

University of Minnesota Medical School

Proposal for Large Scale Testing of Individuals for SARS-CoV-2

Aim: To identify people who can safely go back to work. We will use methods developed at the University of Minnesota that do not rely on external supply chains in order to identify people who have been previously infected with SARS-CoV-2 and who are not shedding the virus (i.e. they can't infect other people). SARS-CoV-2 is the virus that causes COVID-19.

Rationale: Determining an individual's current and past infection with SARS-CoV-2 is necessary to ensure workers will not infect others and can safely return to work themselves.

Proposal:

The University of Minnesota requests \$20.0 million for SARS-CoV-2 testing. COVID-19 has caused a major disruption to Minnesota's economy with over 150,000 individuals applying for weekly unemployment benefits in late March, a number that continues to grow. Many of these individuals are unable to work because of public health measures to limit the spread of the disease. With financial assistance from the State of Minnesota, the University of Minnesota Medical School can rapidly deploy two homegrown tests to get workers back on the job: 1) Polymerase Chain Reaction (PCR) test; and 2) Serologic Antibody test.

The PCR test actually detects virus particles in the nose (meaning someone is contagious). The second test measures antibodies in blood, which means the person has had the infection and has developed an immune response to the virus. We will apply the following logic to determine if someone is currently infected, has resolved the infection or has never been infected:

Test Results	Determination by Individual
Negative to both tests	They have never been infected
Negative PCR test, but have antibodies	They are no longer contagious but have developed immunity
Positive PCR test, but no antibodies	They have an early infection and are contagious
Positive PCR test, and have antibodies	They have an established infection and are contagious

In combination, these two tests can assist with getting Minnesotans back into the workforce. We want to identify people with a negative PCR test but who have antibodies. Additional details on each test are included below:

1. PCR: Early in the pandemic the University of Minnesota recognized the need for our own PCR testing solution to aid in diagnosis of COVID-19. This test is used on swabs collected from the nose. This test does not rely on manufacturers having sufficient numbers of reagents available to send to us, which has been a limiting factor for many centers who test for SARS-CoV-2 by PCR. Our test has been designed and validated at the University of Minnesota, and we can quickly and efficiently increase testing capacity to meet the needs of this proposal.
2. Serologic Testing: The University's Center for Immunology has developed a highly sensitive and specific blood test that can reliably detect antibodies to SARS-CoV-2. If the test is positive, the individual has been infected and would likely be immune to further infection with the specific strain of virus that is circulating in the State. The University of Minnesota is leading the nation with its serologic testing. It was the first to discover the precise mechanism for how the virus can actually attach to a cell and infect it (Dr. Fang Li, College of Veterinary Medicine, Nature, 2020) and using that data we created a test that can detect antibodies in response to the virus (Dr. Marc Jenkins, Medical School). We have validated the test through the Advanced Diagnostic and Research Laboratory (headed by Dr. Amy Karger, Medical School). It is a highly sensitive, made in Minnesota test for past SARS-CoV-2 exposure. We do not rely on outside vendors for reagents to do the testing, as such we do not anticipate supply chain problems.

We propose to screen selected populations with both the PCR and serology tests to identify people who have been infected but now have immunity. With State funding, the Medical School could increase our testing capacity to approximately 10,000 antibody and 10,000 PCR tests per day. We propose to work with the State

of Minnesota to 1) identify the populations to be tested (and the order each group would be tested), 2) develop methods for collection of nasal swabs and blood with appropriate consent by individuals, 3) conduct the testing, and 4) return the results. We estimate the combined cost of the PCR and serologic testing will be between \$25-\$30/person. However, we recognize there is an economy of scale to be achieved with lower costs for higher volume and higher costs for a lower volume.

Why the University of Minnesota: The University of Minnesota is in the strongest position to provide this service to the State because:

- The University of Minnesota is the only land grant institution in the State and our Medical School graduates the majority of physicians, nurses, pharmacists, and other health care providers that serve the people of the State.
- The tests we offer were developed at the University of Minnesota and can be scaled up to meet the needs of this project. There should be no supply chain problems that have plagued commercial tests during this crisis. We are making our own test kits with routine laboratory supplies and reagents; we will not be subject to the same supply shortages and competition for limited resources. Given that other states and nations will be looking to implement similar serology and PCR based screening programs, the University of Minnesota is well-positioned to avoid reliance on diagnostic companies for test kits.
- Collection of samples from around the state will be made easier because
 - Together with Fairview we have 13 hospitals and 60 primary care clinics extending past the nine county metro area as well as a hospital and clinics in the iron range region of our state.
 - Our Medical School campus in Duluth collaborates with Essentia, the largest health care system in the northern part of the state.
 - Our faculty practice in coordination with our University and regional partners can facilitate blood collection in more rural areas.
 - We have existing, extensive collaborations with the Red Lake Nation and other Tribal communities that will facilitate collection within those communities.

The University of Minnesota is in an ideal position to serve the State in this way. We have tests that can be scaled without supply chain concerns, such as shortages of supplies and reagents. We have penetration into almost every county in the State to facilitate sample collection. We have become national leaders in the fight against COVID-19 with our rapid response to develop a clinical infrastructure to support patients, create a comprehensive research agenda to test novel therapies to fight the disease, and address critical support needs like ventilators, mask shortages, and diagnostic tools. We can accomplish this efficiently and quickly.