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

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. Encouraging access to testing while also removing barriers to testing is essential for improving 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 80 commercial tests have secured Emergency Use Authorization (EUA) from the FDA for COVID-19 diagnostic and serology testing. Millions of tests are being manufactured and shipped each week to hospital laboratories, reference and public health laboratories and other health care providers (see below). 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 three main categories of diagnostic tests most-relevant to COVID-19, each playing necessary and complementary roles:

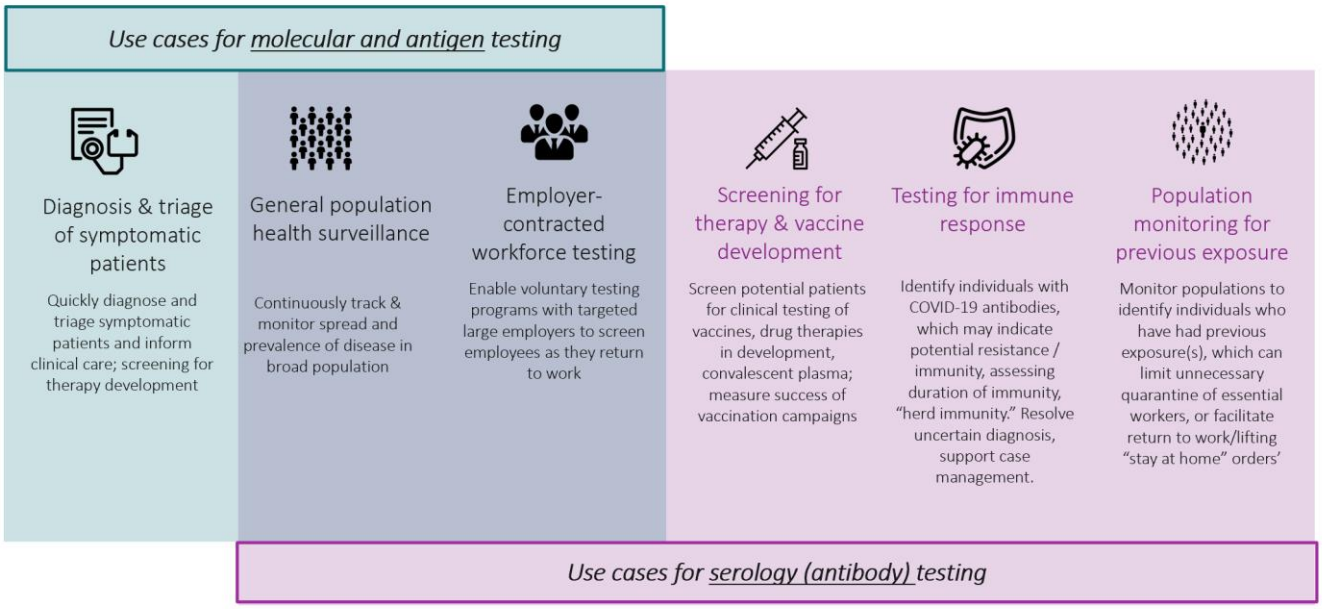
There are three general categories of diagnostic tests most-relevant to COVID-19

	Molecular Diagnostics (MDx)	Antigen testing[1]	Serology (antibody) testing[1]
What does this do?	• Confirms active infection	• Confirms active infection	• Identifies people who have been infected for which an immune response has been triggered • Antibodies are detectable in the blood long after the virus is no longer detectable • Antibodies are detectable in people even if their infection did not cause symptoms • Used in surveillance, case management, find donors of convalescent plasma, resolve uncertain diagnosis • Use cases will expand, eg to avoid quarantine of 1st responders, when antibodies proven to confer immunity
How does this work?	• Detects viral RNA (viral equivalent of DNA) - In nasal / oral swab, oral fluid	• Detects proteins shed on human samples - In nasal / oral swab, oral fluid	• Detects human antibodies to the 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. • Moderate and high-throughput platforms in hospital and reference laboratories can run up to hundreds of tests in 1-4 hours • There are ~ 1,000 high throughput molecular platforms in the U.S. • AdvaMedDx estimates the IVD industry is on track to ship 39M tests in June to labs around the country.	• Point-of-care tests can provide results in minutes • Moderate and high-throughput platforms in hospital and reference laboratories can run up to hundreds of tests in ~2 hours; • There are ~ 10,000 high throughput immunoassay platforms that can run antigen tests in the U.S. • As of June 23 one commercial, point-of-care antigen test has been authorized by FDA. Additional point-of-care and lab-based tests are expected on the market in coming weeks.	• Point-of care tests can provide results in minutes • Moderate and high-throughput platforms in hospital and reference laboratories can run up to hundreds of tests as fast as 10-60 min.; • There are ~ 10,000 high throughput immunoassay platforms that can run serology tests in the U.S. • AdvaMedDx estimates the IVD industry is on track to ship 94M tests in June to labs around the country

• The time to send the sample to the laboratory for analysis and for results to be provided to clinicians and patients can vary

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 complimentary 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 who should be tested; states should align their policies with CDC**: CDC guidance on prioritization for testing of first responders, health care workers and the most vulnerable patients who were symptomatic had been an important guidepost as testing capacity ramped up early this year. ***CDC should revise testing guidelines to facilitate repeat and parallel diagnostic testing (i.e. molecular, antigen, serology, next generation sequencing testing, 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.***

<u>Requests to Congress: Strengthen Coverage & Reimbursement, Ease Ordering, Authorize National Epidemiological Study</u>

- **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 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.).

- **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]

[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."