

TESTING OVERVIEW

OPENING UP

 AMERICA AGAIN



THE CHALLENGE

This is the **first time in history** that the United States Government has ever scaled a testing regime to meet the massive needs of a nationwide pandemic



MOBILIZING ALL OF AMERICA'S RESOURCES

ROLES & RESPONSIBILITIES

FEDERAL GOVERNMENT

Enable Innovation, Scale Supplies, and Provide Strategic Guidance

STATE GOVERNMENTS

Formulate and Implement Testing Plans

PRIVATE SECTOR

Develop and Produce Supplies and Services to Meet Needs of States



8-PART PLAN



STAGE 1: LAUNCH

- ✓ 1. Build the foundation for diagnostic testing
- ✓ 2. Mobilize the private sector to develop tests
- ✓ 3. Issue Emergency Use Authorizations (EUAs) for tests
- ✓ 4. Galvanize commercial and research laboratories and professional associations to ramp up testing capacity
- ✓ 5. Facilitate State efforts to access and utilize all available testing capacity

STAGE 2: SCALE

- ✓ 6. Identify and expand public and private-sector testing infrastructure
- ✓ 7. Strengthen testing supply chain

STAGE 3: SUPPORT OPENING UP AGAIN

- 8. Coordinate with governors to support testing plans and rapid response programs

OPENING UP AMERICA AGAIN BY ACCELERATING TESTING

The Federal Government is helping States ramp up testing capacity as outlined in the President's *Opening Up America Again* Guidelines

 OPENING UP AMERICA AGAIN

Core State Preparedness Responsibilities

TESTING & CONTACT TRACING <ul style="list-style-type: none">✓ Ability to quickly set up safe and efficient screening and testing sites for symptomatic individuals and trace contacts of COVID+ results✓ Ability to test Syndromic/ILI-indicated persons for COVID and trace contacts of COVID+ results✓ Ensure sentinel surveillance sites screening for asymptomatic cases; contacts for COVID+ results are traceable and operate at locations that serve older individuals, lower-income Americans, minorities, and Native Americans)	HEALTHCARE SYSTEM CAPACITY <ul style="list-style-type: none">✓ Ability to quickly and independently supply sufficient Personal Protective Equipment and critical medical equipment to handle dramatic surge in need✓ Ability to surge ICU capacity PLANS <ul style="list-style-type: none">✓ Protect the health and safety of workers in critical industries
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States Must Prepare

TESTING & CONTACT TRACING Safe and efficient screening and testing sites for symptomatic individuals and trace contacts
HEALTHCARE SYSTEM CAPACITY Independently supply sufficient Personal Protective Equipment and critical medical equipment Ability to surge ICU capacity
PLANNING Including: Health and safety of workers in critical industries Monitor conditions and mitigate any rebound or outbreaks





CORE ELEMENTS OF TESTING PLANS

ROBUST DIAGNOSTIC TESTING PLANS

Ensure capability to overcome barriers to efficient testing and inform clinical care and public health decision-making.

TIMELY MONITORING SYSTEMS

Identify any newly emergent cases or clusters of COVID-19 among symptomatic and asymptomatic individuals.

RAPID RESPONSE PROGRAMS

Develop and implement effective isolation and contact tracing strategies for newly diagnosed COVID-19 cases.

STAGE 1: LAUNCH

✓ 1. Build the foundation for diagnostic testing

The Centers for Disease Control and Prevention (CDC) has determined the molecular composition of the virus and published this information in a public database for researchers to use to develop diagnostic tests.

