AdvaMedDx
Vital Insights | Transforming Care

July 29, 2020

Re: Policy Recommendations to Broaden Access to COVID-19 Testing

The Honorable Nancy Pelosi
Speaker of the House
U.S. Capitol Building, H-222
Washington, D.C. 20515

The Honorable Mitch McConnell
Senate Majority Leader
U.S. Capitol Building, S-230
Washington, D.C. 20510

The Honorable Kevin McCarthy
House Minority Leader
U.S. Capitol Building, H-204
Washington, D.C. 20515

The Honorable Charles Schumer
Senate Minority Leader
U.S. Capitol Building, S-221
Washington, D.C. 20510

Dear Speaker Pelosi, Majority Leader McConnell, Leader McCarthy and Leader Schumer:

On behalf of AdvaMedDx, I am writing to share our industry's recommendations to help ensure our nation is positioned to address the public health crisis caused by the coronavirus (COVID-19) outbreak by broadening access to COVID-19 diagnostic testing. AdvaMedDx, a division of the Advanced Medical Technology Association (or AdvaMed), represents the world's leading diagnostic test manufacturers of innovative, quality clinical diagnostic tests serving as essential front-line tools in the fight against COVID-19.

Since the start of the pandemic, the *in vitro* diagnostic (IVD) industry has stepped up to rapidly develop and manufacture innovative diagnostic tests at scale to ensure that clinicians and health officials have the full suite of diagnostic testing available to them – including molecular diagnostics, antigen detection, serology (antibody), and next generation sequencing (NGS) testing – to guide patient care and protect public health. The leading IVD manufacturers are now collectively shipping over 870,000 molecular tests each day to hospitals and laboratories across the U.S. – totaling over 80 million tests shipped since March – enabling nationwide COVID-19 testing rates to surpass 700,000 tests per day. AdvaMedDx members have dramatically increased the pace of research and development – bringing quality tests to market in just months when it typically takes 3-5 years. Over 100 COVID-19 IVDs have received FDA emergency use authorization since March.

As we look ahead, we are focused on doing our part to flatten the curve, including continued ramp up of testing to help us continue the important work of determining how Americans can safely return to work and school. As you continue to work on the next coronavirus relief package, we ask that you consider the following policy recommendations to expand access critical COVID-19 testing:

- Strengthen coverage of testing: Congress should clarify that coverage for COVID-19 testing (including molecular, antigen, serology, next generation sequencing, and any COVID-19 testing included in respiratory panels) is for symptomatic, presymptomatic and asymptomatic individuals regardless of sites of care/service, regardless of a clinician order during the public health emergency (PHE) and extend up to 18 months beyond the PHE. Coverage should be available for both single and multi-target viral panels (e.g., include tests that would differentiate co-circulating viruses during flu season, such as Influenza A/B, respiratory syncytial virus (RSV) and SARS-CoV2. Specifically, coverage should include repeat and parallel testing (simultaneous diagnostic and serological testing) without restrictions by all public and private payers.

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- Bolster reimbursement for COVID-19 testing: All screening and diagnostic testing for symptomatic, presymptomatic and asymptomatic individuals should be reimbursed at rates not less than Medicare, for all public and private health plans, including plans on the federal exchange, regardless of sites of care/service, regardless of an order from a treating physician or non-physician practitioner.

- Ensure appropriate federal funds for testing: Congress should appropriate federal funding to help cover the cost for COVID-19 testing used for surveillance. Further, Congress should provide full federal support for Medicaid plans for all COVID-19 testing for Medicaid, SCHIP and Uninsured: Plans should be reimbursed 100 percent by the federal government. State Medicaid plans, for example, should receive 100 percent Federal Medical Assistance Percentage (FMAP) for all Medicaid and State Children's Health Insurance Program (SCHIP) covered lives and for the cost of testing provided to uninsured individuals.

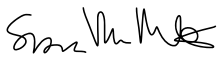
- Freeze future Medicare cuts to the Clinical Laboratory Fee Schedule (CLFS): Building upon the CARES Act and in recognition of the flawed implementation of the Protecting Access to Medicare Act (PAMA) of 2014, Congress should further delay any Medicare cuts to the CLFS cuts until such time as a new framework for establishing payment rates for diagnostic tests can developed.

- Access to Samples: The HHS Secretary should establish a streamlined process for IVD manufacturers and other test developers to access viral samples, to complement CDC development efforts and ensure diversification of testing development and capacity. Delays in access to viral samples can impede rapid development of tests, especially in cases where developers must rely on a single source for samples.

