COVID-19 TESTING RECOMMENDATIONS

State of Idaho Testing Task Force

May 20, 2020

Abstract

Herein are captured the current recommendations for molecular and serologic testing for COVID-19. We note that the science of testing for this condition will continue to evolve as will knowledge around transmission and immunity. For this reason, it will be important that these recommendations are part of a living document, capturing our best recommendations at this time, and requiring frequent and regular update.

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Acknowledgments

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Executive Summary: State of Idaho Testing Task Force

The goals of Idaho's COVID-19 testing recommendations are to limit severe illness or death and support a reopening of our economy by expanding capacity to rapidly diagnose persons with SARS-CoV-2-related illnesses, including among healthcare workers, vulnerable populations, critical infrastructure, and essential services, and to identify asymptomatic infections to reduce spread of SARS-CoV-2.

Testing for SARS-CoV-2, the virus that causes COVID-19, is not a strategy that stands alone, but is critically important because it is directly related to other elements of a comprehensive COVID-19 control strategy. For example, improved education will increase the identification of confirmed cases among symptomatic people and knowledgeable individuals will seek testing; at the same time, the sample collection event can become a prime opportunity for education. Similarly, identification of cases through testing triggers contact tracing, which leads to identification of exposed persons who should also be tested; thus, expanded contact tracing creates the need for expanded testing capacity.

The Governor's shelter-in-place order has slowed the COVID-19 epidemic in Idaho and has given us time to prepare for a well-informed, stepwise reopening of the economy. Continuing shutdown vs reopening the economy has been framed as either/or scenarios: **either** we continue and stop the spread of disease **or** we reopen and allow it to continue. This is false logic. We need to **both** control the spread of disease **and** reopen the economy. This is imperative not only from an economic perspective, but also from a public health perspective. We are already seeing patients with chronic conditions delay necessary care. Moreover, in past economic recessions or depressions, we have seen surges in suicide, substance use, and worsening of chronic health conditions, likely related to the direct relationship between economic downturn and social determinants of health. **With a well-designed and robust plan that includes testing, contact tracing, continued community mitigation (including physical distancing and face coverings), enhanced hygiene and decontamination measures, supported isolation, and robust data intelligence, we can achieve both a reduction in spread and a reopening of the economy.** This executive summary will briefly speak to each of these elements. The remainder of the Task Force's recommendations will be focused on the details of testing.

Testing availability in Idaho has been inadequate to meet our collective needs. Although some healthcare providers have begun to secure adequate testing for their own populations, **the availability and access to testing must be significantly increased to support a well-designed reopening of the state.** We must understand current testing capabilities, identify gaps between current and ideal testing capacity, and prioritize the closure of those gaps in a sequential way. Once we identify the "what" in terms of testing, this work must pivot to the "how," which should include public-private partnerships to effectively meet the needs.

SARS-CoV-2 testing can be molecular or serologic and can be applied in a targeted way or a universal way. **We recommend a phased expansion of targeted molecular testing (combined with contact tracing) and more limited use of serologic testing. We also recommend that test platforms be limited to those with high accuracy, sensitivity, and specificity.** Serologic tests are rapidly developing and are currently best applied to populations of people. Recently released federal guidelines have encouraged the use of such serologic tests within communities and other subpopulations to assess the numbers of people previously infected. Current disease knowledge and serologic test capabilities are not adequate to allow serologic testing to inform clinical decisions or employment management for individuals.

Tracing and testing of contacts of persons with SARS-CoV-2 infection is critical to reduce the spread of COVID-19 in the community, particularly given the large percentage of people who will be asymptomatic, but still infected. Contact tracing presumes that Idahoans will cooperate with public

health officials regardless of the method of tracing and communication. Although there are digital applications that can facilitate this work, Idaho's rural nature and broadband limits will make manual contact tracing programs a foundational component of the solution.

Supported isolation of confirmed cases will be an additional critical success factor when combined with testing. Those who are asked to self-isolate must be supported with policies and services that will protect the individual from a health, social, economic and employment perspective. Moreover, for vulnerable populations such as the homeless or housing-insecure, additional resources will be required to support effective efforts at self-isolation.

We must understand the threat on an individual, population and community basis, as well as more globally. **For this reason, we recommend that increased testing be accompanied by a comprehensive COVID-19 disease monitoring system building on and enhancing the disease surveillance system already in place by the state, which must be armed with both short-term tactical and long-term strategic forecasting capabilities.**

Lines of communication between frontline healthcare providers, either individual entities or as part of a system, must remain wide open, bidirectional, and must continue to inform the state's decisions in response to this pandemic. While testing and data analysis of these results will be very useful in informing decisions, the Idaho Rebounds staged approach also requires adequate healthcare system capacity for care. **We recommend a continued role for a clinically led group, including healthcare delivery system and rural input, supporting the state's response to this pandemic.**

Finally, a robust approach to educating the public, businesses, industry, schools, and others must be accomplished to support the above. In fact, much of the above will also support the opportunity to provide education. In addition to more broadly applied public service announcements, the sample collection event provides a potential excellent opportunity to provide education at a time when we have the attention of the tested person. Similarly, as businesses roll out policies to support physical distancing, hand hygiene, environmental cleaning and disinfection, and testing, broader education about COVID-19, how it is spread, and the need for continued vigilance will be valuable.

Our nation and our state can successfully achieve both control of the COVID-19 pandemic in our area as well as a successful staged reopening of our economy. Achieving this will require an approach that is founded in good scientific and clinical data, and must include **education, targeted testing, contact tracing, supported isolation, physical distancing, hand hygiene, environmental decontamination, robust data intelligence, and predictive modeling.**

Final Conclusions and Recommendations

State of Idaho Testing Task Force

Conclusions

1. Current molecular testing capacity within the state of Idaho is insufficient to meet the projected needs of an ideal targeted testing approach.
    a. Current molecular testing capacity is approximately 18,000-23,000 tests/week.
    b. In an ideal setting, molecular testing capacities across industries and locations would be able to expand to and estimated to 163,200 test/week.
2. Serologic (antibody) testing capacity is adequate to meet current needs

Recommendations for Molecular Testing

1. Testing should be limited to those methods with an FDA Emergency Use Authorization or methods currently in the approval process and tests with high accuracy, sensitivity, and specificity.
2. Targeted testing is conceptualized in four groups of people and prioritized in five tiers as detailed in the testing tiers section of this document. Testing groups include:
    a. Symptomatic people
    b. Asymptomatic subpopulations in which all are tested
    c. Asymptomatic subpopulations in which some are tested (sentinel testing)
    d. Asymptomatic people are tested prior to participation in group events.
3. Given the gap between current molecular testing capacity and need, testing prioritization across groups is recommended in a tiered fashion, such that those in the highest priority tiers should have access to testing before those in lower tiers, allowing for provider discretion for specific situations. As molecular testing capacity increases, we should seek to include all tiers for targeted testing. Please see the testing tiers document for detailed recommendations. Current capacity can likely accommodate Tier 1 and Tier 2 needs.
4. The state should take action to facilitate expansion of testing capacity. Closure of testing capacity gaps should involve expansion of public-private partnerships.
5. A robust communication plan will include education about COVID-19, how the disease is spread, cleaning standards, mask or face covering use, hand hygiene, and physical distancing standards as part of every specimen collection event.

Recommendations for Serologic Testing

1. Testing should be limited to those methods with high sensitivity and specificity with preference for tests with an FDA Emergency Use Authorization or other strong evidence of accurate test performance.
2. The utility of serologic testing is limited with regards to decision making for individual persons, but can be helpful to ascertain population level exposure, identify risk factors for infection, and as a means to counsel patients to continue social distancing and other measures. Additional details are included in the serology recommendation section.
3. Robust education about COVID-19, the meaning of the test result, how the disease is spread, cleaning standards, mask or face covering use, hand hygiene and social distancing should be part of every serologic specimen collection event.

COVID-19 Testing Information and Recommendations

During this pandemic, testing has evolved over time. It is important for healthcare providers to understand the availability, performance, and limitations of the testing modalities as they become available. Timely and accurate testing can facilitate clinical decisions in real time. Test results can also inform important decisions for healthcare delivery systems and provide critical information for local, state and federal leaders to understand the epidemic and design mitigating strategies to slow or control it.