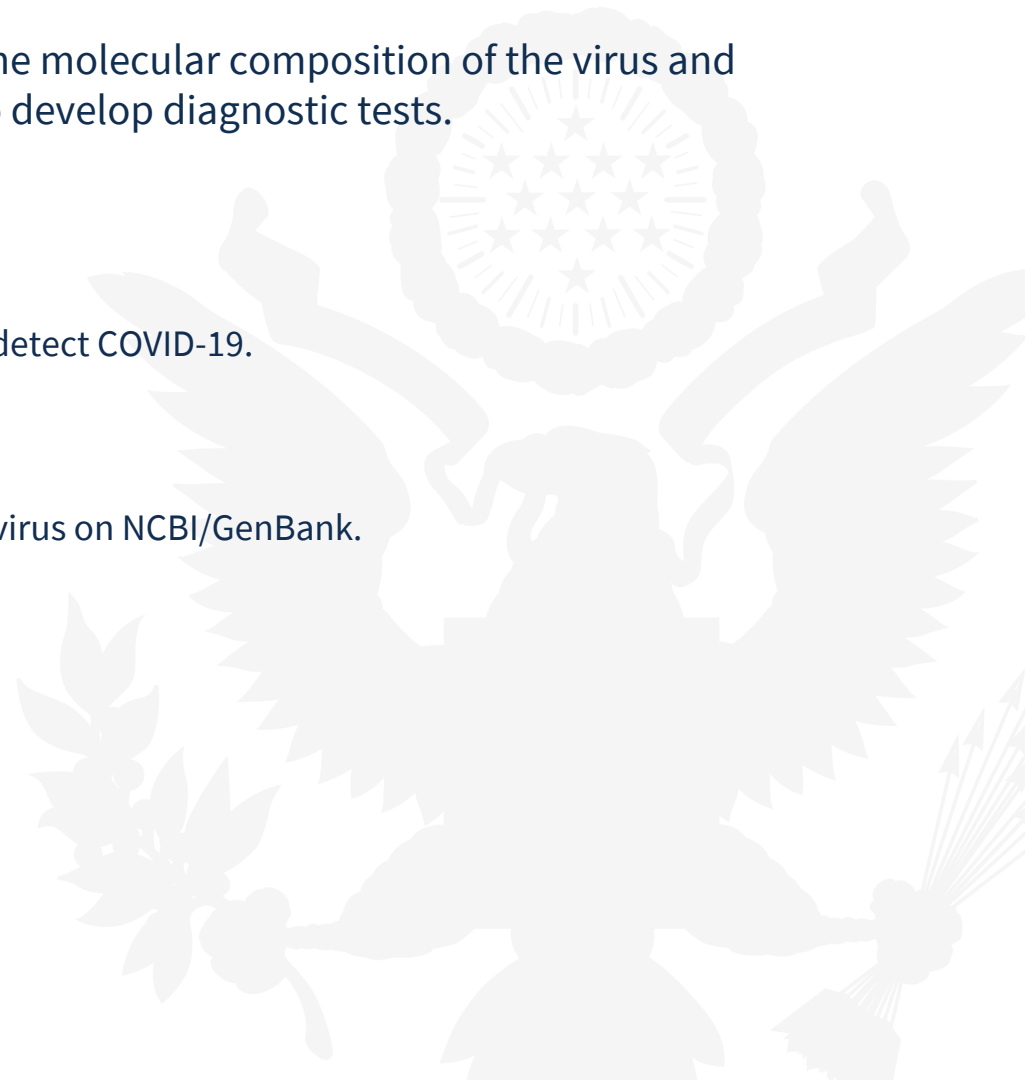
KEY DATES

January 10: CDC begins developing a test for public health laboratories to use to detect COVID-19.

January 18: CDC begins to test specimens for COVID-19.

January 20: CDC confirms the first case of COVID-19 in the United States.

January 24: CDC publishes the genetic sequence of the first domestic case of the virus on NCBI/GenBank.



STAGE 1: LAUNCH

✓ 2. Mobilize the private sector to develop tests

The Food and Drug Administration (FDA) has worked with more than 380 test developers who have indicated their intent to submit requests for EUAs for tests that detect the virus or antibodies to the virus.

The FDA has helped streamline the review process, including by:

- ✓ *Publishing immediately-in-effect guidance for policies specific to this public health emergency*
- ✓ *Providing templates to facilitate EUA submission*
- ✓ *Holding weekly virtual town halls to answer questions from developers*

KEY DATES

January 21: The Biomedical Advanced Research and Development Authority (BARDA) convenes leading diagnostics companies to encourage development of COVID-19 tests.

February 15: BARDA announces funding opportunities for developing COVID-19 diagnostic tests.

February 21: The National Institutes of Health (NIH) provides COVID-19 RNA to diagnostics companies to expedite private-sector test development.

February 29: FDA permits immediate use of laboratory-validated tests, rapidly expanding testing capacity.

March 4: The Vice President and senior Administration officials convene meeting with leading diagnostics companies.

March 7: FDA updates EUA template for laboratories.

March 12: FDA updates EUA template for manufacturers.

STAGE 1: LAUNCH

✓ 3. Issue EUAs for tests

FDA has facilitated scaling of testing capacity to address the public health emergency.