- Utilizing EUA Data and Real-World Evidence: During this public health emergency, sponsors of a wide array of devices and diagnostics have rapidly deployed resources to test and validate new methods and products for diagnosis, treatment, and prevention purposes, in support of emergency use authorizations (EUAs) and other expanded uses. Moreover, a vast amount of clinically valuable data are being generated for products that are EUA authorized and are currently being used to help patients. These real world data should be leveraged to generate real world evidence to ensure that product advancements made during this public health emergency can be utilized to support full marketing status, via subsequent premarket submissions for devices. In addition, in the case of a test for which as part of the EUA process FDA already determined the test qualifies for waived status, FDA should not have to repeat that assessment if the same test is submitted for a subsequent premarket submission after the emergency is over.

For your consideration I have enclosed an attachment detailing AdvaMedDx policy proposals to broaden access to COVID-19 testing.

Sincerely,



Susan Van Meter
Executive Director

Enclosure: Diagnostic Testing for COVID-19: Policy Prescriptions to Broaden Testing, Essential to Virus Containment as Communities Reopen

Diagnostic Testing for COVID-19: Policy Prescriptions to Broaden Testing, Essential to Virus Containment as Communities Reopen

July 29, 2020

In vitro diagnostic (IVD) tests facilitate the early detection of disease and guide appropriate treatment decisions to improve the quality of patient care and public health. These include tests that are front-line tools in the fight against COVID-19 – from diagnosing the infection in symptomatic, asymptomatic and presymptomatic individuals to understanding who has been infected previously, understanding disease epidemiology, to guiding treatment decisions for those diagnosed. These tests may also determine whether individuals who have been exposed have developed immunity to the virus. Leveraging the full array of COVID-19 tests, both lab-based and point-of-care, removing barriers to access to testing is essential to supporting patient care and public health in communities across the U.S.

Commercial Diagnostics Manufacturers have responded quickly and aggressively – and will continue to innovate – to expand the availability of and patient access to diagnostic testing during this pandemic.
Since mid-March, over 100 commercial tests have secured Emergency Use Authorization (EUA) from the FDA for COVID-19 testing.

- ✓ *Nationwide daily tests run are growing rapidly, averaging over 700,000 tests per day in July, enabled by leading commercial manufacturers who have collectively shipped over 80 million molecular tests to hospital laboratories, reference and public health laboratories and other health care providers across the country since March.*

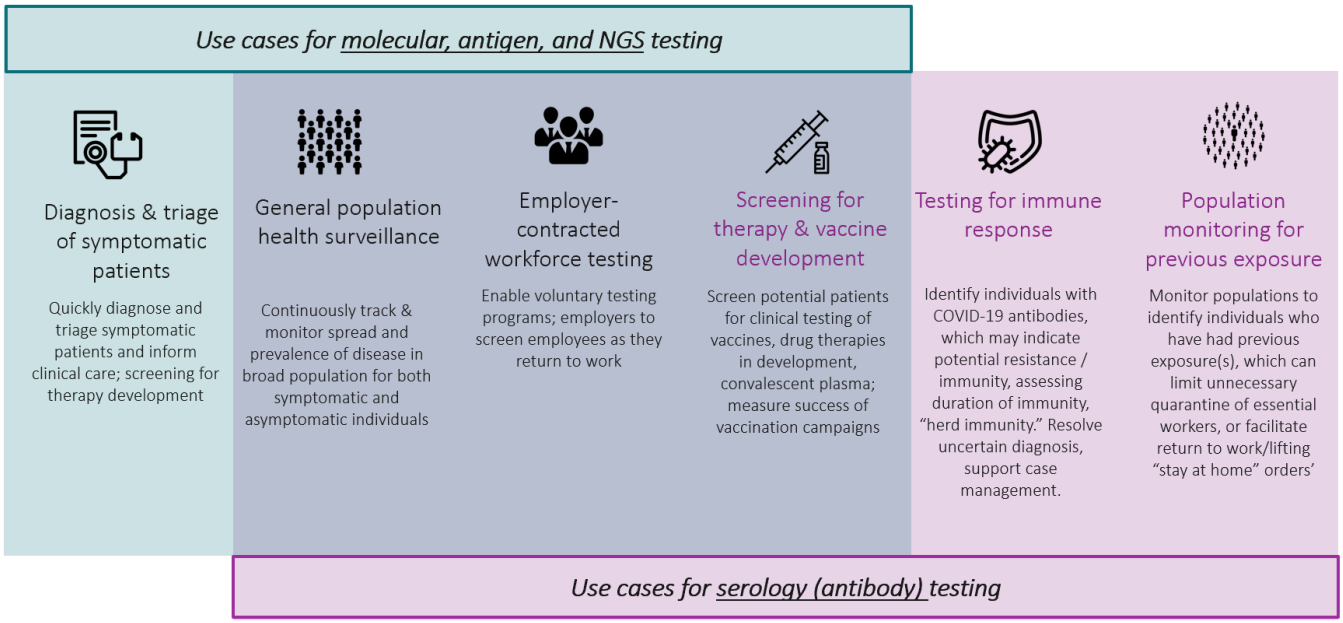
Normally, a manufacturer's efforts to bring a test to market requires 3-5 years. However, in response to the COVID-19 pandemic, the diagnostics industry dramatically increased the pace of research, development and manufacturing to bring quality products to market in just months. Leveraging their experience in designing, developing and manufacturing products to the highest quality standards, manufacturers of these commercial tests have increased coronavirus testing capacity, speed, and throughput to accurately identify cases, guide patient care and protect public health.