Clinical Use of Testing for COVID-19

COVID-19 is the clinical syndrome caused by infection with the virus SARS-CoV-2. In a clinical situation any test ordered should provide information that a clinician can use to initiate or change management in some way that benefits the individual tested or other persons in the same setting (e.g., long-term care facilities, correctional facilities). This disease can be challenging to clinically diagnose given a wide range of symptoms that can overlap with those caused by other pathogens and a constellation of non-specific laboratory and radiographic findings; definitive diagnosis requires demonstrating the presence of viral RNA. Another public health challenge is the risk of asymptomatic individuals transmitting the infection.

Two main types of testing exist: molecular testing and serologic or antibody testing. RT-PCR (reverse transcriptase polymerase chain reaction) amplifies very small quantities of genetic material, in this case RNA, specific to SARS-CoV-2. Detection of amplified RNA does not distinguish whether a virus is infectious. Molecular testing should be used by clinicians caring for a symptomatic patient, because it offers real-time or near real-time information about active infection, which can guide management, isolation, use of PPE, etc. At this time, RT-PCR testing can be performed on several different platforms. Each platform has unique characteristics but provides equally accurate information. Rapid molecular testing for viral RNA is now available through a device manufactured by Abbott for point of care use., which can return results within minutes, but can only perform one test at a time, or around maximally 4–5 per hour. High-throughput platforms can process large numbers of tests (up to 2,000 per day) and deliver results within hours. Finally, out-of-state commercial and academic labs offer similar throughput as a send-out solution with turnarounds in the 2–4-day range. Each of these different modalities ideally will be applied in different clinical settings to optimize efficiency and sustainability.

Recommendations for clinical use of molecular testing:

1. For clinical evaluation of symptomatic patients, molecular (PCR or other testing) should be used.
2. Testing should be limited to those methods with an FDA Emergency Use Authorization or methods currently in the approval process and tests with high accuracy, sensitivity, and specificity.
3. A highly accurate point of care (POC) test for immediate turnaround is critical in certain settings in which it would lead to an immediate change in patient care. A few examples are listed below:

    a. Discontinue isolation in hospitalized patient or ED patient discharging to post-acute facility
    b. Allow a diagnostic or therapeutic procedure (i.e. Surgery, MRI, BMT, etc.)
    c. Begin or modify treatment
    d. Qualify for clinical trial

Serologic (antibody) testing for novel coronavirus can indicate current or past infection by detecting the presence of antibodies that bind to protein(s) of the virus. These tests are developing rapidly, and some have received Emergency Use Authorization (EUA) from the FDA. Each will be evaluated as they become available but are not ready for broad application in clinical care.

Adaptive humoral immunity in humans is characterized by development of antibodies and begins shortly after the viral infection. Typically, the initial antibody produced is IgM which may begin to be produced 5-7 days after initial infection but may not be detected, depending on the assay used, until days later. The human immune system begins to switch over to IgG production later in the infection. IgG is longer lasting and may or may not confer prolonged immunity once the infection clears.

Antibody testing on symptomatic patients early in the infection may not detect antibodies; therefore, it may not be helpful to the practicing clinician initially. Moreover, time to detection of antibodies and correlation to possible immunity in patients recovering from confirmed or suspected COVID-19 is not fully understood.

Having said all of this, there is a narrow niche for clinical use of serologies. For example, in evaluating a past episode of symptoms and trying to discern whether it was related to COVID-19 or a non-COVID-19 condition, antibody testing may be useful to establish whether infection with SARS-CoV-2 occurred.

Recommendations for clinical use of serologic testing:

- As an adjunctive tool for diagnosis of patients who present late in the course of illness, or for whom molecular testing is not practical, but for whom the suspicion of SARS-CoV-2 infection is high.
- Testing patients who believe they are immune to the virus and are therefore not following social distancing guidelines, in order to help document evidence of continued susceptibility and provide an opportunity for discussion about the importance of social distancing, independent of their results

Notes on Sensitivity and Specificity

Sensitivity refers to the ability to detect a disease when it is actually present. Specificity is the likelihood of a negative result when the disease is absent.

Sensitivity of RT-PCR depends on the timing of the test collection and adequacy of the collected sample. In COVID-19, the presence of SARS-CoV-2 viral RNA is highest around the time of symptom onset. From that time on the presence of the virus decreases, as does the ability to detect RNA by RT-PCR. Specificity of RT-PCR is high because it detects unique RNA sequences found only in the SARS-CoV-2 virus without known cross-reactivity. However, because it only detects RNA which can persist after infection, not the intact virion, it may not indicate individual infectivity if positive later in the course of illness.

Sensitivity and specificity for serologic tests is variable and is highly dependent on the time of testing relative to onset of infection. SARS-CoV-2 has demonstrated the ability to acquire new mutations over time, which may further impact the sensitivity and specificity of serologic tests. Some antibody tests detect viral nucleocapsid protein and others detect spike protein. Also, the timing of antibody production may vary substantially depending on overall health, medical diseases, and genetic background of the individual. Due to these factors, each individual serologic test must be evaluated thoroughly.

Epidemiologic Use of Testing for COVID-19

Molecular testing most accurately diagnoses COVID-19 during the acute symptomatic phase of the disease. It may detect the disease 1–2 days before symptom onset (https://www.cdc.gov/coronavirus/2019-ncov/community/strategy-discontinue-isolation.html) or for a very limited time after symptom resolution. Testing outside of this symptomatic window will be plagued by false negative results. Widespread molecular testing of population for SARS-CoV-2 would identify symptomatic persons with the virus and those who are incubating the disease without symptoms (pre-symptomatic and asymptomatic persons). Molecular testing would not detect those individuals who have recovered from infection and cleared the virus.

Given the increasing recognition around the number of asymptomatic or minimally symptomatic infected people, molecular testing can be used to screen certain populations of asymptomatic people prior to an event, such as moving into a congregate living facility or having a surgical procedure in which aerosols might be generated. In this way, it can be used to decrease the incidence of cluster outbreaks and guide the use of appropriate PPE.

In addition, for the same reasons around the numbers of asymptomatic people, it could be used in a sentinel screening way, applied to a subpopulation of high-risk workers in order to detect an outbreak early. Therefore, the use of molecular testing as an epidemiologic tool requires frequent repeated testing of both symptomatic and asymptomatic individuals to try to get an accurate picture of the incidence during an epidemic. This will significantly expand the number of tests required and will only be logical if it is associated with excellent contact tracing and supported isolation.

Serologic testing potentially holds out greater promise for population-based testing to understand the true prevalence of the disease but is limited by test performance and individual variation of the humoral immune response. For epidemiologic purposes, it is also limited by the sensitivity of the test with a disease that has a relatively low prevalence within the population (Bayes' Theorem). Please see the table below for an illustration of test performance with different sensitivity and specificity across populations with different disease prevalence. For example, with a disease prevalence of 5%, a test with 90% sensitivity and specificity would yield a very poor positive predictive value with 2/3 positives being false positives. On the other hand, with the same disease prevalence, a test with 99% sensitivity and specificity would yield a true positive roughly 5 times out of 6.

Impact of Test Sensitivity and Specificity, and Population Prevalence on Positive Predictive Value of Antibody Testing

Less Sensitive and Specific Test				More Sensitive and Specific Test			
Sensitivity	**Specificity**	**Prevalence**	**Positive Predictive Value**	**Sensitivity**	**Specificity**	**Prevalence**	**Positive Predictive Value**
0.9	0.9	0.1%	0.009	0.99	0.99	0.1%	0.09
		0.5%	0.043			0.5%	0.33
		1%	0.083			1%	0.5
		5%	0.32			5%	0.84
		10%	0.5			10%	0.92
		20%	0.69			20%	0.96

A combination of molecular and antibody testing that is both sensitive and specific could be used to more accurately identify acutely infected, recovered, and susceptible individuals. As we more fully understand possible protection to further infection from antibodies, this strategy may identify those who have acquired infection and who may now be immune. If these data were accurate, comprehensive, and transparent, it would facilitate decisions about when, how, and with whom to consider relaxing community mitigation efforts. It could identify those who may be infectious and should be isolated. It could identify high-risk susceptible individuals for protection or reverse isolation. Finally, it could set the stage for treatment, prophylaxis or vaccination as these become available.