KEY DATES

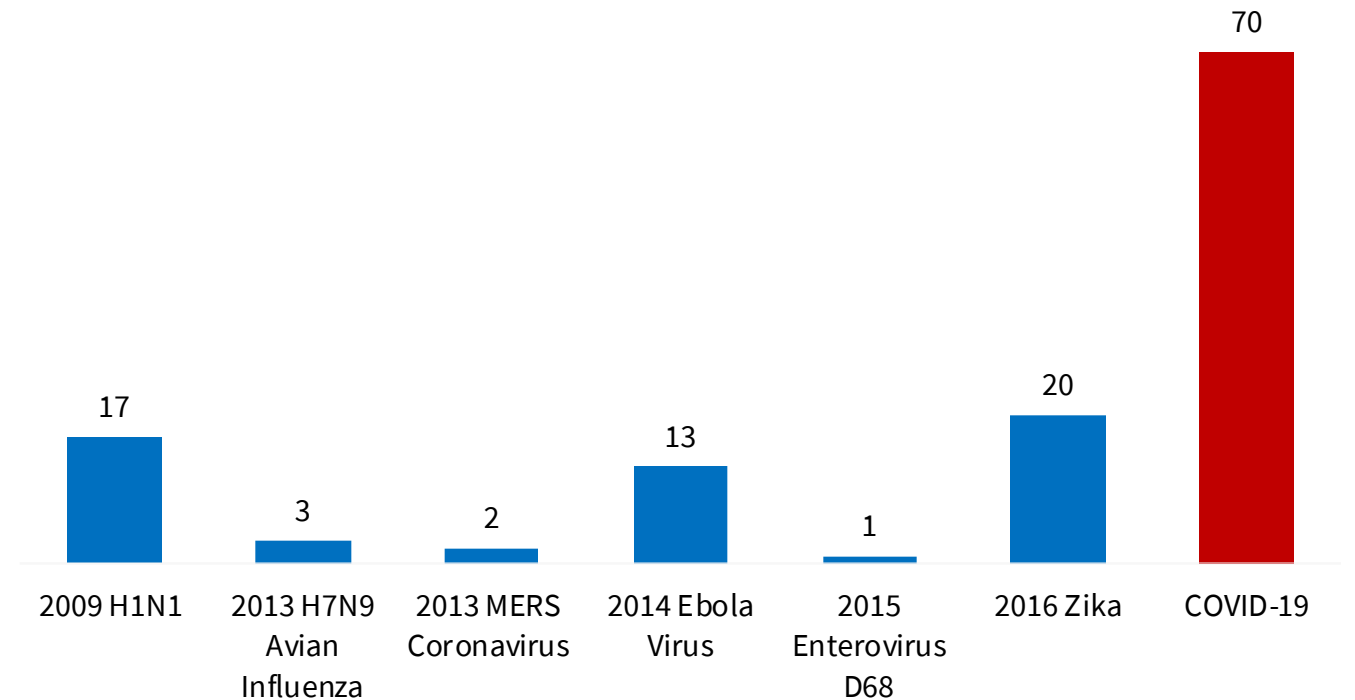
March 13: FDA issues an EUA for Roche's cobas COVID-19 test within 24 hours of receiving the application.

March 18: FDA issues the first emergency use authorization for a point-of-care COVID-19 diagnostic test (Abbott).

April 21: FDA authorizes the first COVID-19 diagnostic test with a home collection option (LabCorp).

As of April 27: FDA has issued 70 EUAs (62 for molecular tests and 8 for serological tests).