There are four general categories of diagnostic tests most-relevant to COVID-19

	Molecular Diagnostics (MDx)	Antigen Testing	Next Generation Sequencing (NGS)	Serology (antibody) Testing
What does this do?	Confirms active infection	Confirms active infection	• Confirms active infection • Used in surveillance and contact tracing	• **Identifies people who have been infected for which an immune response has been triggered** – even after the virus is no longer detectable including for people who never had symptoms; resolve uncertain diagnosis • Conduct surveillance, find donors of convalescent plasma; vaccine development • Us post-vaccination to ascertain sustained immune response
How does this work?	**Detects viral RNA** (viral equivalent of DNA) • In nasal / oral swab, oral fluid	**Detects viral proteins shed in human samples** • In nasal / oral swab, oral fluid	**Detects numerous RNA targets** from the SARS-CoV-2 genome • In nasal swab, with potential for expansion to oral swabs, oral fluid	**Detects human antibodies** to a given pathogen (e.g. the COVID-19 virus) • In blood samples
How quickly are results reported?	• **Point-of-care tests** can provide results in minutes • Tests run on moderate and high-throughput platforms in hospital and reference laboratories can process **up to thousands of tests in 1-4 hours**	• **Point-of-care tests** can provide results in minutes • Tests run on moderate and high-throughput platforms in labs can process **up to hundreds of tests in ~2 hours**	NGS platforms can run hundreds+ samples in ~8-12 hours	• **Point-of-care tests** can provide results in minutes • **High throughput platforms** in labs can run hundreds of tests with result in as quickly as 10 – 60 minutes
How many platforms are there?	• There are over **20,000 point-of-care, molecular analyzers** in the U.S. • There are **~1,000 high throughput molecular platforms** in the U.S. • 72 FDA EUA are on the market • **65M** tests have been shipped to labs in the US since March	• There are **~ 65,000 point-of-care analyzers** in the U.S. that can run 40-50 tests per hour • There are **~10,000 high throughput immunoassay platforms** that can run antigen tests in the U.S. • 2 EUAs for point of care tests are on the market	**There is capacity in the U.S. to ultimately perform 750k tests per day.** • 1 FDA EUA is on the market	• There are **50,000+ immunoassay, point-of-care analyzers** in the U.S. • There are **~10,000 high throughput immunoassay platforms** that can run serology tests in the U.S. • 22 commercial FDA EUAs are on the market • AdvaMedDx member serology tests are high quality, FDA authorized tests

Note: The above is a generalized summary based on industry experience, not specific to COVID-19, and not necessarily applicable to every specific test / situation
1. Antigen and serology (antibody) testing are both also known as "immunoassays"

There are 6 overarching and complementary use cases for COVID-19 diagnostic tests



To improve public health, ensure broad-based, timely and efficient access to COVID-19 testing and enable a safer return to work, school and worshiping in communities across America – we recommend the following policies:

Requests to the Administration: Testing Guidelines, EUA Policy, PAMA Relief

- **CDC should broaden guidance on testing; states should align their policies with CDC:** CDC should revise testing guidelines to ensure clinicians have access to all tests necessary to care for patient and public health, recognizing that patients may need repeat testing over time as well as parallel testing (i.e. molecular + serology simulatnaeously etc.) of symptomatic, presymptomatic and asymptomatic individuals. We also recommend that state health departments follow these recommendations.

