TESTING BLUEPRINT

OPENING UP AMERICA AGAIN

THE WHITE HOUSE

CDC

FDA

BLUEPRINT FOR TESTING PLANS AND RAPID RESPONSE PROGRAMS

PARTNERING WITH STATES TO PUT AMERICA BACK TO WORK

"America continues to make steady progress in our war against the virus. Our testing is expanding very rapidly by millions and millions of people. We are also helping governors to develop strategies to smartly deploy their testing capacity to protect vulnerable and underserved populations while getting Americans at lower risk back safely to work."

PRESIDENT DONALD J. TRUMP

INTRODUCTION

On April 16, 2020, the President unveiled *Opening Up America Again* Guidelines, a three-phased approach to reopening based on the advice of public health experts. These Guidelines are helping State and local officials reopen their economies and get people back to work, while protecting the health and safety of the American people.

This Blueprint is designed to facilitate State development and implementation of the robust testing plans and rapid response programs called for in the President's Guidelines. Having these plans and programs in place will help States prevent and contain local outbreaks that may occur as economic and social activities expand across the country.

TESTING ROLES AND RESPONSIBILITIES

This Blueprint describes a partnership between Federal, State, local, and tribal governments, along with the private sector and professional associations, to continue to meet the country's testing needs. The general areas of responsibility within this partnership are:

Federal Government

- Publish guidelines for *Opening Up America Again* and provide a Blueprint for the testing plans and rapid response programs called for by those guidelines.
- Provide strategic direction and technical assistance regarding the best use of available testing technologies.
- In partnership with States, strategically align laboratory testing supplies and capacity with existing and anticipated laboratory needs.
- Provide expedited regulatory authorizations for tests and testing equipment.
- Publish and update procedural guidance for administering diagnostic tests (i.e., prioritization algorithms and protocols).

- In partnership with the private sector, accelerate research and development of innovative diagnostic tests (e.g., rapid, non-invasive Point-of-Care (POC) tests).
- Identify and share best practices and provide technical assistance to State, local, and tribal governments to improve their testing, surveillance, and contact tracing programs.
- Act as supplier of last resort.

State, Local, and Tribal Governments

- Develop testing plans and rapid response programs, as called for by the President's Guidelines.
- Maximize the use of all available testing platforms and venues (e.g., private, public, hospital, clinic-based laboratories).
- Identify and overcome barriers to efficient testing (e.g., underutilization of deployed assets, misallocation of supplies, logistical failures).
- Develop and implement sentinel monitoring and rapid response programs.[1]

Private Sector and Professional Associations

- Develop new technologies.
- Seek emergency use authorization (EUA) for new technologies, as appropriate.
- Accelerate production of tests and materials (e.g., swabs).
- Share data and information from clinical trials with other stakeholders.
- Expand testing partnerships with State, local, and tribal governments.

TESTING PLANS AND RAPID RESPONSE PROGRAMS

Core Principles

Testing plans and rapid response programs will be federally supported, State managed, and locally executed. The following principles should guide States as they develop and execute programs and plans that are tailored to their unique circumstances and challenges:

- Every symptomatic patient should receive a timely and accurate diagnostic test.
- To enable early detection, potential community spread should be actively assessed through a strategic approach that identifies asymptomatic individuals who test positive through sentinel monitoring 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.

[1] 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.

- 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 POC antigen and POC nucleic acid 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 like first responders, essential workers, healthcare providers, and vulnerable populations.
- Data and evidence should drive plan adaptations.

Core Elements

Robust Diagnostic Testing Plans

Robust State diagnostic testing plans will maximize testing across all platforms and venues, with protocols for responding to both localized and widespread outbreaks. States must have systems in place to collect and report critical data, as well as to anticipate and respond to statewide and local testing needs. State plans should also prioritize the testing needs of vulnerable and otherwise high-risk populations, including the elderly and healthcare workers, and address end-to-end logistics of testing and contact tracing (from sample collection to delivery of results). Finally, States should assess the resource needs associated with their plans.

States with robust diagnostic testing plans will be able to ensure that people with symptoms can be tested and receive results within timeframes that are useful for clinical care and public health decision making.

The Federal Government is supporting States by expanding the number of testing platforms, increasing testing and laboratory supplies, unlocking full laboratory capacity, and enhancing sample collection.

