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 the Supplies and Services Required to Meet State Needs

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

Core Elements of Testing Plans

ROBUST DIAGNOSTIC TESTING PLAN

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

TIMELY MONITORING SYSTEM

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

RAPID RESPONSE PROGRAM

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

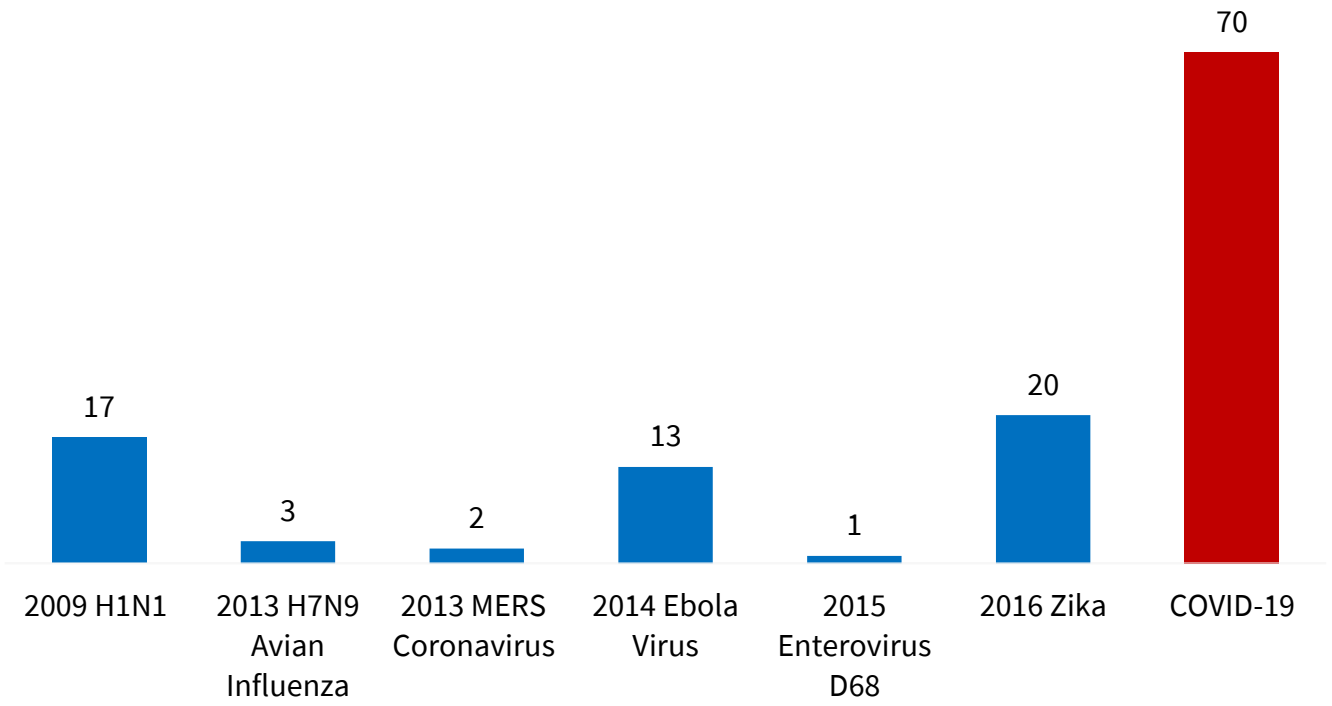
March 13: FDA issued an EUA for Roche's cobas COVID-19 test within 24 hours of receiving the application.

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

April 21: FDA authorized 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

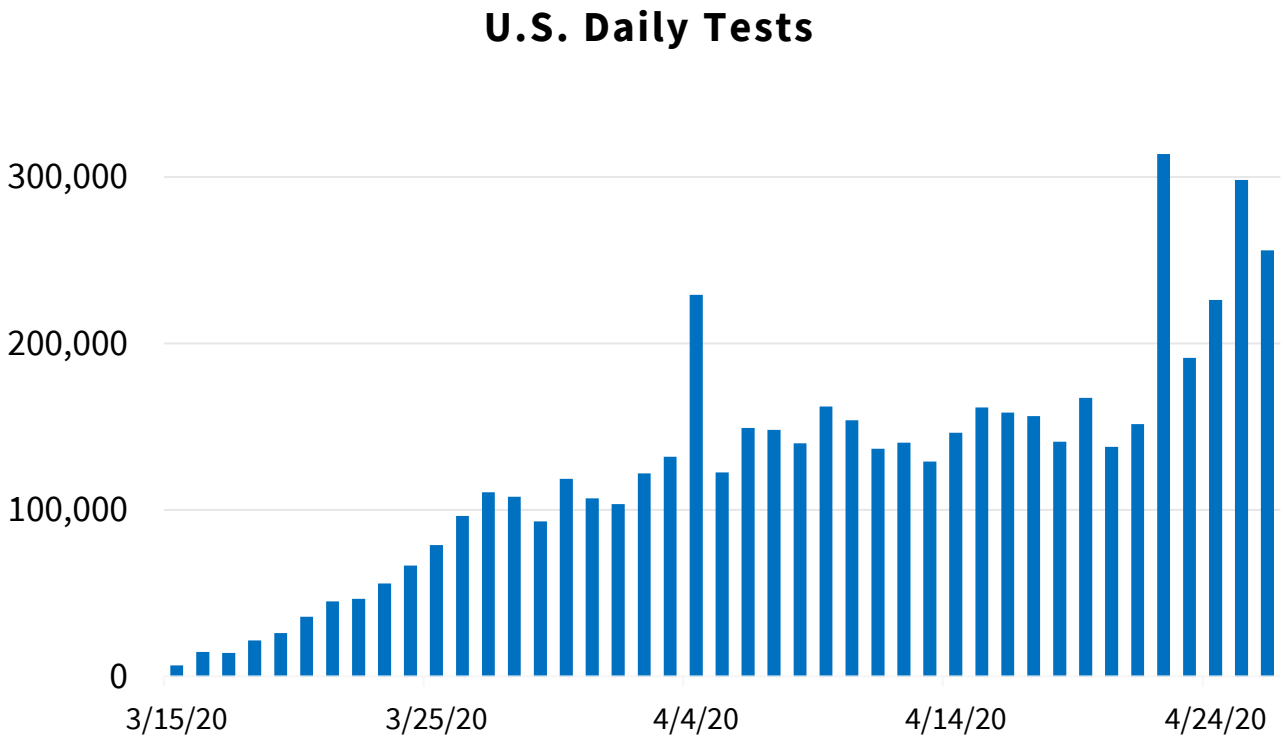


Source: FDA

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.