- **FDA should facilitate rapid updates to tests authorized under EUAs**: As our economy moves towards broader re-opening, and we confront the possibility of new hotspots and potential flare-ups, the testing needs will change. Moreover, limitations in testing supplies have led to the need to use alternate forms of swabs, transport media, and other necessary aspects of a test system. ***FDA should facilitate rapid updates to tests, as necessary, based on appropriate validation of changes of tests that have received EUA authorization.***

- ***FDA should issue an EUA template for over the counter (OTC) testing:*** FDA should develop and disseminate, via an EUA template, controls to facilitate over the counter (OTC) testing for COVID-19, subject to testing being performed in appropriate laboratories, or at home with FDA authorized self-collection and self-testing in the home setting options we anticipate will be coming onto the market. Currently, all authorized tests are prescription-only. Providing OTC testing options will broaden availability and expand access to tests.

- **FDA and States should simplify ordering of all COVID-19 tests:** Medicare changed its policy during the Public Health Emergency so that an order from a treating physician or non-physician practitioner is not required as a condition of

Medicare coverage of COVID-19 diagnostic laboratory testing during the Public Health Emergency. CMS similarly removed these requirements for an influenza virus and respiratory syncytial virus (RSV) diagnostic laboratory test that is necessary to establish or rule out a COVID-19 diagnosis. ***Current FDA requirements for an order for COVID-19 molecular, antigen, serological and next generation sequencing tests should be lifted, and states should be encouraged by HHS to follow suit, reducing barriers to accessing testing.***

- **CMS should ensure coverage and payment for new diagnostics tests authorized under EUA:** A new FDA-CMS parallel review process should be established so that CMS and its contractors launch coverage, coding, and payment for tests at the same time the EUA is granted.

- **CMS should smooth implementation of PAMA:** Laboratories are experiencing deep revenue reductions due to a significant downturn in elective and non-COVID related services in hospitals and other health care settings. COVID-19 testing is not offsetting these losses. Further, laboratories are experiencing deep Medicare cuts for the vast majority of tests per the Protecting Access to Medicare Act (PAMA) of 2014. ***The Administration should examine its authority to smooth the implementation of these reductions, delaying further rounds of reductions to ease the burden on laboratories. This delay would allow Congress additional time to legislate refinements to PAMA.***

Requests to Congress: Strengthen Coverage & Reimbursement, Ease Ordering, Authorize National Epidemiological Study

- **Strengthen coverage of testing:** Recently, private health plans have been raising concerns about covering COVID-19 testing, despite the Families First Act and CARES Act provisions designed to ensure coverage of testing. Further, for example, several private sector health plans have issued non-coverage or severely restrictive coverage policies for COVID-19 serological/antibody testing. ***Congress should clarify that coverage for COVID-19 testing (i.e., molecular, antigen, serology, next generation sequencing and any COVID-19 testing included in respiratory panels or combined COVID-19 – Flu A/B tests, etc.) is for symptomatic, presymptomatic and asymptomatic individuals to protect both patient and public health, regardless of sites of care/service, regardless of a clinician order. Specifically, for all public and private payers:***

    - ***Repeat testing*** should be covered without overly restrictive limitations that impede patient access, regardless of the site of care.
    - ***Parallel testing*** (simultaneous diagnostic (molecular or antigen tests) testing with serological testing) also should be covered without restrictions by all public and private payers.
    - ***Testing prior to medical, surgical or dental procedures, or prior to admission to a healthcare facility*** (e.g., hospital, surgical center, cancer hospital, skilled nursing facility, dialysis center, etc) should be covered. This could include COVID-19 tests as part of multi-analyte panels that differentiate co-circulating respiratory viral targets (eg., flu, RSV, CoV-2).

- **Bolster reimbursement for COVID-19 testing; ensure appropriate federal funds for testing:** Laboratories, striving to meet the nation's COVID-19 testing needs, have experienced significant downturns as elective procedures and services declined dramatically since the pandemic began. To ensure laboratories can provide COVID-19 and other testing, Congress should:

    - ***Require reimbursement for all COVID-19 testing at rates not less than Medicare*:** All screening and diagnostic testing for symptomatic, presymptomatic and asymptomatic individuals should be reimbursed at rates not less than Medicare, for all public and private health plans, including plans on the federal exchange, regardless of sites of care/service, regardless of an order from a treating physician or non-physician practitioner. Over the Counter FDA authorized COVID-19 tests should also be reimbursable through an individual's public or private health insurer. ***Congress should appropriate federal funding to help cover the cost for COVID-19 testing used for surveillance.***

- ***Provide full federal support for Medicaid plans for all COVID-19 testing for Medicaid, SCHIP and Uninsured:*** Plans should be reimbursed 100 percent by the federal government. State Medicaid plans, for example, should receive 100 percent Federal Medical Assistance Percentage (FMAP) for all Medicaid and State Children's Health Insurance Program (SCHIP) covered lives and for the cost of testing provided to uninsured individuals.