Testing EUAs for Viral Outbreaks

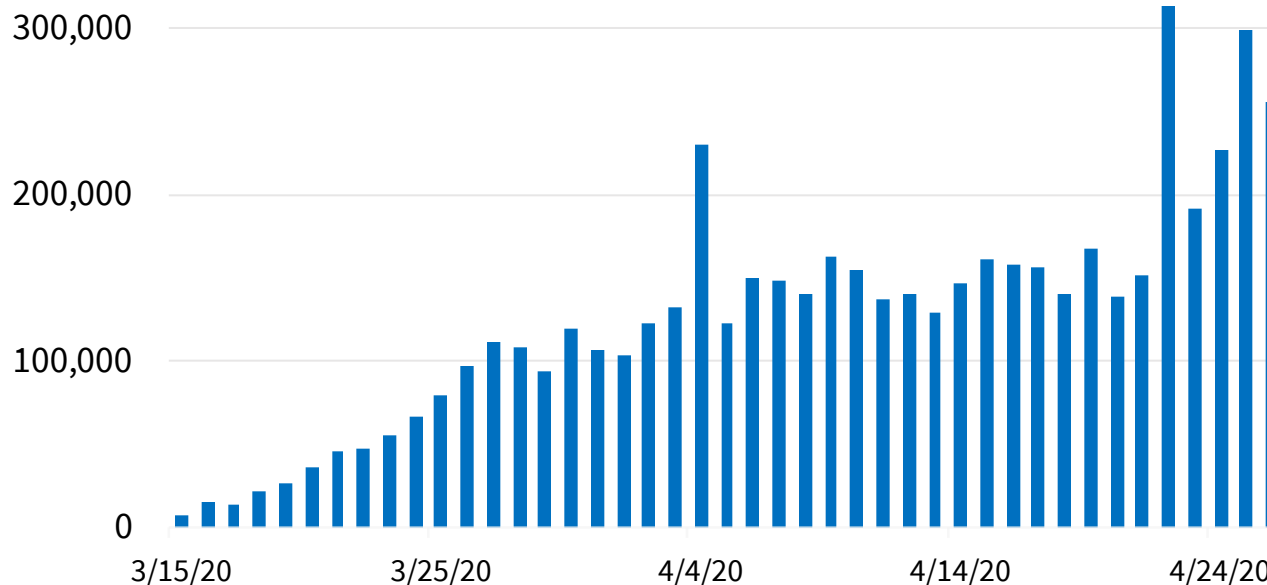


Source: FDA

STAGE 1: LAUNCH

- ✓ **4. Galvanize commercial and research laboratories and professional associations to ramp up testing capacity**
The Administration has encouraged diagnostic test manufacturers, commercial laboratories, and professional societies to expand capacity for existing nucleic acid testing platforms.

United States Daily Tests



Source: The COVID Tracking Project

KEY DATES

March to Early April: The Administration, in consultation with large diagnostic test manufacturers, identifies locations of laboratory-based machines in the country.

April 17: The Administration convenes meeting with the American Society for Microbiology to facilitate enhanced utilization of existing nationwide laboratory capacity.

Ongoing: The Administration is providing technical assistance to all States and territories as they maximize utilization of existing laboratory capacity.

STAGE 1: LAUNCH

✓ 5. Facilitate State efforts to access and utilize all available testing capacity

The Administration has reached out to governors to help them better utilize the testing capacity within their States.

KEY DATES

January to Present: The President, Vice President, and senior Administration officials hold more than a dozen governors-only briefings, many of which have focused on joint Federal-State efforts to expand testing throughout the country. In addition, the White House organizes numerous calls to enhance testing coordination efforts at the State, local, and tribal levels.

April 21: The White House organizes a briefing call between key senior Administration officials and large diagnostic test manufacturers (Abbott, Roche, and Thermo Fischer Scientific) with governors' senior staff, state health officers, state lab officials, state epidemiologists, and state emergency managers on near-term COVID-19 testing priorities.

By April 25: The Administration finalizes a database of nationwide laboratory capacity and publishes maps displaying their locations. The Administration also conducts at least one individual working session with every State to provide advice about testing capacity, including the location of specific testing platforms.

STAGE 2: SCALE

✓ 6. Identify and expand public and private-sector testing infrastructure

The Administration has supported and expanded the public and private-sector testing infrastructure to accelerate testing in communities across the country.

KEY DATES

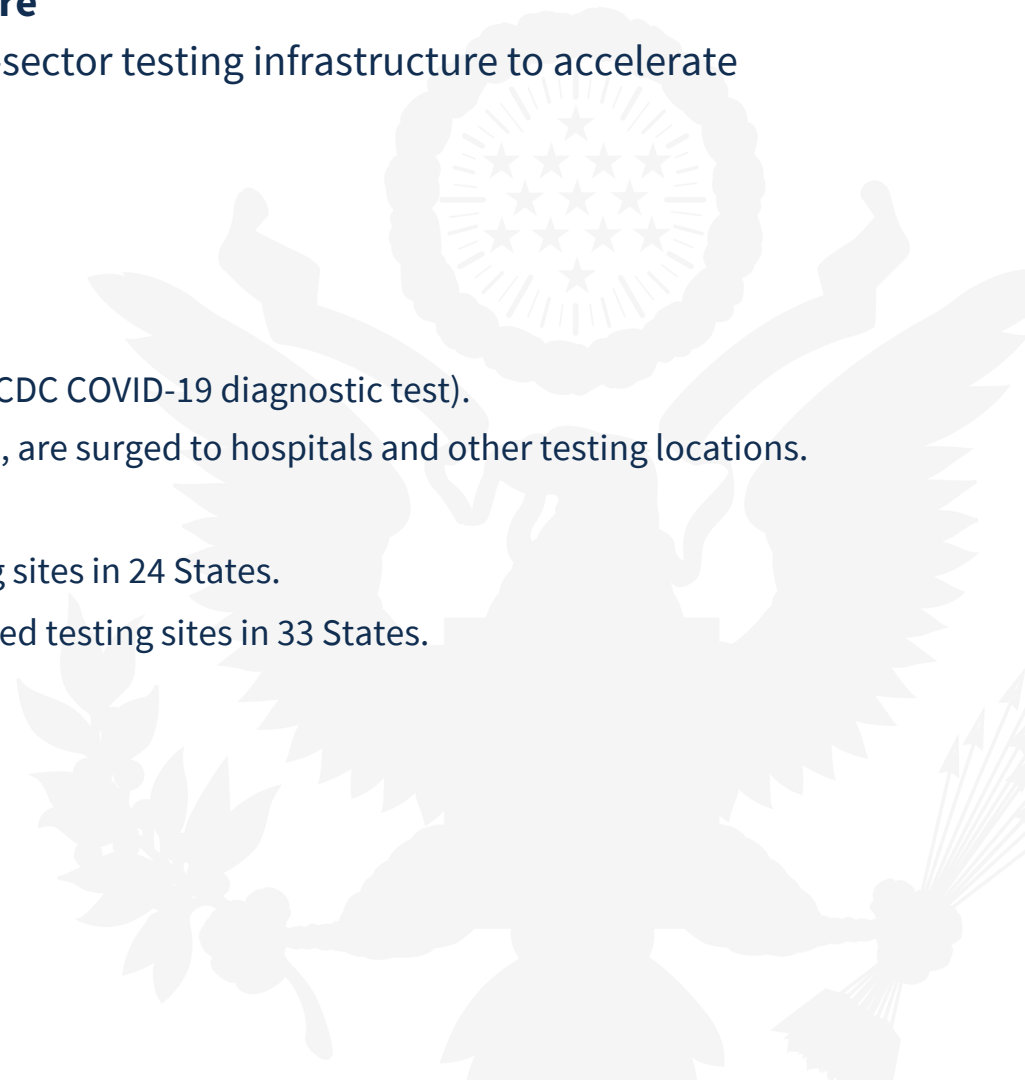
February 29: FDA authorizes New York state laboratory diagnostic test (first non-CDC COVID-19 diagnostic test).

Early March to Present: Millions of new tests, including Point-of-Care (POC) tests, are surged to hospitals and other testing locations.

March 19: CVS launches the first retail-based testing site in Massachusetts.

As of April 25: United States retailers are operating 80 federally supported testing sites in 24 States.

By May 1: United States retailers will be operating a total of 100 federally supported testing sites in 33 States.



STAGE 2: SCALE

✓ 7. Strengthen testing supply chain

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.

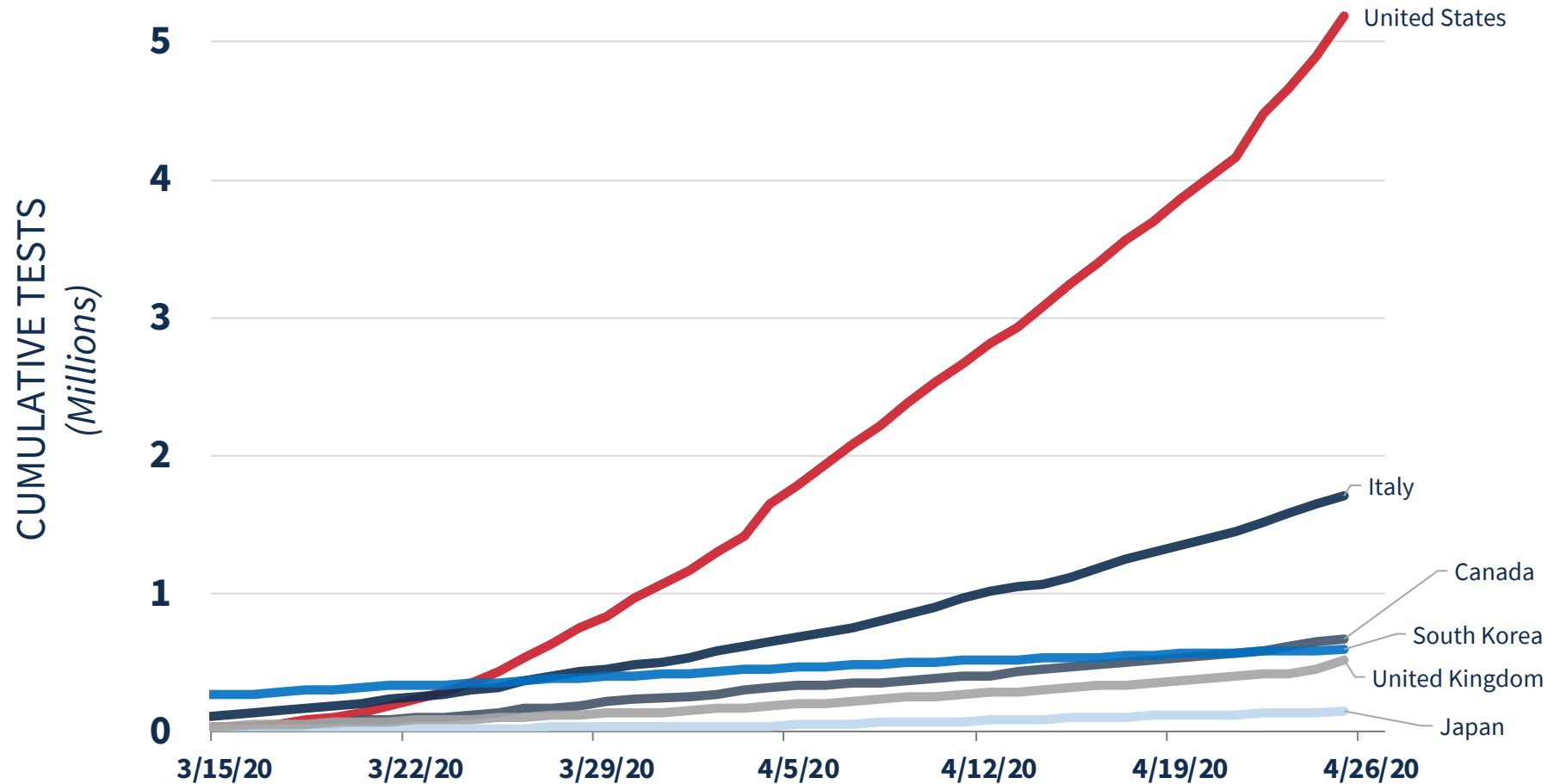
KEY ACTIONS (Ongoing)

- ✓ More than **5.2 million tests** have been performed in the United States.
- ✓ Private laboratory testing supply companies ramp up manufacturing capacity of **extraction kits, PCR kits, and reagents**.
- ✓ The Federal Government partners with multiple companies to expand domestic production of critical specimen collection supplies such as **swabs and collection tubes**.
- ✓ The Federal Government has directly procured **6.7 million swabs, 3.3 million transport media, 15 million lancets, and 15 million alcohol pads**.
- ✓ **Project AirBridge** has completed 86 flights, with 26 more scheduled for the near future, which have transported **71.3 million masks, 8.5 million gowns, and 724.8 million gloves** to the United States from countries around the world. In total, the Federal Government has facilitated the nationwide delivery of **175.2 million masks, 14.7 million gowns, and 793.8 million gloves**.

