments. SDPHL is also advocating with the manufacturer Cepheid for improved allocation of Xpert Xpress SARS-CoV-2 tests for South Dakota; there are 58 idle GeneXpert instruments throughout South Dakota, many of which are located in rural communities and communities that serve American Indians from South Dakota's nine Sioux Nations. Also, in support of at-risk and vulnerable populations, SDPHL readied its Mobile Laboratory for deployment in South Dakota. SDPHL is prepared to deploy its Mobile Laboratory with Abbott ID Now, Cepheid GeneXpert, and/or Biofire FilmArray instruments to provide rapid testing services for communities that do not have traditional laboratory infrastructure for the detection of SARS-CoV-2 or have at-risk populations that may be disproportionately impacted by COVID-

19. SDDOH has also facilitated connections with the commercial laboratories Quest and LabCorp. Commercial laboratory partners will provide SARS-CoV-2 testing capability during times of testing surge such as targeted and mass testing events. Finally, SDPHL is evaluating the role of antigen testing as a point-of-care alternative to molecular diagnostic testing. South Dakota has many communities that lack the sophisticated infrastructure and budget needed to support platforms from Cepheid, Biofire, or Hologic. The Quidel antigen test is a reasonable alternative that will provide rural and frontier communities immediate access to SARS-CoV-2 testing. (b) South Dakota is a state with predominantly rural, isolated communities that lack retail and medical infrastructure common to larger cities. In support of rural communities in South Dakota, resources such as the Abbott ID Now have been placed in healthcare facilities in communities geographically isolated from larger cities that possess the vast majority of South Dakota's medical and public health infrastructure. In support of SARS-CoV-2 testing, SDDOH advocates for non-traditional approaches to specimen collection such as the alternative specimen collection sites in Rapid City, Huron, Pierre, and Sioux Falls. SDDOH also supports the use of mobile laboratories operated by Sanford Health and the South Dakota Public Health Laboratory to reach rural and at-risk communities including those communities with vulnerable populations such as individuals with advanced age and American Indians. SDDOH also supports mass collection events such as the collection event conducted in Sioux Falls, SD in support of employees of the Smithfield meatpacking plant, and continues to facilitate linkages between South Dakota's critical infrastructure industries and local healthcare providers to assure access to SARS-CoV-2 testing. Looking forward, SDDOH is investigating the use of the Quidel Sofia 2 analyzer and SARS Antigen test in rural communities that do not have access to more sophisticated diagnostic testing platforms such as the Cepheid GeneXpert, Abbott m2000, Hologic Panther, or RT-PCR capabilities. SDDOH is also evaluating opportunities to place lateral flow serological tests in rural clinics and hospitals. (c) SDDOH maintains close communication with healthcare partners in South Dakota that provide serological testing for COVID-19. Avera and Monument healthcare systems in South Dakota currently use Mayo Clinic Laboratories COVID-19 serological testing services; Mayo currently uses the Epitope antibody test. Sanford and Avera Health are investigating use of the Diasorin antibody test while the SDPHL is investigating Abbott, Chembio, and bioMerieux tests. SDDOH has advised all healthcare systems in South Dakota to approach antibody testing with caution due to the many unanswered questions regarding development of protective immunity to SARS-CoV-2 infections and the possibility for reinfection. SDDOH strongly recommends to all clinical partners that an antibody test for previous SARS-CoV-2 always be considered in the full clinical context for every patient including diagnostic test result(s). SDDOH continues to work with healthcare and public health partners to investigate the responsible use of COVID-19 serological testing. The SDDOH serology testing strategy will develop as more information about SARS-CoV-2 antibody response and immunity become available. (d) In partnership with the CDC and APHL, SDPHL constructed a public health laboratory network that includes South Dakota's five major healthcare systems (Sanford, Avera, Monument, Veteran's Affairs, and Indian Health Services) and numerous independent healthcare facilities and providers. SDDOH maintains constant communication with diverse facilities and provider groups throughout South Dakota to ensure alignment among the healthcare teams. SDDOH communicates to these groups using Health Alert Network (HAN) and a diverse group of Listservs. SDDOH also provides weekly outreach using teleconferences and webinars with the following groups: healthcare system leadership and staff, tribal leadership, Indian Health Services (IHS) leadership, long-term care leadership and staff, infection prevention staff, and laboratory leadership and staff. SDDOH uses teleconferences and webinars to

inform and align healthcare partners to jurisdictional COVID-19 goals such as diversification of laboratory testing capabilities, expansion of testing capacity, and improved access to testing for all South Dakotans. In addition to these efforts, the SDPHL facilitates almost daily communication with laboratory leaders across South Dakota to assess specimen collection and testing needs, supply inventory, staffing, and plans for implementation of new SARS-CoV-2 testing platforms including antibody and antigen testing. This information has been used to direct COVID-19 resources and effort.

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*	35,280	44,100							79,380
Serology	4,410	8,820							13,230
TOTAL	39,690	52,920	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 through- put	Daily serologic through- put	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
South Dakota Public Health Laboratory - Pierre, SD	Public health lab		1,445	300		SDPHL supports testing for long-term care residents and other individuals in congregate care settings, Native American populations associated with South Dakota's nine Sioux Nations, rural communities with reduced access to healthcare services, underinsured and uninsured populations, homeless individuals or individuals that recently experienced homelessness, and critical infrastructure in South Dakota.

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)
Sanford Health System - South Dakota	Hospitals or clinical facility		1,648	300		The Sanford Health system supports testing for long-term care residents and other individuals in congregate care settings, Native American populations associated with South Dakota's nine Sioux Nations, and rural communities with reduced access to healthcare services.
Avera Health System - South Dakota	Hospitals or clinical facility		864	300		The Avera system supports testing for long-term care residents and other individuals in congregate care settings, Native American populations associated with South Dakota's nine Sioux Nations, rural communities with reduced access to healthcare services, and critical infrastructure workers in South Dakota.

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)
Avera Institute for Human Genetics - Sioux Falls, SD	Hospitals or clinical facility		253	0		Avera AIHG supports the Avera system mission including at-risk populations described immediately above.
Monument Health - Rapid City, SD	Hospitals or clinical facility		28	0		Monument Health - Rapid City supports testing for long-term care residents and other individuals in congregate care settings, Native American populations associated with South Dakota's nine Sioux Nations, and rural communities with reduced access to healthcare services.
Monument Health - Spearfish, SD	Hospitals or clinical facility		24	0		Provides healthcare services to the Lawrence County area; hospital with no known testing capability on-site; instrument placement will improve testing capability west-river
Community Health Center of the Black Hills - Rapid City, SD	Federally Qualified Health Center		24	0		Provides critical healthcare services for vulnerable populations in the Pennington County area; instrument placement will improve testing capability west-river

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)
Fall River Hospital - Hot Springs, SD	Hospitals or clinical facility		24	0		Provides healthcare services for vulnerable populations in the Sioux Falls/Minnehaha County area including low-income populations; instrument placement will improve testing capability in southeast South Dakota
Bennett County Hospital - Martin, South Dakota	Hospitals or clinical facility		24	0		Provides healthcare to the Bennett County area including vulnerable populations from Pine Ridge and Rosebud reservations; instrument placement will improve testing capability west-river
Mobridge Hospital - Mobridge, SD	Hospitals or clinical facility		24	0		Provides healthcare services to the Walworth County area; independent hospital with no COVID-19 testing capability; instrument placement will provide testing capability in northcentral South Dakota
South Dakota Human Services Center - Yankton, SD	Hospitals or clinical facility		24	0		Provides critical healthcare services for vulnerable populations in the Yankton County area; instrument placement will improve testing capability in southeast South Dakota

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)
Falls Community Health - Sioux Falls, SD	Federally Qualified Health Center		48	0		Provides healthcare services for vulnerable populations in the Sioux Falls/Minnehaha County area including low-income populations; instrument placement will improve testing capability in southeast South Dakota
Huron Regional Medical Center - Huron, SD	Hospitals or clinical facility		48	0		Provides healthcare services for the Beadle County area; independent hospital with no COVID-19 testing capability; previous COVID-19 hotspot; instrument placement will improve testing capability in east central South Dakota
Community Memorial Hospital - Redfield, SD	Hospitals or clinical facility		24	0		Provides healthcare services in the Spink County area; provides healthcare services to South Dakota Development Center; independent hospital with no testing capability on-site; instrument placement will improve testing capability in northeast South Dakota

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)
Prairie Lakes Hospital - Watertown, SD	Hospitals or clinical facility		24	0		Provides healthcare services to the Codington County area; independent hospital with no COVID-19 testing capability; instrument placement will improve testing capability in northeast South Dakota
Cheyenne Rive Health Center - Eagle Butte, SD	Hospitals or clinical facility		24	0		Indian Health Services; serves Cheyenne River Sioux Tribe
Rosebud Indian Health Service Hospital - Rosebud, SD	Hospitals or clinical facility		24	0		Indian Health Services; serves Rosebud Sioux Tribe
Pine Ridge Hospital	Hospitals or clinical facility		48	0		Serves Oglala Sioux Tribe
Lower Brule Indian Health Service Unit	Hospitals or clinical facility		24	0		Indian Health Services; serves Lower Brule Sioux Tribe
Wagner Indian Health Service Unit	Hospitals or clinical facility		24	0		Indian Health Services; serves Yankton Sioux Tribe

