

COVID-19: THE ROLE OF *IN VITRO* DIAGNOSTIC TESTING - BACKGROUND

August 19, 2020

AdvaMedDx member companies produce innovative, high-quality *in vitro* diagnostic (IVD) tests that facilitate the early detection of disease and the guiding of appropriate treatments 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 an active infection to identifying those who have been infected in the past even after the virus is no longer detectable, to supporting surveillance and vaccine development efforts.

AdvaMed and its members established a national COVID-19 Test Supply Registry as part of our commitment to providing key data to policymakers and the public in our collective work mobilizing against the pandemic.

- In furtherance of the diagnostics industry's effort to support our nation's COVID-19 response, AdvaMed, in partnership with 13 leading commercial diagnostics manufacturers, launched a [national COVID-19 test supply registry](#) to help state and federal governments in their pandemic responses by providing real-time, actionable data on tests and testing supplies being shipped around the country. These data are delivered via weekly reports to federal and state policy makers. Public editions of the weekly Registry reports are available [here](#).
- The national Registry is a partnership between AdvaMed and the following commercial diagnostics manufacturers: Abbott, BD, bioMérieux, Bio-Rad, Beckman Coulter, Cepheid, Hologic, Ortho Clinical Diagnostics, QIAGEN, Roche Diagnostics, Sekisui Diagnostics, Siemens Healthineers, and Thermo Fisher Scientific. The companies involved account for about 95% of the tests shipped in the U.S.

AdvaMedDx and its member companies are supporting the public health response to COVID-19 by working around the clock to produce commercially available diagnostic tests as quickly as possible – delivering over 120 million IVDs to hospitals and laboratories since the start of the outbreak, enabling nationwide testing capacity to exceed 750,000 tests per day on average, and growing. Manufacturers are also working in close cooperation with federal departments and agencies, including FDA, as well as state officials, to help get tests to areas where they are most needed.

- A manufacturer's efforts to bring a test to market typically 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.
- To date, over 120 commercially available IVDs for COVID-19 have received Emergency Use Authorization (EUA) from FDA – dramatically increasing national coronavirus testing capacity, speed, and throughput to guide patient care and protect public health.
- Clinicians and public health officials utilize the full suite of COVID-19 testing technologies, in the laboratory and at the point-of-care, to diagnose the infection in symptomatic, asymptomatic and presymptomatic individuals, for understanding who has been infected previously, understanding disease epidemiology, and guiding treatment decisions for those diagnosed.
- IVD manufacturers are part of a larger testing ecosystem that includes hospital, public health and reference laboratories – all critically needed to increase testing capacity.

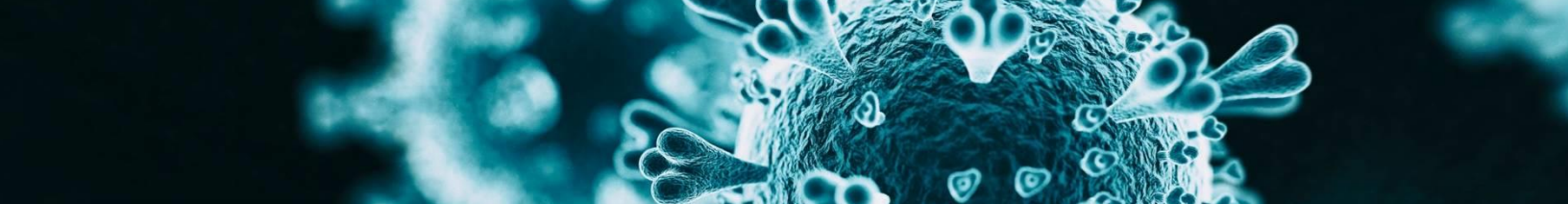


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There are **four** general categories of diagnostic tests most relevant to COVID-19: **molecular diagnostics, antigen testing, next generation sequencing (NGS) and serology (antibody) testing.**

- **Molecular Diagnostics:** These tests confirm an active infection in a patient by detecting the virus's genetic material (RNA). Performed in labs or at the point of care, the tests are used to track the spread of the disease, quickly diagnose and triage COVID-19 patients, and support voluntary employer testing programs to screen employees as they return to work.
- **Antigen Detection Tests:** These tests are used to confirm an active infection by detecting viral proteins (antigens) in patient samples. Performed in labs or at the point of care, antigen tests can enable general population health surveillance, diagnose and triage COVID-19 patients, and support voluntary employer workforce testing.
- **Next Generation Sequencing (NGS) Tests:** NGS testing helps confirm active infection by detecting numerous genetic (RNA) targets of the virus. NGS testing is also used in surveillance and contact tracing to track viral origin, mutations, and spread patterns, and for other research purposes.
- **Serology (Antibody) Tests:** These are blood-based tests that can be used to identify whether individuals have been exposed to COVID-19 by detecting human antibodies to the pathogen. Serology testing can be used in parallel with molecular, antigen, or NGS testing to help resolve uncertain diagnosis and support case management. Serology testing also supports surveillance, identification of convalescent plasma donors, and vaccine and therapeutic development.

IVD tests are run on instruments or platforms.

- Unlike manual tests developed by laboratories that may take longer to return a result, IVD tests generally can return results in 1-4 hours or less. Platforms/instruments are devices that can be designed for use in small and large clinical labs, and even at the point of care, often with automated workflows, and integrated software, to perform accurate, reliable diagnostic testing.

An IVD test kit consists of components and materials that are used to perform the diagnostic on an IVD instrument or platform. Test kits typically contain anywhere from 25 to 1,000 tests, with an average of about 100 tests in a test kit. An IVD test kit for COVID-19 molecular testing generally consists of the following components:

- **Extraction Reagents** – These are the specialized materials used to extract the pathogen's RNA or DNA from the patient sample. These reagents are not specific to any particular pathogen.
- **Amplification Reagents** – These particular reagents and associated materials (probes, primers, enzymes) can allow for the replication of a pathogen's RNA or DNA so that it can be detected. Amplification reagents are very specific to the pathogen a test seeks to detect.
- **Antibodies (for serology tests)** – Serology tests require synthetic antibodies made to detect human antibodies against the COVID-19 virus and produce a signal that can be read by an instrument.
- **Internal Controls** – These materials or solutions are used to verify that the instrument and reagents are functioning properly.
- **Other required materials that may not be included in an IVD kit include:**
 - The IVD instrument or platform to perform the test.
 - Patient specimen collection devices (such as swabs) and transport medium.
 - External controls to ensure the system, including specimen processing, functions properly.

To learn more about IVDs for COVID-19 that have received EUAs, see the AdvaMedDx website [here](#), or the FDA site [here](#).



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