TOTAL TESTS CONDUCTED BY COUNTRY

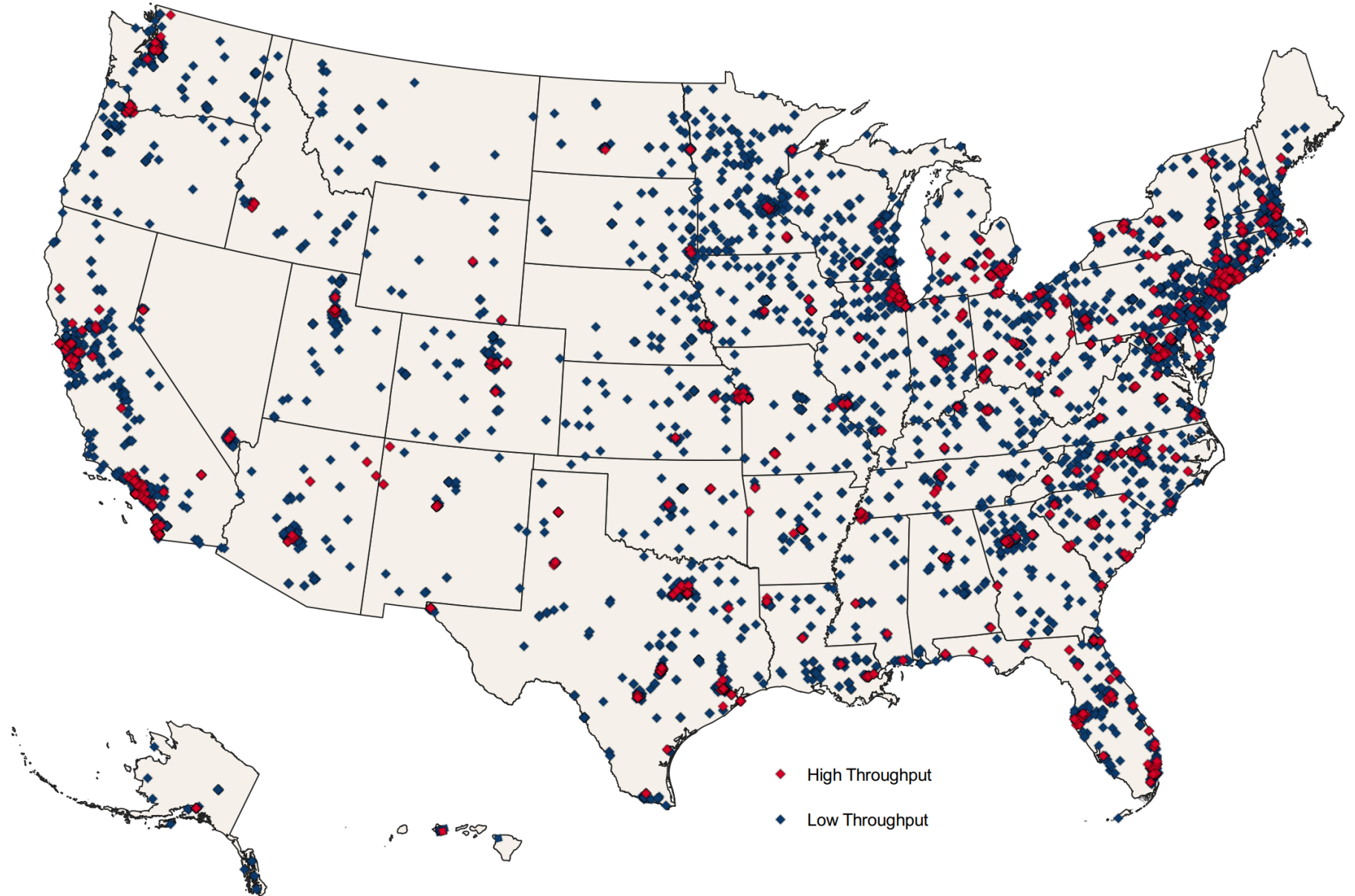


The United States has conducted more tests than Australia, Austria, Canada, France, India, Italy, Japan, Singapore, Sweden, South Korea, and the United Kingdom combined.



Source: University of Oxford, Our World in Data.