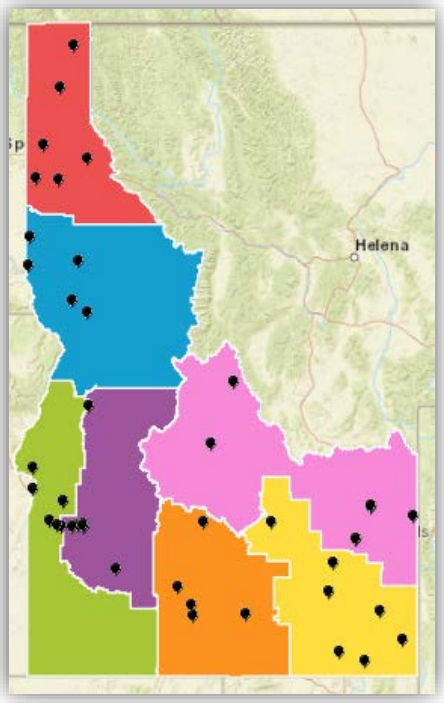
Recommendations for epidemiologic use of molecular testing:

1. Molecular and antibody testing should be limited to those methods with FDA Emergency Use Authorization.
2. Continue the current approach of using targeted molecular testing largely for clinical purposes, but also support its use to improve surveillance and sentinel testing (see Testing Tiers section for details).

Test types: Local Clinical Laboratory Testing Capacity for COVID-19 in Idaho

Executive Summary

A key to the success of the Idaho Rebounds campaign is having a distributed network of local clinical testing laboratories to supplement the testing provided by reference laboratories. **Local accurate and timely testing using only FDA Emergency Use Authorization methods in the appropriate setting is necessary** to provide rapid COVID-19 testing for symptomatic persons in the community, healthcare workers, hospitalized patients, long-term care residents and staff, and other high priority populations. To improve situational awareness in Idaho, the Idaho Bureau of Laboratories (IBL) weekly will survey Idaho moderate and high complexity CLIA laboratories and those waived laboratories that have the necessary instrumentation to perform COVID-19 molecular testing. This weekly survey will provide updated tactical information about Idaho's readiness to respond at the local level while at the same time assessing if laboratories are using high quality methods that are approved for their clinical setting. Additionally, these survey data will allow Idaho to more accurately identify testing barriers and provide needed information for the deployment of laboratory materials supplied by the federal government. The figure below indicates locations in the initial survey respondents by public health district. Additional laboratories will be added as testing capacity is identified or grows.



The weekly COVID-19 testing survey asks about: number of test collection kits on hand, the quantity needed to meet demand, testing instrumentation available, tests performed in-house, tests sent to reference laboratories, current turnaround times, and barriers to testing. These questions will only require a few minutes for participating laboratories to complete. Survey data will inform decisions about the distribution of collection kits and provide insight about what vendors the state may contact to secure needed testing materials. Baseline statistics for the 47 laboratories surveyed as of May 9, 2020, are shown in the table below. The survey results indicate that there is some local testing capacity in each of Idaho's seven public health districts. Eighteen of the 47 labs surveyed reported no access to local testing because of a lack of appropriate instrumentation or testing materials. All laboratories reported having access to sample collection kits, however, most requested more than they had on hand.

Moving forward the IBL Data Scientist will work with IBL Lab Improvement Section staff, survey respondents, and others in the Division of Public Health (DPH) to provide weekly updates in a visually intuitive dashboard. This data dashboard will be hosted on a secure DHW server. Access will be through secure login identification and password.

Public Health District Statewide Testing and Capacity Numbers

Table information as of May 9, 2020. Data are provisional and subject to change.

Health District	Facilities Surveyed	Current Supply of Kits	Kits Used per Week	Weekly Testing Capacity	Weekly Max Capacity[#]
PHD1	6	996	139	582	630
PHD2	5	2,350	170	120	1,500
PHD3	6	2,328	132	86	1,303
PHD4	8	14,356	2,180	3,890	8,750
PHD5	5	1,218	790	249	1,415
PHD6	8	1,532	67	152	2,606
PHD7	9	2,180	220	320	1,666
Reference Lab ELRs*	NA	NA	NA	2,089	Demand based 5,000+
Total State Summary	**47**	**24,960**	**3,698**	**7,488**	**22,870**

**Electronic Laboratory Reports. [#]Weekly max capacity valued is 17,870 tests from Idaho Clinical Labs plus 5,000 tests from reference labs.*

IBL received 15 Abbott IDNow instruments from HHS and with the assistance of DPH and the public health district directors distributed these instruments to the locations shown in the table below. Many of these are rural critical access hospitals that did not have local testing available. All the sites in the table will be included as survey participants. These sites will start to report numbers in the coming weeks once they are trained, verify the instrument on-site, and start requesting test kits and testing patients.

Abbott IDNow Instrument Deployment Locations

Site	Location	Number of Instruments
Cascade Medical Center	Cascade	1
Desert Sage Health Center	Mountain Home	1
Family Health Services	Jerome & Twin Falls	2
Southwest District Health	SWDH Mobile Lab	1
Weiser Memorial Hospital	Weiser	1
Idaho Department of Corrections	Kuna	1
Clearwater Valley Hospital	Orofino	1
St. Joseph/Pathologists Regional Laboratory	Lewiston	1
Shoshone Medical Center	Kellogg	1
Benewah Community Hospital	St. Maries	1
Caribou Memorial Hospital	Soda Springs	1
Franklin County Memorial Center	Preston	1
Salmon River Medical Clinic	Stanley	1
Grand Peaks Medical	St. Anthony	1

In addition, the following out-of-state reference laboratories offer testing to Idaho residents: ARUP, Quest, Bioreference, Interpath, Labcorp, Mayo, Oregon Health and Sciences University laboratory and the University of Washington Department of Virology. While these laboratories significantly increase tests available to Idahoans, they are an out-of-state resource and therefore it's not possible to ensure their capacity would be available in the future, if demand increased from all states.

Mandatory viral molecular testing for elective procedures in Idaho limited to health systems and hospitals will increase the viral molecular test volumes by several fold.

Reference

FDA Emergency Use Authorizations: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Projected Need for Testing and Estimated Gap

Testing Need Estimate

~30,000-163,200 tests per week

Summary

Two factors contribute to projections for the needed number of viral molecular tests. The first is population-based need, and the second is demand-based need. Population-based need is derived from calculations that estimate the number of tests required to detect new cases in a population. These calculations are usually independent of the actual demographics of each state. As cases increase, a larger proportion of targeted population-based epidemiologic testing should occur. The required number of viral molecular tests required to arrive at population-based estimates may vary. Some models would require up to 2% of the population to be tested per week. Demand-based testing requirements are derived from the number of tests needed to test specific groups, including symptomatic individuals, those undergoing invasive procedures, and health care workers. Employers desiring to test their employees may also drive demand-based testing. These requests may not contribute to population-based infection calculations. To calculate the total testing demand, we would add population-based and demand-based tests.

Methods and Data Collection

Informal telephone survey of hospital-based medical labs about current tests and estimated needs with elective surgeries.

Inquired from Idaho testing task force committee members.

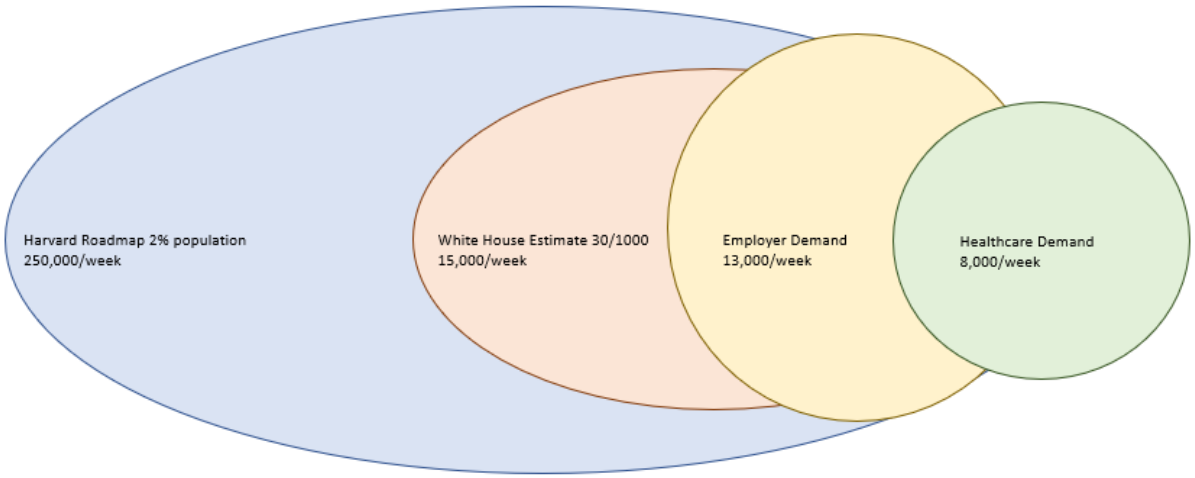
Estimated need of Idaho employers with 1,000 employees or more, based on either 10% or 25% of employees tested each week.

Reviewed population-based testing recommendations from several sources.

Elective Aerosol-generating Procedures Requiring a SARS-CoV-2 Test Prior to Procedure

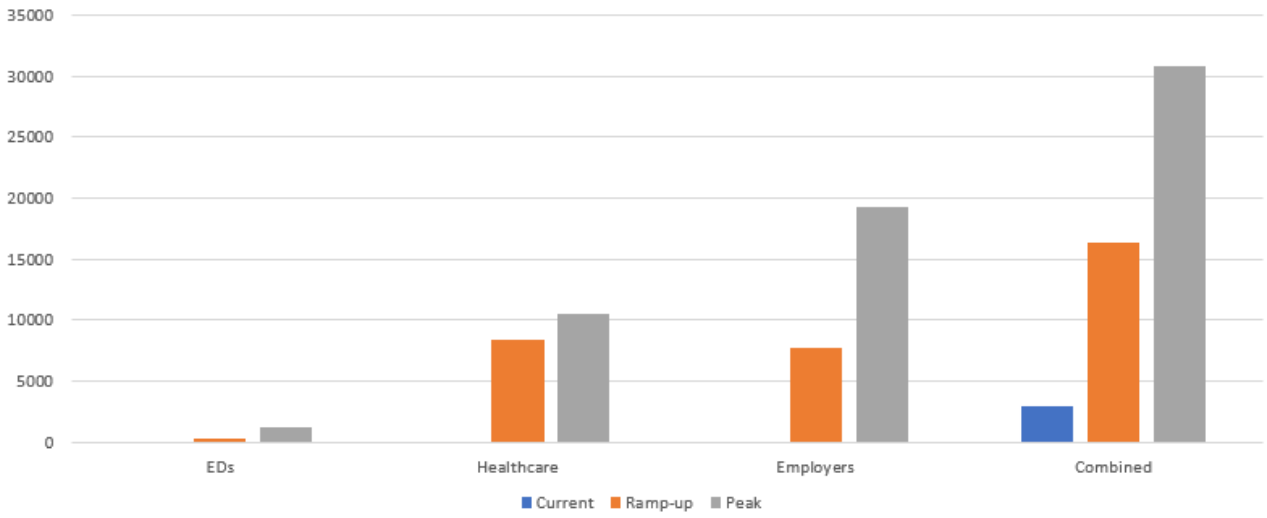
1. All elective surgeries
2. All polysomnography with PAP titration
3. All bronchoscopies
4. All laryngoscopies
5. All interventional cardiovascular procedures that require anesthesia
6. All appropriate GI procedures
7. Imaging studies that require anesthesia

Testing Estimates Graph



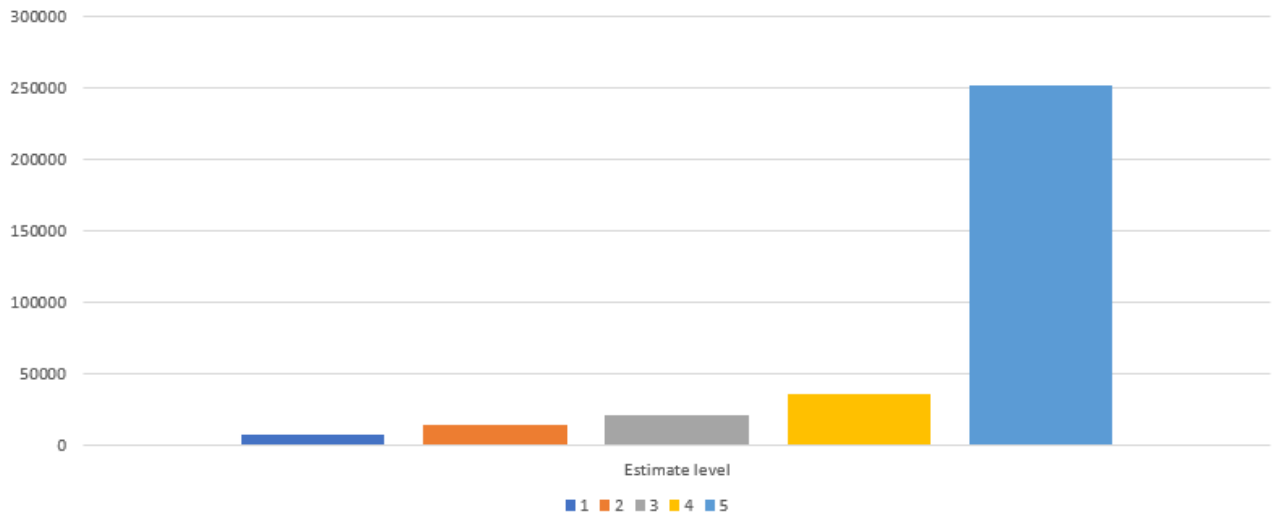
Demand-Based Graph

Testing per week



Population-Based Graph

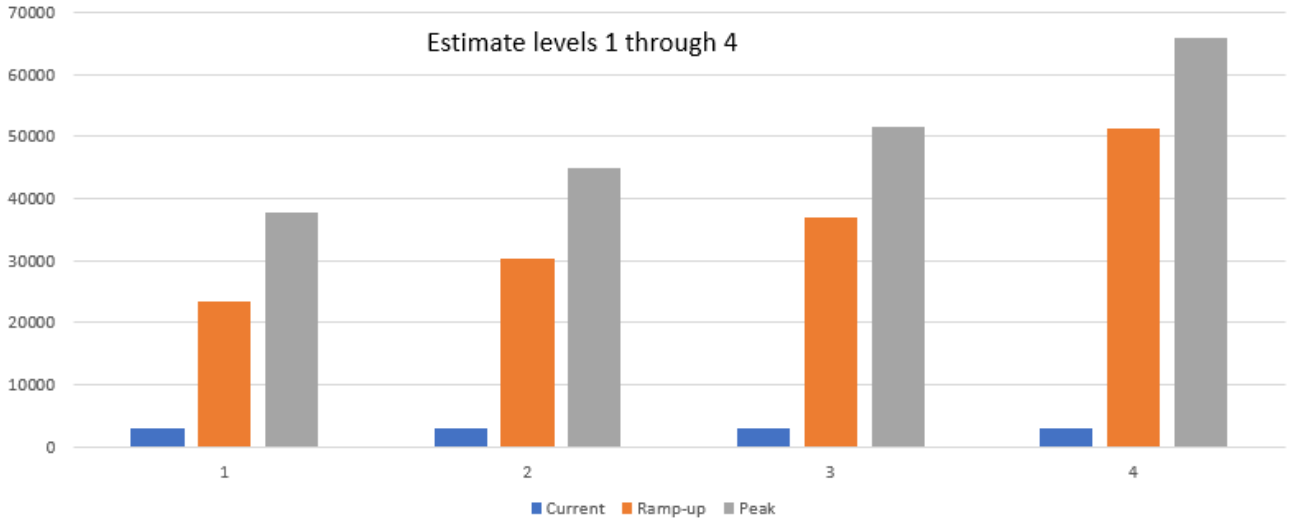
Testing per week



Median: 20,650 Average: 43,651 Range: 7,000 – 252,000

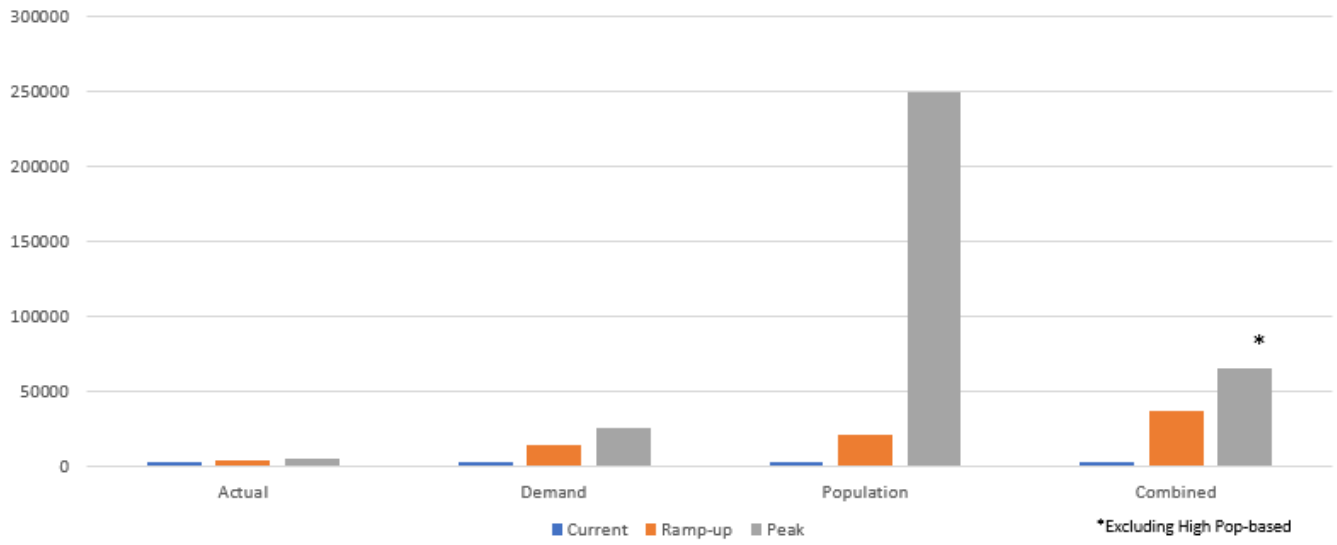
Combined: Demand + Population-Based Graph

Testing per week



Summary Graph

Testing per week



Population-Based Operations Needs

Testing per week

		Capacity	Current Demand (# tests/week)	Ramp-up Demand (# tests/week)	Peak Demand (# tests/week)
Population-Based	Population of Idaho: 1,800,000				
Harvard roadmap	2%-6%				252,000
Rockefeller	1%				18,000
White house estimate	34/1,000				15,300
JHA - Harvard	45/1,000				20,250
Herd immunity *	50%				17,300
	75%				25,960
Transmission-based					
Deaths per day **	1				7,000
	2				14,000
	3				21,000
	4				28,000
	5				35,000
	10				70,000
Contact-based					
EDs					
Visits per week 12,000					
Percent for COVID					
High 10% ***					1,200
Med 5%				350	
Low 2%			140		
Contacts per positive					
5			70	175	600
10			140	350	1,200
15			210	525	1,800

* To get to level of herd immunity in 12 months and assuming 10% detection rate and 10% positivity

** Take the number of forecasted deaths and suggest that the cases started 2 weeks earlier. Then using 1% or .5% mortality, extrapolate back to cases. Assuming our positivity rate of 10%

*** Testing symptomatic ED visits and their contacts

Selected Healthcare Facilities' Operations Needs

Testing per week – Estimate on May 14, 2020

	Capacity	Current Demand (# tests/week)	Ramp-up Demand (# tests/week)	Peak Demand
St. Luke's		1,600	3,100	
Saint Alphonsus		490	1,700	
Treasure Valley Hospital		0	275	
Weiser		10	25	
North Canyon		12	35	
Emmett		10	20	
WVMC		20	70	
Portneuf		55	275	
Mountain View		30	200	
EIRMC		60	210	
Teton		25	90	
Franklin		25	90	
Caribou		3	10	
Bear Lake		15	50	
St Josephs		160	275	
Gritman		100	300	
St. Mary's		14	28	
Clearwater		15	30	
Kootenai		400	1,400	
Shoshone		10	20	
Bonner		80	160	
Total		**3,134**	**8,363**	**10,454**

Additional Employer Considerations from Crush the Curve Idaho

Recent testing data indicate that if 10% of molecular tests are positive for SARS-COV-2, not enough testing is being done. Crush the Curve Idaho (CTCI) estimates that a more appropriate goal would be a ratio of 2%. With an expectation of 500 cases per day, that would indicate up to 25,000 tests per day should be performed. With a focus on employee testing, and as less than half of the state population is employed during ideal times, a conservative estimate might be 12,000 tests per day of employees. That equates to about 1.6% of employees being tested each day, but it shouldn't be random. It should be concentrated in the riskiest areas including public-facing employees and those who are required to work in close proximity to others. If 240 employees test positive on a given day, we expect there will be a need for 5 to 8 additional tests of contacts for each of them, or about 2,000 tests per day. This will be difficult to accomplish with the current molecular test methods, but still achievable. Less invasive specimen collection methods (e.g., a saliva test) should be added to the tool kit, particularly if the results could be made available within a relatively short time frame. CTCI believes that if such a test were even 80% as effective as the current molecular test, the fact that it could be administered more easily would allow us to more than double testing and greatly increase the percentage of new cases identified.

Composite Table Estimating Weekly Testing Capacity Needs in Idaho by Method of Estimation of Testing Needs

Demand Only		**Ramp-up**	**Peak**
		# tests/week	# tests/week
Healthcare		8,363	10,454
EDs		350	1,200
Business		7,690	19,225
Total		16,403	30,879
Population Only			
Range	7,000-252, 000		
Average	43,651		
Median	20,650		
Estimate level	Priority 1	7,000	
	Priority 2	14,000	
	Priority 3		20,625
	Priority 4		35,000
	Priority 5		252,000
Demand plus population-based			
Demand		16,403	30,879
Demand + pop_1		23,403	37,879
Demand + pop_2		30,403	44,879
Demand + pop_3		37,028	51,504
Demand + pop_4		51,403	65,879
Demand + pop_5		268,403	282,879

Testing Tiers: Recommended for molecular testing of symptomatic and asymptomatic individuals

SARS-CoV-2 Testing Prioritization

Idaho's critical priorities for COVID-19 response are to rapidly diagnose persons with SARS-CoV-2-related illnesses, including healthcare workers, vulnerable populations, critical infrastructure employees, and essential services, and to identify asymptomatic infections to reduce spread of SARS-CoV-2, particularly in high risk populations and in the community. Recommended testing strategies and test prioritization take into consideration federal testing principles and guidelines from the White House, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), and employee risk exposure levels as described by the United States Department of Labor and the Occupational Safety and Health Administration (OSHA). In addition, access should be compliant with Americans with Disabilities Act (ADA) guidelines. Continued shortages of laboratory reagents preclude simultaneous adoption of all components of these recommendations, and recommendations may need to be adapted to local conditions and supplies. These recommendations focus on molecular (i.e., nucleic acid) testing. Recommendations may evolve as more information becomes available; for example, if IgG antibody presence is determined to confer protective immunity to COVID-19, antibody test utility would be significantly different and recommendations for antibody testing would change. In addition, as new testing platforms become available that make testing more affordable and accessible, these guidelines will be updated.