- ***Freeze future Medicare cuts to the Clinical Laboratory Fee Schedule (CLFS):*** Building upon the CARES Act and in recognition of the flawed implementation of PAMA, Congress should further delay any Medicare cuts to the CLFS cuts until such time as a new framework for establishing payment rates for diagnostic tests can developed.

- **Establish a nation-wide COVID-19 epidemiological survey:** The CDC, NIH, and FDA are collaborating with other public and private sector stakeholders on metropolitan, community and special population seroprevalence studies. The largest of these studies seeks to analyze 300,000 patient samples over the next year nationwide. In order to understand the true prevalence of COVID-19 in the U.S. a bolder, truly comprehensive seroprevalence survey assessing the exposure to COVID-19 in all communities – urban, suburban and rural across the country is needed. The implications of exposure are being discovered real-time as clinicians and scientists leverage these finding to improve patient care and protect public health. **Congress should authorize and fund a large scale, scientifically rigorous, coordinated, local-level serology (antibody) testing survey to ensure clinicians, public health officials, and policymakers have the most robust, real-time information about the virus and its transmission.**

  - ***Federal funds should be provided to CDC, NIH and FDA to oversee the program federally, with funds allocated to state, local and tribal governments*** to support rigorously designed, scientifically valid study regarding disease prevalence at the local level. In addition to the general population, testing should also be targeted at high-risk individuals (i.e., nursing home residents, first responders, and health care workers).

  - ***Only high-quality serology tests authorized by FDA with EUA that meet performance thresholds determined by the Secretary should be used.***

  - ***Congress should further ensure that ongoing CDC, NIH and FDA supported seroprevalence studies provide full study details including information about which specific serology tests being used, with real-time results reporting.***

- **Simplify ordering of all COVID-19 tests for individuals and groups:**
  - ***Following Medicare's lead, Medicaid and private health plans, should remove as a condition of coverage and reimbursement any requirements for an order from a treating physician or non-physician practitioner for COVID-19 molecular, serology, antigen, next generation sequencing or other diagnostic tests for an individual.***

  - **Congress should clarify that a physician or non-physician practitioner should be permitted to provide blanket testing authorization for asymptomatic individuals and non-clinical settings** (i.e. workplaces, schools, houses of worship and other locations where groups of individuals gather). These changes should apply to all public and private payers for all COVID-19 testing (i.e. molecular, antigen, serology testing, next generation sequencing, etc.). FDA is indicating it is allowable to use a blanket order from a health care provider for screening of asymptomatic individuals at a school, for example, if no claims are made and the commercial IVD manufacturer does indeed possess an EUA or had appropriately notified FDA that it would provide an EUA within the requisite period of time.

- **Expand sites where sample collection and sample analysis can occur to non-traditional settings such as workplaces, schools, houses of worship, and other locations where groups gather.** These locations should be permitted to serve as

locations for sample collection for laboratory testing, or rapid point-of-care testing. The Administration recently made a change to allow a Certificate of Waiver laboratory to extend its existing certificate to operate a temporary COVID-19 testing site in an off-site location, such as a long-term care facility. Presently, the temporary COVID-19 testing site is only

permitted to perform waived tests, consistent with the laboratory's existing certificate and must be under the direction of the existing lab director.[i] State policy varies across the country, in many cases precluding this flexibility necessary for public health.

- ***Congress should clarify that during the public health emergency, sample collection and sample analysis, is permitted at non-traditional testing sites including at schools, places of employment and houses of worship, etc., under the direction of a CLIA-laboratory.*** Federal policy should supersede state policy during the emergency period. Note that FDA authorized self-collection kits could be effectively leveraged in such circumstances.

- **Further, in cases where molecular, antigen or serology testing (sample collection for laboratory tests, or point-of-care testing) is <u>not</u> intended for any medical decision making, no obligation to meet any CLIA-waiver criteria should be required.** As with tests employers might utilize for actuarial medical exams, testing for purposes of informing workplace staff configurations, is not intended for medical decision making.[ii]

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[i] CMS. Frequently Asked Questions (FAQs), CLIA Guidance During the COVID-19 Emergency. Retrieved from: https://www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf

[ii] CMS regulation suggests sites that perform sample collection or testing <u>not</u> intended for medical decision making, are not laboratories and therefore not subject to CLIA, as per 42 CFR § 493.2 Definitions
"Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories."