

Executive Summary

A National Decision Point: Effective Testing and

Screening for Covid-19





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The Covid-19 pandemic is still spreading throughout the United States. Over 30,000 Americans continue to test positive daily, and hundreds are dying every day.

Economic activity has plunged and a record number of Americans are out of work. Millions of jobs may have disappeared forever. Most of the nation's school children have not returned to classrooms full time this fall, straining families as well as employers.

Many universities have returned to online-only classes after outbreaks caused sudden closures. Nursing homes and other long-term care facilities have been decimated by disease with their residents locked in isolation. A vaccine could bring relief, but its wide availability and impact is months away if not longer. In the meantime, few institutions have broadly-accepted plans for reopening safely.

This must change. The best tools for shifting back to some form of normalcy are effective masking and distancing measures to mitigate spread, coupled with sufficient Covid-19 tests paired with sophisticated strategies for their effective use. This report describes how to offer the latter in ways that can be tailored to local circumstances and risk tolerances. The goal is to give schools, businesses, and other critical institutions a pathway toward operating safely even for higher-risk populations and with continuing community spread.

There are four basic elements to a testing strategy that can contain outbreaks, inform public health decision-making, and respond to local Covid-19 prevalence rates:

- Assessments of the risks of infection and death depending on local spread and population characteristics.
- Meaningful and measurable goals for acceptable infection reduction through screening and surveillance.
- Calculation of budgetary and administrative constraints.

• Adequate supplies of sufficiently reliable tests.

Challenges in achieving this last element have long been a critical concern. Supply constraints have largely limited Covid-19 testing to symptomatic and essential workers. But that is changing with the development of growing supplies of rapid and low-cost tests for regular screening. Screening holds the potential to protect nursing homes, reopen schools, and detect and contain outbreaks in at-risk work and community settings.

The United States needs far more tests because the United States has far more Covid-19 infections. At present infection rates, a basic screening strategy will require approximately 200 million tests each month for students and staff at the nation's primary and secondary schools and residents and staff at nursing homes for them to open safely and in stages. But fewer than 25 million Covid-19 tests are now reported monthly in the United States. Even if infection rates decline, the testing needed in just schools and nursing homes exceeds the nation's entire capacity now.

But the nation's capacity to conduct screening tests is rising, and is projected to grow much further. By October 2020, based on recent and announced expected market entry, point-of-care tests will rise to at least 70 million tests per month. By January, that number could rise to almost 200 million tests per month. More growth is possible - if additional tests enter the market, if additional research laboratory capacity is recruited and supported, and if manufacturers make further investments to increase supply. To get this done, the federal government must provide more guidance, assistance and advance funding to manufacturers and payers, and should take further steps to coordinate these efforts with state and local governments. Without further steps to implement

and achieve a national testing strategy, state and local governments supported by the private sector and initiatives like that of The Rockefeller Foundation must step in.

These initiatives require a basic assessment of market needs, and that starts with three steps:

- The federal government should issue guidelines that state, and local officials can use to refine their local protocols for regular diagnostic, screening, and surveillance testing for active infections.
- Federal, state, and local governments should expand pilot testing initiatives to build the real world evidence base on test accuracy and on effective testing strategies for the range of risk settings and populations.
- 3. The federal government should develop a short- and long-term plan to procure and distribute tests to states, localities, and businesses and share and coordinate these plans with relevant stakeholders to ensure that receiving entities can plan to meet their testing needs and to allow manufacturers to better understand the demand for testing in the coming months.

Beyond the market assessment, new supports must be provided to increase both the number and types of tests available in order to offer appropriate routine screening of asymptomatic individuals. Among the steps:

- The Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the Centers for Disease Control and Prevention should issue clearer written guidance about regulatory flexibility, pathways, templates, and other tools to support screening and surveillance.
- 2. The federal and state governments should support advance purchase contracts to assure needed testing capacity is available for priority populations for the remainder of the pandemic, including testing relevant to a vaccine. Our estimates suggest that several billion dollars per month in additional spending commitments for testing for the coming months could close the testing gap.
- 3. Use information provided by manufacturers and key suppliers to increase manufacturing capacity of key supplies and reagents, especially for laboratory tests.

In the absence of further Federal action, continued

leadership from states, local governments, and the private sector can help achieve these needed changes. The United States is at a critical point in the pandemic, facing many more months of the severe health and economic disruptions that go along with significant infection spread throughout the country – but now with the potential to avoid that outcome through the effective use of innovative, large-scale testing.