Summary of Priority Recommendations

Priority 1 (approximately 16,900 tests/week)

Priority	Groups
	SYMPTOMATIC INDIVIDUALS
1	• Hospitalized patients • Healthcare workers • First responders
1	• Residents in long-term care facilities with symptoms, or who are close contacts of a confirmed case or part of an outbreak investigation • Patients 65 years of age and older with symptoms • Patients with underlying conditions with symptoms
1	• Inmates and staff of correctional facilities • Symptomatic residents and staff of residential care facilities • Residents and staff of homeless and other group shelters • Other vulnerable populations in crowded living conditions
1	• Critical infrastructure workers with symptoms • Congregate essential business workers • Essential workers
1	• Contacts of confirmed cases • Contacts of probable cases • Prioritize by exposure assessment
	ASYMPTOMATIC INDIVIDUALS
1	Hospitalized patients (see notes)*
1	All incoming residents and new staff in: • Long-term care facilities • Correctional facilities • Residential care facilities • Homeless shelters • Other congregate housing of vulnerable populations
1	• Asymptomatic contacts as part of a cluster investigation • Asymptomatic contacts in long term care facility including residents and staff • Asymptomatic contacts of confirmed cases • Broaden testing outreach in community when cases have occurred in people who come from racial and minority ethnic groups disproportionately affected by adverse COVID-19 outcomes in underserved communities (e.g. African Americans, Hispanics and Latinos, Native American Tribes)
1	• Patients before potential aerosol-generating procedure

Priority 2 (approximately 26,000 tests/week)

Priority	Groups
	SYMPTOMATIC INDIVIDUALS
2	People with frequent and close contact with international travelers or large numbers of the general public
	ASYMPTOMATIC INDIVIDUALS
2	Residents and staff in congregate living facilities with most vulnerable populations (long-term care facilities, correctional facilities, residential care facilities, homeless shelters) as part of routine surveillance
2	Employees of critical infrastructure/essential businesses in congregate settings, especially in close proximity with suboptimal ventilation (e.g., meat packing plant)

Priority 3 (approximately 43,000 tests/week)

Priority	Groups
	SYMPTOMATIC INDIVIDUALS
3	All other workers and public
3	All specimens submitted for seasonal influenza surveillance
	ASYMPTOMATIC INDIVIDUALS
3	Employees of critical infrastructure or essential businesses with high volume public-facing working conditions (e.g., large retail grocers)
3	Healthcare workers, first responder teams, and mortuary staff

Priority 4 (approximately 60,000 tests/week)

Priority	Groups
	ASYMPTOMATIC INDIVIDUALS
4	• Schools with congregate living conditions (e.g., dormitories or barracks) • Teachers in schools where classroom size exceeds 10 people • Daycares exceeding 10 children
4	Employees of non-essential businesses with congregate or public-facing working conditions (e.g., restaurants, high volume retail)
4	Participants in group guided travel where cloth face coverings and maintaining physical distance of 6 feet apart is not practical (e.g., river rafting)

Priority 5 (approximately 5,000 tests/week)

Priority	Groups
	ASYMPTOMATIC INDIVIDUALS
5	Athletes prior to any collision or contact sporting event (e.g., football, wrestling, basketball, martial arts)
5	Travelers returning from areas of community transmission via commercial carrier
5	Sporting Events (Attendees, staff)
5	Non-contact Athlete/Performance Groups

Testing Groups and Priority Tiers

These recommendations organize molecular testing into four groupings of individuals based upon core principles. In addition, across the groups, priority tiering has been applied due to current constrained testing capacity. It would be anticipated that Tier 1 needs would be met before Tier 2 needs are met, and so on. Please see the previous page for a summary of Tier recommendations. No hierarchy is implied by the order that groups are listed within priority group categories

Group A: Test all symptomatic people (nucleic acid or antigen test)

Consistent with the first recommendation in the federal guidelines and applies to all OSHA risk strata.

Total Estimate: 3,600 per week (range 2,400-17,200)

Priority	Objective	Groups	TAT Need	Estimated Numbers per week	Proposed Collection Site	Proposed Testing Laboratory Type	Additional Notes
1	Protect healthcare workers and first responders	• Hospitalized patients • Healthcare workers • First responders	Same day	1,200	Healthcare facility	High throughput, local	
1	Ensure that those who are at highest risk of complication of infection are rapidly identified and appropriately triaged	• Residents in long-term care facilities with symptoms, or who are close contacts of a confirmed case or part of an outbreak investigation • Patients 65 years of age and older with symptoms • Patients with underlying conditions with symptoms	Same day	800	• On-site collection via RRT, if available facility • Healthcare facility	High throughput, local	All symptomatic residents and staff in LTCF, as outlined by Long-term Care Facilities Strike Team
1	Limit COVID-19 in congregate settings with vulnerable populations	• Inmates and staff of correctional facilities • Residents and staff of residential care facilities. • Residents and staff of homeless and other group shelters • Other vulnerable populations in crowded living conditions	Hours for incoming residents and inmates	800	On-site	• Point of care if probability of false negatives is minimal • High throughput, local	
1	Early detection and control in critical infrastructure and essential businesses	• Critical infrastructure workers with symptoms • Congregate essential business workers • Essential workers	Same day	400	On-site if available or healthcare facility	High throughput, local	

Priority	Objective	Groups	TAT Need	Estimated Numbers per week	Proposed Collection Site	Proposed Testing Laboratory Type	Additional Notes
1	Control spread from public health clusters and selected contact tracing	• Contacts of confirmed cases • Contacts of probable cases • Prioritize by exposure assessment	Same day	200	• Home sampling • Healthcare facility	High throughput, local	
2	Early detection and control in medium exposure risk worksites	• Frequent and close contact with international travelers • Frequent and close contact with large numbers of the general public	Same day to days	50	On site	High throughput, local or commercial	
3	Detection and control in low exposure risk worksites	All other workers and public	Days	1,000	Home or onsite	High throughput, local or commercial	
3	Assess seasonality and geographic distribution	All specimens submitted for seasonal influenza surveillance	Days	500	Healthcare facility	Standard procedures at Idaho Bureau of Laboratories	

Group B: Test all asymptomatic people in certain situations (nucleic acid or antigen test)

Consistent with the federal guidelines and applies to confirmed contacts, patients in healthcare facilities, people upon admission to congregate living facilities, and those identified as priority by public health officials.

Total Estimate: 12,500 per week (range 10,000-16,000)

Priority	Objective	Groups	TAT Need	Estimated Numbers per week	Proposed Collection Site	Proposed Testing Laboratory Type	Additional Notes
1	Protect healthcare workers and other patients; conserve PPE and isolation beds through cohorting	Hospitalized patients	Same day	2,000	Healthcare facility	High throughput, local	Potentially apply to all acute care admissions as determined by community activity, hospital activity, and cohorting needs.
1	Limit introduction into congregate settings with vulnerable populations	All incoming residents and new staff in: • Long-term care facilities • Correctional facilities • Residential care facilities • Homeless shelters • Other congregate housing of vulnerable populations	Hours	500	• Healthcare facility if transfer • Onsite	Point of care if probability of false negatives is minimal	All new patient admissions to facilities be tested for SARS-CoV-2 should be included in priority 1 category, as per Long- term Car Facilities Strike Team
1	Control spread from public health clusters and contact investigation Early detection in vulnerable populations with outcome disparities	• Asymptomatic contacts as part of a cluster investigation in the community • Asymptomatic contacts in long term care facilities with one or more lab confirmed cases including all residents and staff • Asymptomatic contacts of confirmed cases • Broaden testing outreach in community when cases have occurred in people who come from racial and minority ethnic groups disproportionately affected by adverse COVID-19 outcomes in underserved communities): • African Americans • Hispanics and Latinos • Native American Tribe if identified as disproportionately affected	Same day to days	1,000	• Home sampling • Temporary sites Healthcare facilities	High throughput, local or commercial laboratories	Implement public health measures per CDC guidelines. Serial testing when supplies are sufficient. Long-term Care Facilities recommendations are consistent with Strike Team guidance.
1	Conserve PPE	Patients not already known to be infected with COVID-19 before potential aerosol-generating procedure	Hours	10,000	Healthcare facility	• High throughput, local • POC	Apply to all non-emergent potential aerosol-generating procedures

Group C: Enhanced surveillance of asymptomatic people in sentinel populations (nucleic acid or antigen test)

Consistent with the federal guidelines to apply to certain subpopulations and prioritized according to OSHA risk-stratification guidelines.

