Capacity for COVID-19 Testing
Current Status and Considerations

Read the full memo here

Overview of Major Updates As of May 14

Federal Updates

State Testing Plans Due to HHS

States are required to submit COVID-19 plans for testing, contact tracing, surveillance and related activities under the April 24 Paycheck Protection Program and Healthcare Enhancement Act. On May 14, HHS sent a letter requiring states to submit testing plans by May 30, 2020 along with a template with additional information. Each plan must align with the Opening Up America Again Guidelines. Designated funds will be distributed based on a formula that considers the states' population as well as prevalence of COVID-19. The White House also announced that states should aim to test 2% of their populations in May and that they will provide 12.9 million swabs and 10 million tubes of transport media.

FDA Issues new Emergency Use Authorizations (EUAs)

- The Food and Drug Administration (FDA) issued the first EUA for an antigen test from Quidel Corporation for samples taken by nasal swab on May 9. Antigen tests look for pieces of the virus in samples. The tests are rapid and very good at identifying positive results but the FDA notes that negative results may need to be confirmed.
- Rutgers University RUCDR Infinite Biologics received EUA for at home saliva sample collection on May 8.
- FDA issued an EUA for the first CRISPR-based diagnostic test to Sherlock BioSciences, Inc. on May 6.

HRSA Awards $583 Million to Health Centers for COVID-19 Testing

The Health Resources and Services Administration (HRSA) awarded nearly $583 million to 1,385 HRSA-funded health centers across the states and territories on May 7, as authorized under the April 24 Paycheck Protection Program and Health Care Enhancement Act. Find the list of award recipients here.

FDA Updated Guidance on Serology Testing Approvals

- The FDA released updated guidance on serology tests on May 4, which now requires manufacturers producing serology tests to submit an EUA request to FDA.
- FDA also released a new webpage that lists the serology tests that have received EUA and information on their performance as reported during the EUA process.
- FDA announced that with the National Cancer Institute they will begin independently validating certain antibody tests, including those that were not the subject of an EUA and those under FDA review.

CDC Testing Priority Guidelines Updated

The Centers for Disease Control and Prevention (CDC) updated their guidance on testing for COVID-19 on May 4. The updated guidance continues to prioritize hospitalized patients, healthcare workers, and residents in congregate living settings and has expanded to prioritize any high priority groups identified by public health officials or clinicians.

CMS No Longer Requires Physicians Order for Testing

The Centers for Medicare and Medicaid Services (CMS) announced on April 30, that COVID-19 testing no longer requires a physician's order for reimbursement by Medicare, facilitating collection in the community.

DPA Contract Awarded for Swabs

The Department of Defense announced on April 29, that Puritan Medical Products was awarded a $75 million Defense Production Act (DPA) Title 3 contract to increase swab production by 20 million per month, bringing their total production to 40 million swabs per month starting in May.

NIH Rapid Acceleration of Diagnostics (RADx) "Shark Tank" Program

The National Institutes of Health (NIH) announced their RADx program, which will include a national competition in the style of "shark tank" with participants vying for a portion of the $500 million fund. NIH aims to have the resulting tests deployed by the end of summer or early fall after validation, clinical tests, and scale up.

White House Testing Overview and Blueprint

The White House released the Opening Up America Again Testing Overview and Blueprint on April 27 to accompany the president's Guidelines for Opening Up America Again. The plan reinforces that the federal government is the supplier of last resort.

State and Industry Updates

State Testing Priority Guidance

As testing capacity continues to expand and some states move towards reopening, states (e.g., Utah, North Dakota, Wisconsin) are increasingly expanding their testing priority guidance to include essential workers and others who are symptomatic.

Updated Estimates of State Testing Needs

Harvard's Global Health Institute released updated estimates of the number of tests that states should aim to be completing per day by May 15 in order to safely reopen parts of their state. They estimate the U.S. should be doing more than 900,000 tests per day (the U.S. is currently testing around 250,000 per day, according to data from the COVID Tracking Project). Importantly, each state's specific testing needs vary based on the size of the outbreak in their communities. The estimates serve as a minimum, since they assume that physical distancing will continue through May 15 and several states have begun lifting restrictions. The authors note that testing alone should not be the deciding factor in whether to reopen, but is an important component with case numbers and adequate contact tracing and isolation supports.

Mobile Testing

States (e.g., New York and Utah), localities (e.g., Seattle, New Orleans, Harrisonburg), and the commercial sector are beginning mobile testing to facilitate access for communities of color and low-income Americans.

Community-based testing sites

HHS created a new webpage with information on community-based testing sites in partnership with retail and pharmacy chains. Rite Aid and CVS also announced their plans to open testing sites at existing store locations utilizing parking lots and drive through windows. Rite Aid also expanded COVID-19 testing criteria at all of their testing sites to include adults who are not exhibiting any symptoms of the virus.

Serology updates

- Preliminary antibody results are reported from New York, Santa Clara, California, and Miami, Florida. Preliminary results demonstrate that actual infection rates are far greater than indicated.
- Twelve serology tests have now received EUA from the FDA. One of the most recent to receive approval is from Roche Diagnostics and claims to be very accurate with 100% sensitivity and 98% specificity. Roche announced that they will be able to produce tens of millions of tests per month by June.
- Recent independent reports from the Johns Hopkins Center for Health Security and the Infectious Disease Society of America emphasize that while validation of current tests continue and outstanding questions about protective immunity remain, serology testing is currently most appropriate for surveillance and research and not for diagnosis or staffing decisions. Both reports highlight important privacy, legal, and ethical considerations of using serologic testing for immunity passports.

Interpretation of COVID-19 Testing Results

A recent article in JAMA provides information on interpreting the results of COVID-19 testing and includes a helpful graphic (at right) that estimates when certain test types and sample collection methods are most accurate.