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

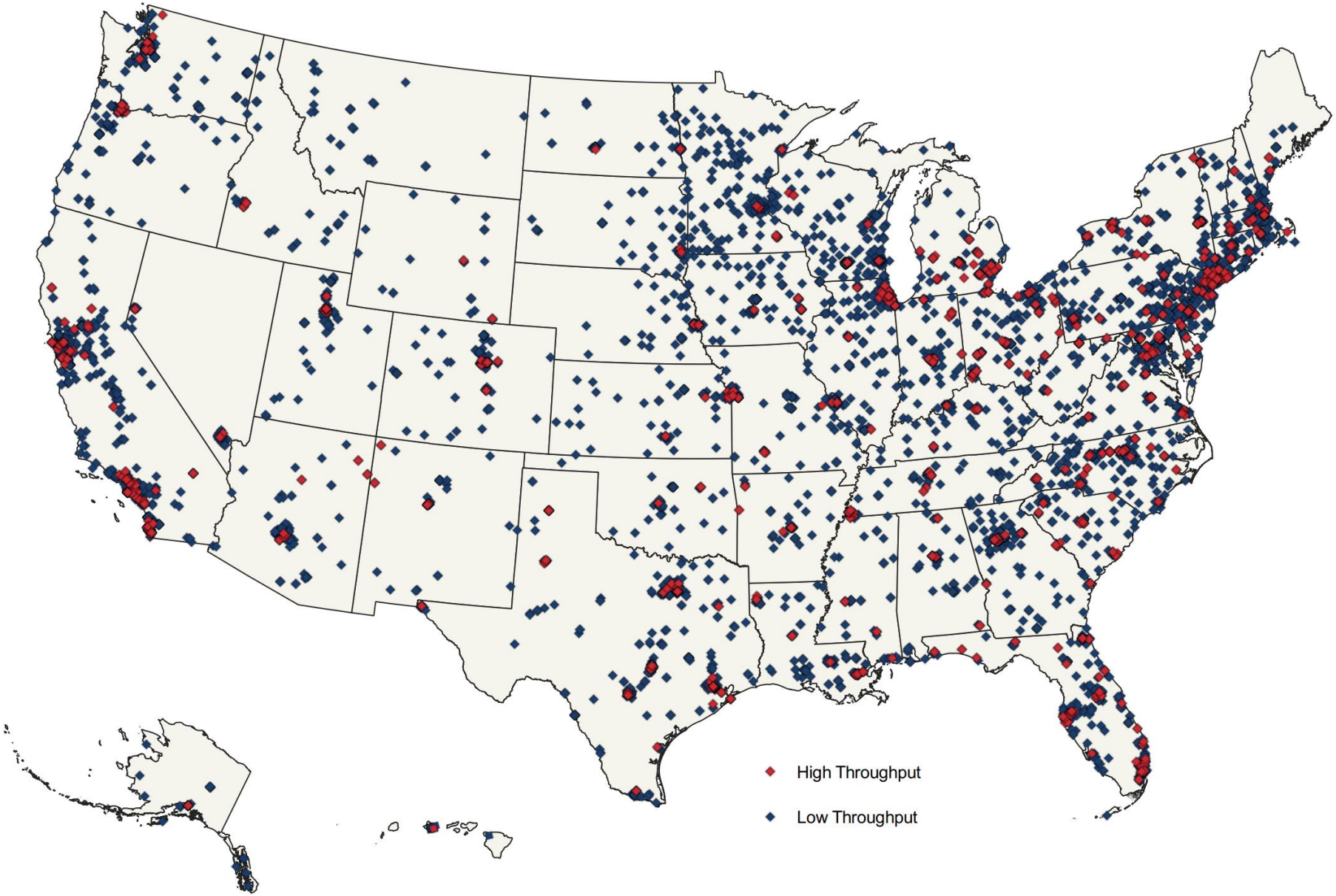
The Administration has increased the availability of testing and laboratory supplies by working directly with manufacturers and distributors to increase production capacity through direct procurement, application of Titles I and III of the Defense Production Act, formation of public-private partnerships, and improved allocation criteria that help ensure supplies reach the locations where they are needed the most.

> **The United States has processed more than 5.2 million samples. That is more than the combined total of Australia, Austria, Canada, France, India, Italy, Japan, Singapore, Sweden, South Korea, and the United Kingdom.**