Total Estimate: 101,250 per week (range 25,000-125,000)

Priority	Objective	Groups	TAT Need	Estimated Numbers	Proposed Collection Site	Proposed Testing Laboratory Type	Additional Notes
2	Early detection at critical locations	Congregate living facilities with most vulnerable populations (long-term care facilities, correctional facilities, residential care facilities, homeless shelters): residents and staff	Same day	LTF: 1,250 DOC: 9698 SNF: 3896 RALF: 10,746	On-site	• High throughput, local • POC	Priority 2 should include testing at regular intervals of asymptomatic HCP who reside or work in counties with known community spread of SARS-CoV-2 or who work in other healthcare facilities with cases of COVID-19.
2	Early detection in critical infrastructure or essential businesses with higher transmission risk	Employees of critical infrastructure or essential businesses in congregate settings, especially those working in close proximity with suboptimal ventilation (e.g., meat packing plant)	Same day	250	Home or on-site	High throughput, local	OSHA medium risk category, PPE likely inadequate
3	Early detection in critical infrastructure or essential businesses with higher exposure risk	Employees of critical infrastructure or essential businesses with high volume public-facing working conditions (e.g., large retail grocers)	Same day	20,000			
3	Early detection in critical workforce at high risk who should be protected by PPE	Healthcare workers (especially providers of underserved populations) first responder teams, and mortuary staff	Same day	20,000	Facility	High throughput, local	OSHA high exposure risk category, PPE adequate
4	Early detection in population with potential for rapid spread	• Schools with congregate living conditions (e.g., dormitories or barracks) • Teachers in schools where classroom size exceeds 10 people • Daycares exceeding 10 children	Same day	TBD	On-site	High throughput, local	OSHA medium risk category, not categorized as essential business
4	Early detection of community spread	Employees of non-essential businesses with congregate or public-facing working conditions (e.g., restaurants, high volume retail)	Days	60,000	Home or on-site	High throughput, local or commercial	OSHA medium risk category, not categorized as essential business

Group D: Screening of asymptomatic persons prior to participation in group events (e.g., group travel, sporting events, entertainment)

These are not included in current federal guidelines and are considered non-essential. Nonetheless, we believe that solutions should be developed for these important portions of our economy.

Total Estimate: 2,000 per week (range 1,250-5,000)

Priority	Objective	Groups	TAT Need	Estimated Numbers	Proposed Collection Site	Proposed Testing Laboratory Type	Additional Notes
4		Participants in group guided travel where cloth face coverings and maintaining physical distance of 6 feet apart is not practical (e.g., river rafting)	Hours	1,250	Designated testing sites around state based upon departure location	POC	Important part of Idaho economy. Consideration should be given to group size and presence of out-of-state travelers.
5		Athletes prior to any collision or contact sporting event (e.g., football, wrestling, basketball, martial arts)	Hours	750	Facility collection	POC	
5		Travelers returning from areas of community transmission via commercial carrier.	Same day	TBD	Airport and bus station or train depot collection site	High throughput, local	
5		Sporting Events	POCT if available				Symptom screening and temp check on entry, universal masking, POCT testing availability
5		Non-Contact Athlete/Performance Groups					No routine testing, but symptom checking apps, universal masking where able and social distancing practices

Recommended Minimum Goals for Serologic Testing of Populations

Recommendations Regarding Serology (Antibody Testing)

Medical Providers

- While serology testing holds promise, it should not currently be used to determine immunity to the SARS-CoV-2 virus for individuals, as science is lacking as to whether the presence of antibodies to the virus confers protective immunity, and, if so, the duration of that immunity. The sensitivity and specificity of serology varies by manufacturer. In addition, the positive predictive value will vary depending on the pre-test probability of having been infected; persons at low risk of prior infection who test positive are more likely to have a false positive result.
- Seroconversion provides greater evidence of recent infection than a single positive serum antibody test.
- Serology testing can be clinically useful if ordered on a case-by-case basis for specific circumstances, *e.g.*:
    - As an adjunctive tool for diagnosis of patients who present late in the course of illness, or for whom molecular testing is not practical, but for whom the suspicion of SARS-CoV-2 infection is high.
    - Testing patients who believe they are immune to the virus and are therefore not following social distancing guidelines, in order to help document evidence of continued susceptibility and provide an opportunity for discussion about the importance of social distancing, independent of their results

Employers

- Serology may be considered by employers for the following purposes:
    - Serial antibody testing to document whether seroconversion is occurring in employees (*e.g.*, high-risk healthcare workers), when included as part of a quality program (note this is not currently a proven strategy)
    - As part of a response to a case or outbreak in a facility, to determine if undetected exposure and infection has occurred among employees (e.g., long-term care facility)
    - Despite promise for its use in monitoring of special populations such as essential workers outside the healthcare setting, there is not enough evidence yet to make a recommendation regarding this use. As new assays are developed, and evaluated, they will be routinely reviewed, and recommendations updated as needed. We will also learn more over time about whether seroconversion confers immunity and, if so, for how long. Sources will include the medical literature, and websites such as https://covidtestingproject.org and https://www.finddx.org/covid-19/dx-data/
- Serology testing should not be used to alter employee work responsibilities, and employers should offer the same level of protection to all employees regardless of test results.

Blood Donation Centers

- Centers may use serology for screening people who are fully recovered from SARS-CoV-2 disease to donate plasma to help current COVID-19 patients

Public Health Uses

- Serology testing of certain populations (*e.g.*, entire communities) can be a useful public health tool to determine the extent of exposure in the population.
- Community serosurveys offered by public or private entities may provide valuable information for public health planning and should be developed to provide useful information for the COVID-19 response, while also serving individual participant interests in learning of their test results in a timely manner if feasible. When antibody testing is done on a larger population and demographic and exposure information is also collected, serosurveys can help identify groups at higher risk of infection.
- Public health officials, healthcare agencies, and the private sector should continue to partner to investigate and determine the best use of serologic testing in Idaho, as it evolves over time.

Selection of Tests and Serial Testing

- Providers should select serology tests with performance features based on independent evaluations such as those published on the FDA site EUA Authorized Serology Test Performance.
- Some serology tests incorporate IgM and IgG; there are theoretical concerns with cross-reactivity with other coronaviruses, so providers should take care to review the performance of such tests before use.
- Providers may consider serial testing, using two different serology tests that detect antibodies against a different viral antigen or epitope, to improve the utility of serology testing.
- Currently, no specific recommendations are available, but this will continue to be reviewed, and recommendations made when the science is clearer.
- At present, the following antibody tests have EUA authorization and may be considered for use in serial testing.

Available EUA Serological Tests, by Antigen Utilized as of May 9, 2020		
Spike Protein (S)	**Nucleocapsid Protein (N)**	**Not Stated**
Euroimmun	Roche	Ortho-Vitros IgM-IgG
DiaSorin	Abbott	Cellex
Ortho -Vitros IgG	ChemBio	
AutoBio		

For additional information see the FDA EUA listing at.
https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Appendix A

COVID-19 Resource Links

- Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19, Published by IDSA, 5/6/2020 https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/ [idsociety.org]
- COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured https://www.hrsa.gov/coviduninsuredclaim [hrsa.gov]
- FDA STATEMENT: Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts, Published April 18, 2020 https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-test-validation-and-education-efforts

Appendix B

Federal Guidelines Around Testing

(as of 4/29/2020)

- Every symptomatic patient should receive a timely and accurate molecular viral test.
- To enable early detection, potential community spread should be actively assessed through a strategic approach that identifies asymptomatic people.
- Sentinel monitoring should be performed at critical locations, including senior and other congregate living settings and healthcare clinics (particularly those in underserved urban and tribal settings).
- Containment of potential outbreaks, including those uncovered by sentinel monitoring, should be accomplished through systems for contact tracing.
- Sentinel monitoring involves targeted, voluntary testing of asymptomatic individuals at "sentinel sites," which are selected locations that are likely to see cases of the disease.
- Molecular testing capacity should be able to be quickly deployed to hot spots, as indicated by monitoring tools such as the Influenza-Like-Illness Surveillance Network (ILI Net) and the National Syndromic Surveillance Program (NSSP) operated by the Centers for Disease Control and Prevention (CDC).
- New technologies, including point-of-care (POC) antigen and POC nucleic acid detection tests, should be leveraged to enhance testing capacity, accuracy, capability, and speed.
- Antibody tests should be used to help assess the number of people in a community who have been previously infected by the virus, especially within critical groups (first responders, essential workers, healthcare providers, and vulnerable populations).

Opening Up America Again: Testing Blueprint

- White House, Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA). 4/27/2020 https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Blueprint.pdf

Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)

- Per the CDC: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html. Last reviewed 5/3/2020. Accessed 5/3/2020.

Priorities for SARS-CoV-2 Molecular Testing for COVID-19 Diagnosis

High Priority

- Hospitalized patients
- Healthcare facility workers, workers in congregate living settings, and first responders **with** symptoms
- Residents in long-term care facilities or other congregate living settings, including correctional and detention facilities and shelters, **with** symptoms

Persons identified by public health officials or clinicians as high priority

- Persons **with** symptoms of a possible infection with COVID-19, including fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat.
- Persons **without** symptoms who come from racial and ethnic minority groups disproportionately affected by adverse COVID-19 outcomes — currently African Americans, Hispanics and Latinos, some American Indian tribes (e.g., Navajo Nation).
- Persons **without** symptoms who are prioritized by health departments or clinicians, including but not limited to: public health monitoring, sentinel surveillance, presence of underlying medical condition or disability, residency in a congregate housing setting such as a homeless shelter or long term care facility, or screening of other asymptomatic individuals according to state and local plans.

COVID-19 Serology Surveillance Strategy

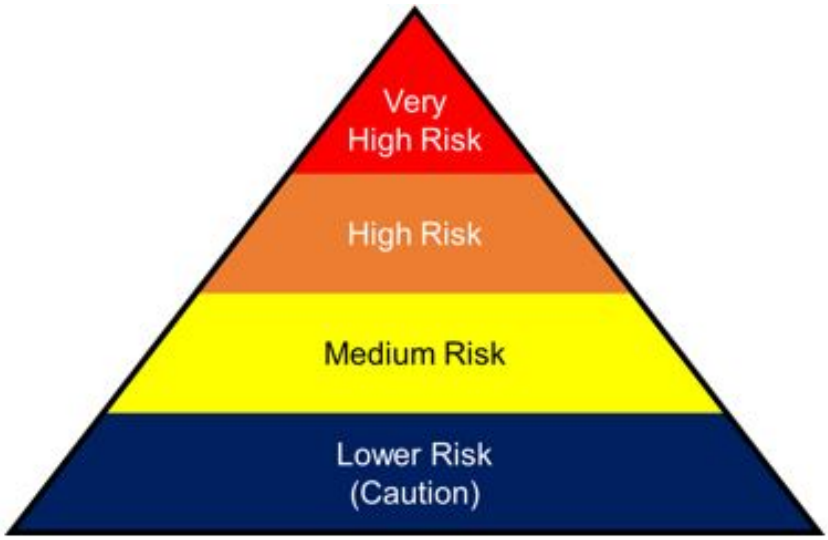
CDC. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html. Last reviewed 4/28/2020. Accessed 5/3/2020.

CDC has an overarching strategy for learning more about how many people have been infected with SARS-CoV-2, the virus that causes COVID-19, and how it is spreading through the U.S. population. This strategy includes using serologic testing or surveillance to better understand how many infections with SARS-CoV-2 have occurred:

- At different points in time,
- In different locations, and
- Within different populations in the United States.
- Objectives of Surveillance of U.S. Serology Testing
- To provide a more complete estimate of how common COVID-19 is (or the incidence of infection)
- To guide control measures, such as social distancing

OSHA Risk Exposure Levels

OSHA has divided job tasks into four risk exposure levels: very high, high, medium, and lower risk, as shown in the occupational risk pyramid, below. The four exposure risk levels represent the probable distribution of risk. Most American workers will likely fall in the lower exposure risk (caution) or medium exposure risk levels.



Lower Exposure Risk (Caution)

Jobs that do not require contact with people known to be, or suspected of being, infected with SARS-CoV-2. Workers in this category have minimal occupational contact with the public and other coworkers. Examples include:

- Remote workers (i.e., those working from home during the pandemic).
- Office workers who do not have frequent close contact with coworkers, customers, or the public.
- Manufacturing and industrial facility workers who do not have frequent close contact with coworkers, customers, or the public.
- Healthcare workers providing only telemedicine services.
- Long-distance truck drivers.

Medium Exposure Risk

Jobs that require frequent/close contact with people who may be infected, but who are not known to have or suspected of having COVID-19. Workers in this category include:

- Those who may have frequent contact with travelers who return from international locations with widespread COVID-19 transmission.
- Those who may have contact with the general public (e.g., in schools, high population density work environments, and some high-volume retail settings).

High Exposure Risk

Jobs with a high potential for exposure to known or suspected sources of SARS-CoV-2. Workers in this category include:

- Healthcare delivery and support staff (hospital staff who must enter patients' rooms) exposed to known or suspected COVID-19 patients.
- Medical transport workers (ambulance vehicle operators) moving known or suspected COVID-19 patients in enclosed vehicles.
- Mortuary workers involved in preparing bodies for burial or cremation of people known to have, or suspected of having, COVID-19 at the time of death.

Very High Exposure Risk

Jobs with a very high potential for exposure to known or suspected sources of SARS-CoV-2 during specific medical, postmortem, or laboratory procedures. Workers in this category include:

- Healthcare workers (e.g., doctors, nurses, dentists, paramedics, emergency medical technicians) performing aerosol-generating procedures (e.g., intubation, cough induction procedures, bronchoscopies, some dental procedures and exams, or invasive specimen collection) on known or suspected COVID-19 patients.
- Healthcare or laboratory personnel collecting or handling specimens from known or suspected COVID-19 patients (e.g., manipulating cultures from known or suspected COVID-19 patients).
- Morgue workers performing autopsies, which generally involve aerosol-generating procedures, on the bodies of people who are known to have, or are suspected of having, COVID-19 at the time of their death.

Appendix C

Infectious Disease Society of America Statement

from April 20, 2020

- The antibody response in infected patients remains largely unknown, and the clinical values of antibody testing have not been fully demonstrated.
- Seroprevalence data will be important in understanding the scale of the pandemic and future vaccine utility.
- Potential utility of serology in SARS-CoV-2
    - Detection of molecular-negative cases, especially for patients who present late with a very low viral load below the detection limit of RT-PCR assays, or when lower respiratory tract sampling is not possible
    - Identification of convalescent plasma donors
    - Epidemiologic studies of disease prevalence in the community.
    - Verification of vaccine response once antibody correlate(s) of protection identified.
- Potential drawbacks if serological assays are not well-validated:
    - False negative risks if performed early in disease course, especially in mild disease
    - False positive risks, particularly with tests for Immunoglobulin M (IgM) and potential cross-reactivity with common cold coronaviruses (e.g. HKU1, NL63, OC43, 229E).

Uses of Serology

Current Uses

- Serosurveys for public health purposes
- Optional, personal interest in those who believe they may have been exposed
- Case-by-case use when trying to determine if persons in high-risk jobs, or with personal health vulnerabilities, are resolving their infection
- Diagnosis of persons with symptoms but who were not PCR tested, or are PCR negative (e.g. younger stroke patients)

Possible Future Uses

- Determination of immunity to determine ability to change behavior (e.g., travel, return to work)
- Vaccine trials