- **Expanding the number of testing platforms.** Throughout this pandemic, the Administration has galvanized the private sector to develop new testing technologies. As part of these efforts, the Food and Drug Administration (FDA) has issued 70 EUAs for tests (62 diagnostic tests and 8 serological tests). When appropriate, the FDA has expanded these authorizations to accommodate the use of increasingly innovative testing technologies, such as high-complexity, molecular-based, laboratory-developed tests. In just 2 months, the country has gone from no commercially available tests to millions of such tests being performed on existing platforms. In conjunction, these efforts will increase testing simplicity and speed without compromising quality or reliability.

- **Increasing testing and laboratory supplies.** The Administration has increased the availability of testing and laboratory supplies by working directly with manufacturers and distributors to increase production capacity through direct procurement, application of Titles I and III of the Defense Production Act, formation of public-private partnerships, and improved allocation criteria that help ensure supplies reach the locations where they are needed the most. In addition, the Administration has engaged with hundreds of laboratories across the country to better understand the testing ecosystem and potential shortages of items, including swabs, transport media, and RNA extraction kits. Along with FDA actions to authorize the use of alternative testing supplies, this information has greatly enhanced the ability to efficiently acquire and effectively distribute critical supplies around the country.

- **Unlocking full laboratory capacity.** Even with sufficient supplies, utilization of existing platforms must increase in order to test at full capacity. The Administration has completed a full inventory of all platforms that exist in each State, down to the zip code level. The Administration has also had extensive discussions with some of the Nation's largest laboratory directors and laboratory associations to better understand barriers to testing at full capacity (e.g., underutilization of deployed assets, misallocation of supplies, logistical failures). These conversations have enabled the Administration to work with States to better align supplies and capacity around each State's testing needs and capabilities. As a result of these efforts, States and laboratories are systematically overcoming barriers to maximizing the use of existing platforms, greatly expanding their testing capacity.

- **Enhancing sample collection.** The Administration has partnered with medical experts to improve sample collection. Previously, samples had to be collected from the nasopharyngeal space, which required a licensed provider to probe deeply into the nasal cavity. Today, tests can be administered using a far less intrusive—and far more comfortable—technique that uses a swab of the front of the nose or mouth. In addition to added comfort, these newer approaches enable self-collection and observed self-collection, greatly reducing the amount of personal protective equipment required for testing.

Timely Monitoring Systems

States must be able to proactively monitor for and respond to local outbreaks. This requires leveraging the best available testing methods and technologies to readily identify both symptomatic and asymptomatic cases and to contain outbreaks to isolated geographic areas.

States should make use of well-established, nationwide clinical monitoring systems, such as ILI Net and NSSP, throughout the summer and beyond so they can quickly identify any areas of potential outbreak and surge resources as needed. States can supplement the information from these systems using other clinical monitoring methods, including electronic case

reporting (ECR). By making effective use of this information, State, local, and tribal governments can gain better visibility into critical metrics, including daily cases, hospitalizations, and mortality, and will be better positioned to prioritize testing resources and respond to any outbreak, including by requesting additional Federal support in a timely manner.

States, in coordination with the CDC, must also develop innovative and robust systems to identify asymptomatic cases. This can be accomplished through sentinel monitoring systems at critical locations, including senior and other congregate living settings and Federal and federally supported health clinics (particularly those in underserved urban and tribal settings). Identifying asymptomatic cases in these settings is a high priority because the people who live in them and use them are at high risk for both infection and poor clinical outcomes. To help set up these systems, the Administration is providing technical assistance to all States and territories as they maximize utilization of existing laboratory capacity. The Administration is also working with States to identify other high-priority locations, such as food processing plants, as potential sites for sentinel monitoring.

Rapid Response Programs

States should develop rapid response programs that enable quick isolation and contact tracing of individuals who test positive, whether they are symptomatic or asymptomatic. Anyone who has come into contact with an individual who has tested positive should be screened for symptoms, and those who are symptomatic should be tested.

Contact tracing can be prioritized as follows:

- High-risk exposure contacts (e.g., close contacts).
- Healthcare worker contacts.
- Contacts who work with or are part of a vulnerable population.
- A high volume of low-risk contacts.

Overall, contact tracing can help prevent or contain outbreaks, especially within senior and other congregate living settings in which the residents are particularly vulnerable to rapid spread. It also enables tailored isolation recommendations that apply only to those at heightened risk.