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)
Fort Thompson Indian Health Service Unit	Hospitals or clinical facility		24	0		Indian Health Services; serves Crow Creek Sioux Tribe
Sisseton Indian Health Service Unit	Hospitals or clinical facility		24	0		Indian Health Services; serves Sisseton Wahpeton Oyate Tribe
Flandreau Health Center	Hospitals or clinical facility		24	0		Serves Flandreau Santee Sioux Tribe
Oyaate Health Center	Hospitals or clinical facility		24	0		Serves tribale members in the Rapid City, SD area
Veteran's Affairs Medical Center - Sioux Falls, SD	Hospitals or clinical facility		20	0		Provides health care to US military including aging population of veterans with significant comorbidities
Veteran's Affairs Medical Center - Fort Meade, SD	Commercial or private lab		20	0		Provides health care to US military including aging population of veterans with significant comorbidities

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.

(a) Since the beginning of the COVID-19 event, SDDOH has been an advocate for diversification of testing platforms to detect SARS-CoV-2 from respiratory specimens. SDDOH has directly assisted two of South Dakota's largest healthcare systems (Sanford Health and Avera) with SARS-CoV-2 RT-PCR test development and validation. SDDOH has also be a strong advocate for expansion of SARS-CoV-2 testing capacity through placement of laboratory equipment and supplies throughout South Dakota. SDDOH has achieved these goals through strategic use of state and federal funds, advocacy for clinical and public health testing needs with federal partners, and direct support of clinical partners with testing equipment and supplies. Looking forward, SDPHL will continue to assist healthcare partners acquire critical instrumentation such as high-throughput instruments for Sanford Health (Abbott m2000) and a Monument Health (Hologic Panther). SDDOH will also continue to support clinical partners with Abbott ID Now test kits (locations described above and in Table #2), and as many as 36 locations with Quidel Sofia 2 analyzers and COVID antigen tests. SDDOH will also assist clinical partners as new tests, platforms, and technologies become available such as the Biofire FilmArray RP2.1 capable of providing syndromic testing for respiratory illnesses including COVID-19. SDDOH will pair test equipment and supplies with the capabilities of South Dakota clinical laboratories, and will broaden access to SARS-CoV-2 testing for many South Dakota communities, including at-risk communities and vulnerable populations on South Dakota's nine tribal reservations. (b) South Dakota is the home 268 long-term care facilities with almost 25,000 residents and staff and nine Sioux Nations that comprise almost 9% of South Dakota's population; elderly citizens and members of the South Dakota Sioux Nations are two of South Dakota's most vulnerable populations. Additionally, SDDOH recognizes the important role of first responders, military, healthcare, and critical infrastructure workers in South Dakota. These populations have been and will continue to be a top priority for SARS-CoV-2 testing. High-priority groups also include severely ill individuals that require hospitalization, individuals living in congregate settings such as jails and prisons, and homeless individuals or individuals that have recently experienced homelessness. SDDOH established these population as high-priority during the first two months of the COVID-19 event which strongly influenced healthcare partners across South Dakota to also consider these populations as high-priority. Clinical and public health partners now provide testing for all symptomatic individuals and select populations of asymptomatic individuals (described above) through routine clinical consultation processes, as well as access to testing through mass testing events. (c) The greatest barrier to efficient testing in South Dakota is availability of specimen collection and testing supplies. The top supply-chain difficulties are flocked swabs, commercially prepared viral transport medium, Cepheid GeneXpert COVID test kits, and Hologic Panther test supplies. Additional supply-chain difficulties include nucleic acid extraction kits and consumable plastic supplies for RT-PCR testing at clinical and public health laboratories. Some of these supply-chain difficulties have been overcome by federal allocation of specimen collection supplies to SDDOH which are immediately made available clinical partners statewide. SDDOH has also driven diversification of SARS-CoV-2 testing capabilities statewide which has eased the burden on certain supply-chains. SDDOH maintains frequent communication with clinical partners in an effort to evaluate supply-chain status on a near-real-time basis which allows clinical and public health partners to pivot towards or away from certain supply-

chains. Constant communication and supply-chain management are only two ways that SDDOH ensures fidelity of end-to-end logistics for SARS-CoV-2 testing. SDDOH also works with clinical and public health partners to ensure pre-analytical processes are in place to support optimal specimen collection using diversified supplies such as foam swabs and sterile saline, and collection of less invasive specimens such as oropharyngeal and nasal swabs. SDDOH also works with clinical and public health partners to ensure post-analytical processes allow for rapid notification of SARS-CoV-2 test results to healthcare providers, state epidemiology staff, and the CDC. Coupled with the analytical process described elsewhere in this report, both pre-analytical and post-analytical process for SARS-CoV-2 testing ensure a strong and flexible end-to-end process that supports COVID-19 objectives from specimen collection through data reporting. (d) SDDOH is a strong proponent for the responsible use of serological tests for COVID-19. SDPHL has validated two tests from the manufacturers Chembio (COVID-19 IgM/IgG test) and Abbott (SARS-CoV-2 IgG Immunoassay) and intends to evaluate COVID-19 serological tests from bioMerieux on its existing VIDAS3 instrument. SDPHL will implement serological testing in early June. SDPHL will provide paired antibody testing using both an automated IgG test (Abbott) and a manual lateral-flow test (Chembio), a serological test regime that is aligned with recent federal recommendations. SDDOH is moving forward very cautiously with COVID-19 serological testing due to the uncertainty regarding development of protective immunity to SARS-CoV-2 following initial infection and the ability to be reinfected. SDDOH continues to provide the message to the larger South Dakota community that a single antibody test cannot be used to determine if an individual is immune to SARS-CoV-2 and should stop physical distancing practices and other mitigation strategies that prevent the spread of COVID-19. SDPHL will disclaimer all COVID-19 serological test reports with the statement that "presence of antibodies to SARS-CoV-2 does not indicate immunity or resistance to infection, and does not mean that a person is no longer shedding virus or is no longer infectious". (e) SDDOH implemented an incident command structure (ICS) during the first weeks of the COVID-19 event. SDDOH established an Operations Section that includes Community Mitigation, Laboratory, and Epidemiology branches, as well as a Logistics Section to manage SDDOH COVID-19 resources. Community Mitigation, Laboratory, and Epidemiology branches are fully integrated to ensure alignment between mitigation efforts, laboratory testing, case investigation, and contact tracing. SDDOH has established a policy for sentinel surveillance testing in long-term care facilities and among American Indians, two of South Dakota's most vulnerable populations. SDDOH has established goals to provide sentinel surveillance for 2% of South Dakota's long-term care residents and staff each week, and 2% of South Dakota's tribal population each month. SDDOH has also established policies for point prevalence surveys in healthcare and congregate living facilities to ensure appropriate infection prevention measures are implemented following identification of COVID-19 in a facility. All testing activities are carefully vetted and discussed by the SDDOH COVID management team to ensure resources are used for maximum benefit. The SDDOH COVID management team assesses specimen collection and testing requests and helps match the needs of South Dakotas business, healthcare facilities, and other programs to the appropriate laboratory. SDDOH fully leverages the capabilities of clinical, public health, and commercial laboratories to meet SARS-CoV-2 testing needs for a diverse population. (f) SDDOH has a dedicated finance team to support COVID-19 efforts. All purchases in support of COVID-19 activities are given the highest priority and purchasing processes have been streamlined to promote efficiency and timeliness. Hiring and on-boarding of new staff in support of COVID-19 have also been streamlined to ensure efficient transition of personnel into COVID-19 operations. SDDOH has on-boarded personnel from CDC, South Dakota National Guard, and other agencies within state government. SDDOH closely monitors numerous supply chains in support of SARS-

CoV-2 testing. Supply chain management is a partnership between finance, laboratory, and logistics staff within the SDDOH COVID-19 ICS. High-priority supplies include specimen collection supplies, testing supplies, and testing equipment. Supply acquisition has been aided considerably by federal support including specimen collection supply and Abbott ID Now test kit allocations. However, with federal allocations set to end in June and public health agencies returning to the open market, there is considerable concern about availability of supplies for specimen collection and testing. Equipment purchase and placement continues to be a significant issue in South Dakota. High-throughput platforms in support of Sanford Health (Abbott m2000) and SDPHL (Hologic Panther) have been pending for months. Additional equipment and supplies will be required to fully implement SARS-CoV-2 testing to meet state and federal goals. These needs are outlined in Table #2 below.

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	1							1	
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)	1-Abbott m2000	1-Biofire Torch 1-Hologic Panther 30- Quidel Sofia Analyzers							0	
Volume of additional swabs needed to meet planned testing levels ⁺⁺	0	0							0	
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels**	0	0							0	

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	22Kmo - Hologic Panther; 6K/mo - Abbott m2000; 3K/mo Cepheid GeneXpert; 3k/mo RT-PCR (Assorted manufacturers); COVID Ag; 1,280/mo Abbott ID Now COVID	27Kmo - Hologic Panther; 7K/mo - Abbott m2000; 4K/mo Cepheid GeneXpert; 4k/mo RT-PCR (Assorted manufacturers); COVID Ag; 2,100/mo Abbott ID Now COVID							
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Number of additional* equipment and devices to meet planned testing levels	0	0							0

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	4,500	8,850							

^{*} 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.