KEY ACTIONS *(Ongoing)*

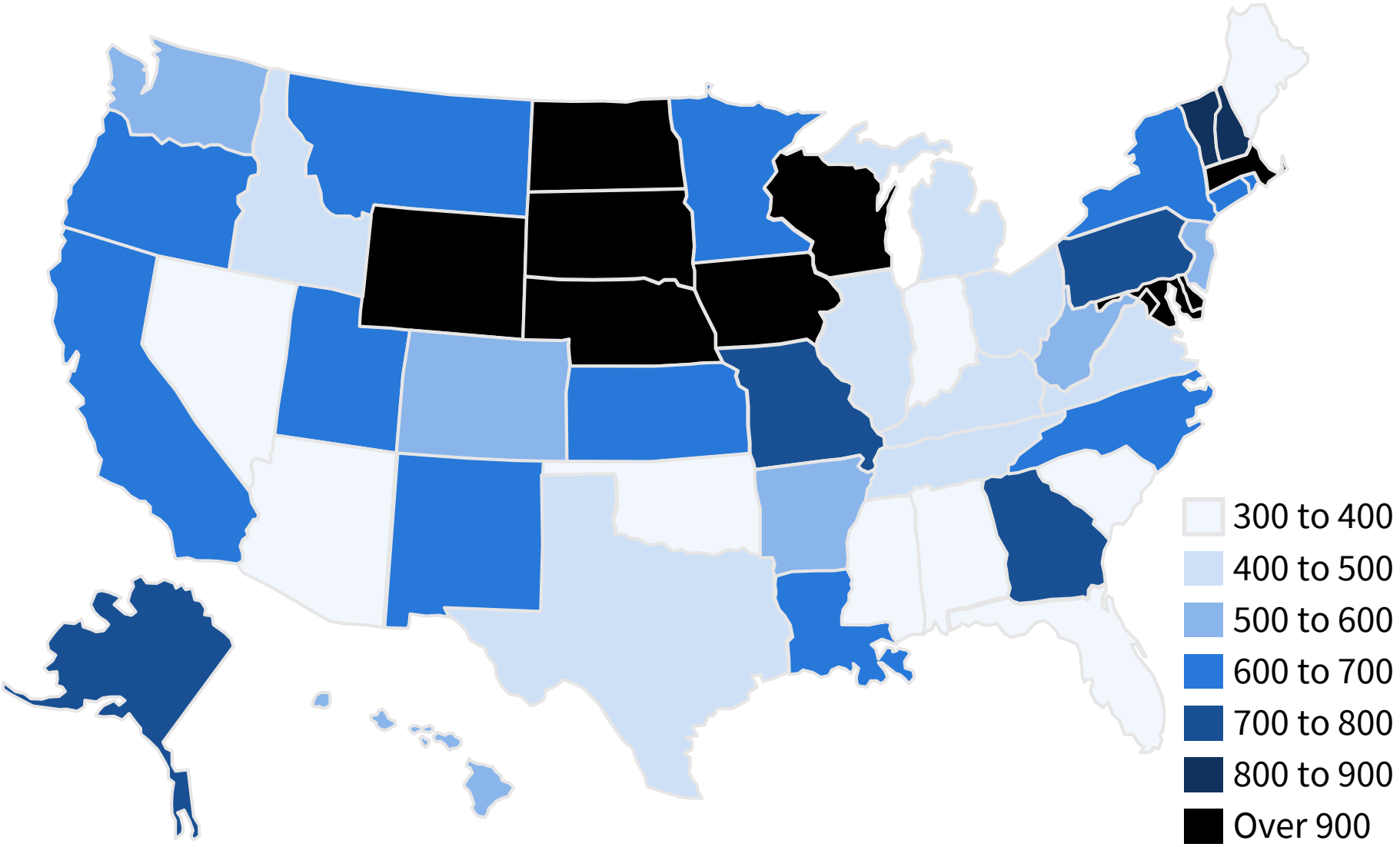
- ✓ **Project AirBridge** has completed 86 flights with 26 more scheduled for the near future transporting **71.3 million masks, 8.5 million gowns,** and **724.8 million gloves** to the United States from countries around the world. In total, the Federal Government has facilitated the nationwide delivery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

COVID-19 LABORATORY TESTING CAPACITY



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

MONTHLY TESTING CAPACITY PER 1,000 PEOPLE



Source: Based on data provided to HHS from selected diagnostic 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