The Administration will provide technical assistance to States so they can trace contacts effectively. To facilitate this support, CDC is operating a new, nationwide program through which community protection teams are assisting State, local, and tribal health departments in performing core public health functions, including epidemiology, monitoring, laboratory analytics, and contact tracing. Every day, CDC is embedding increasing numbers of experts into public health workforces nationwide in support of ongoing contact-tracing efforts.

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Together, these elements of testing plans and rapid response programs will enable State and local officials to quickly isolate cases, respond to local outbreaks, and create confidence that citizens are safe to engage in social and business activities.

PATH FORWARD

In addition to the elements above, the Administration is continuing to improve America's testing capabilities and capacity. As part of these efforts, the Administration is working with diagnostics companies and academic researchers to develop the next generation of tests, testing platforms, and testing protocols.

Antibody testing is a particularly important area of ongoing inquiry. Highly specific and sensitive antibody tests will enable a better understanding of the spread of the virus and identify those who have already been infected. These tests, however, must be very accurate and reliable to guard against false positives, which can lead people to incorrectly believe they had the virus and may be immune from further infection. The Administration is exploring how accuracy and reliability of antibody tests can be improved through the aggregation of two successive tests under certain circumstances (*see* Appendix). States and laboratories should independently validate antibody tests that the FDA has not yet authorized. The FDA will provide technical assistance to States and laboratories upon request.

The Administration is also working to improve the accuracy and speed of diagnostic testing, while simultaneously supporting the development of novel testing platforms that can unlock even more testing capacity. These efforts include the creation of an antigen test that can quickly and accurately detect active infection for use as an effective screening tool. They also involve the development of a simplified, rapid POC nucleic acid test that can be performed in any setting and produce a straightforward "yes or no" answer. Researchers are actively exploring the ability to use genome sequencing as a COVID-19 diagnostic test, which could result in millions of additional tests being completed each day.

Finally, the Administration will update diagnostic testing algorithms and protocols in order to account for seasonality of influenza and other diseases that may occur concurrently. This effort is needed because, in Fall 2020, COVID-19 could co-circulate with influenza or other respiratory viruses. Under this scenario, anyone with an influenza-like illness may be recommended to undergo a testing sequence, a dual antigen test, or a dual nucleic acid test to enable effective diagnoses of COVID-19 even in the context of a co-circulating disease.

CONCLUSION

The Federal Government will continue to support States accelerate testing plans and programs that help enable America to Open Up Again. This Blueprint will help States maximize testing capability and protect health and safety during this pandemic and beyond.

APPENDIX

PREDICTIVE VALUE OF SEQUENTIAL TESTING REGIME

Below are tables demonstrating how the use of two antibody tests rather than one dramatically improves the predictive value of a testing program, particularly in low prevalence environments. Higher positive predictive values (PPV) indicate that you most likely had the disease and produced antibodies in response. Higher negative predictive values (NPV) indicate you do not have antibodies and most likely have not had the disease.

PREVALENCE	30.0%

TEST 1	
Sen1	Sp1
95.0%	95.0%

TEST 1			
%Pos1 (Test1=pos)	**PPV1 for (Test1=pos)**	%Neg1 (Test1=neg)	NPV1 for (Test1=neg)
32.0%	**89.1%**	68.0%	97.8%

TEST 2	
Sen2	Sp2
95.0%	95.0%

TEST 2			
%Pos2 (Test2=pos)	**PPV2 for (Test2=pos)**	%Neg2 (Test2=neg)	NPV2 for (Test2=neg)
32.0%	**89.1%**	68.0%	97.8%

COMBINED					
%Pos (Test1=pos, Test2=pos)	**PPV for (Test1=pos, Test2=pos)**	%Discordant (Test1=pos, Test2=neg)	NPV for (Test1=pos, Test2=neg)	%Neg (Test1=neg)	NPV for (Test1=neg)
27.3%	**99.4%**	4.8%	70.0%	68.0%	97.8%

PREVALENCE	20.0%

TEST 1	
Sen1	Sp1
95.0%	95.0%

TEST 1			
%Pos1 (Test1=pos)	**PPV1 for (Test1=pos)**	%Neg1 (Test1=neg)	NPV1 for (Test1=neg)
23.0%	**82.6%**	77.0%	98.7%

TEST 2	
Sen2	Sp2
95.0%	95.0%

TEST 2			
%Pos2 (Test2=pos)	**PPV2 for (Test2=pos)**	%Neg2 (Test2=neg)	NPV2 for (Test2=neg)
23.0%	**82.6%**	77.0%	98.7%