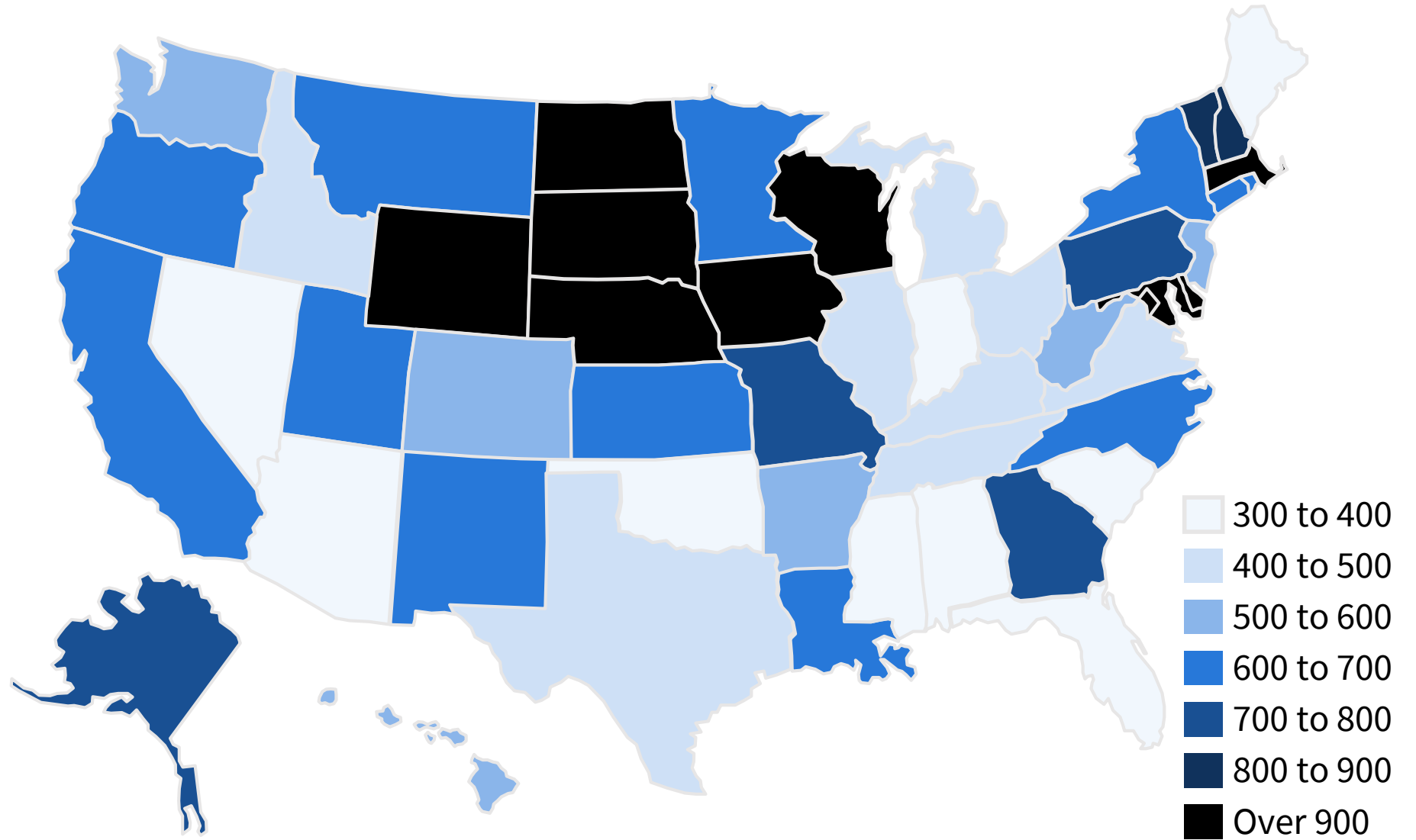
COVID-19 LABORATORY TESTING CAPACITY



- ◆ High Throughput
- ◆ Low Throughput

Source: Based on data provided to the Department of Health and Human Services (HHS) from select diagnostics companies

**MONTHLY
TESTING
CAPACITY PER
1,000 PEOPLE**



Source: Based on data provided to HHS from select diagnostics companies

STAGE 3: SUPPORT OPENING UP AGAIN

○ 8. Coordinate with governors to support testing plans and rapid response programs

The Administration has provided a Blueprint that describes roles and responsibilities, as well as principles and elements of the robust testing plans and rapid response programs called for in the President's Guidelines.

CONTINUED FEDERAL GOVERNMENT SUPPORT WILL INCLUDE:

- Providing **expedited regulatory approvals** for tests and testing equipment.
- Publishing and updating **procedural guidance** for administering diagnostic tests (i.e., prioritization algorithms and protocols).
- In partnership with the private sector, accelerating **research and development of innovative diagnostic tests**, such as:
 - Highly specific and sensitive **antibody tests**.
 - An **antigen test** to detect active infection quickly and accurately.
 - Advancing simplified, rapid **POC nucleic acid testing**.
 - **Genomic sequencing technology**.
- Identifying and sharing **best practices** and providing **technical assistance** to State, local, and tribal governments to improve their testing, surveillance, and contact tracing programs.
- Acting as **supplier of last resort**.

PATH FORWARD

The Federal Government will continue to support State efforts to accelerate testing plans and programs that help enable America to Open Up Again