COMBINED					
%Pos (Test1=pos, Test2=pos)	**PPV for (Test1=pos, Test2=pos)**	%Discordant (Test1=pos, Test2=neg)	NPV for (Test1=pos, Test2=neg)	%Neg (Test1=neg)	NPV for (Test1=neg)
18.3%	**98.9%**	4.8%	80.0%	77.0%	98.7%

PREVALENCE	10.0%

TEST 1	
Sen1	Sp1
95.0%	95.0%

TEST 1			
%Pos1 (Test1=pos)	**PPV1 for (Test1=pos)**	%Neg1 (Test1=neg)	NPV1 for (Test1=neg)
14.0%	**67.9%**	86.0%	99.4%

TEST 2	
Sen2	Sp2
95.0%	95.0%

TEST 2			
%Pos2 (Test2=pos)	**PPV2 for (Test2=pos)**	%Neg2 (Test2=neg)	NPV2 for (Test2=neg)
14.0%	**67.9%**	86.0%	99.4%

COMBINED

%Pos (Test1=pos, Test2=pos)	**PPV for (Test1=pos, Test2=pos)**	%Discordant (Test1=pos, Test2=neg)	NPV for (Test1=pos, Test2=neg)	%Neg (Test1=neg)	NPV for (Test1=neg)
9.3%	**97.6%**	4.8%	90.0%	86.0%	99.4%

PREVALENCE	5.0%

TEST 1	
Sen1	Sp1
95.0%	95.0%

TEST 1			
%Pos1 (Test1=pos)	**PPV1 for (Test1=pos)**	%Neg1 (Test1=neg)	NPV1 for (Test1=neg)
9.5%	**50.0%**	90.5%	99.7%

TEST 2	
Sen2	Sp2
95.0%	95.0%

TEST 2			
%Pos2 (Test2=pos)	**PPV2 for (Test2=pos)**	%Neg2 (Test2=neg)	NPV2 for (Test2=neg)
9.5%	**50.0%**	90.5%	99.7%

COMBINED

%Pos (Test1=pos, Test2=pos)	**PPV for (Test1=pos, Test2=pos)**	%Discordant (Test1=pos, Test2=neg)	NPV for (Test1=pos, Test2=neg)	%Neg (Test1=neg)	NPV for (Test1=neg)
4.8%	**95.0%**	4.8%	95.0%	90.5%	99.7%

PREVALENCE	2.0%

TEST 1	
Sen1	Sp1
95.0%	95.0%

TEST 1			
%Pos1 (Test1=pos)	**PPV1 for (Test1=pos)**	%Neg1 (Test1=neg)	NPV1 for (Test1=neg)
6.8%	**27.9%**	93.2%	99.9%

TEST 2	
Sen2	Sp2
95.0%	95.0%

TEST 2			
%Pos2 (Test2=pos)	**PPV2 for (Test2=pos)**	%Neg2 (Test2=neg)	NPV2 for (Test2=neg)
6.8%	**27.9%**	93.2%	99.9%

COMBINED

%Pos (Test1=pos, Test2=pos)	**PPV for (Test1=pos, Test2=pos)**	%Discordant (Test1=pos, Test2=neg)	NPV for (Test1=pos, Test2=neg)	%Neg (Test1=neg)	NPV for (Test1=neg)
2.1%	**88.0%**	4.8%	98.0%	93.2%	99.9%

PREVALENCE	1.0%

TEST 1

Sen1	Sp1
95.0%	95.0%

TEST 1

%Pos1 (Test1=pos)	**PPV1 for (Test1=pos)**	%Neg1 (Test1=neg)	NPV1 for (Test1=neg)
5.9%	**16.1%**	94.1%	99.9%

TEST 2

Sen2	Sp2
95.0%	95.0%

TEST 2

%Pos2 (Test2=pos)	**PPV2 for (Test2=pos)**	%Neg2 (Test2=neg)	NPV2 for (Test2=neg)
5.9%	**16.1%**	94.1%	99.9%

COMBINED

%Pos (Test1=pos, Test2=pos)	**PPV for (Test1=pos, Test2=pos)**	%Discordant (Test1=pos, Test2=neg)	NPV for (Test1=pos, Test2=neg)	%Neg (Test1=neg)	NPV for (Test1=neg)
1.2%	**78.5%**	4.8%	99.0%	94.1%	99.9%

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