AdvaMed Pre-Hearing Brief
International Trade Commission Investigation No. 332-580
COVID-19 Related Goods: The U.S. Industry, Market, Trade & Supply Chain Challenges
Public Hearing – Sept. 23, 2020

About AdvaMed

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical technology association, with over 400 members ranging from the largest to the smallest medical technology innovators and companies. Our member companies manufacture products essential to preventing, detecting and treating COVID-19 – such as personal protective equipment, *in vitro* diagnostic tests, and ventilators – as well as other life-changing technologies ranging from cardiovascular and orthopedic implants, to cancer diagnostics, surgical instruments and digital health products. These technologies help save and improve millions of lives every day.

Headquartered in Washington, D.C., AdvaMed has a global presence – including Europe, China, India, Japan and Latin America – though about 75 percent of our members are America-based small- and medium-sized enterprises. The U.S. medical technology industry is spread throughout all 50 states, comprising over 13,000 facilities nationwide. These facilities support over 500,000 high-paying American jobs, or about 2 million U.S. jobs including both direct and indirect employment, generating approximately $180 billion in domestic medtech production.

AdvaMedDx, a division of AdvaMed, represents the world's leading diagnostic test manufacturers. They develop and manufacture innovative, quality clinical diagnostic tests and technologies, including tests serving as essential front-line tools in the fight against COVID-19.

Executive Summary

This pre-hearing submission has the following objectives:

1. Review the ways in which our industry has responded quickly to the pandemic and rapidly ramped up production of critical medical supplies, and has continued to innovate to meet the moment. Notwithstanding these efforts, there is still more work to do as the pandemic remains with us and demand for some critical medical technologies continues.

2. Explore the various critical medical supplies needed to tackle COVID-19, highlight the complexities of the global supply chains for these technologies, and identify bottlenecks and barriers that have come about as a result of this unprecedented global pandemic.

3. Provide data on COVID-19 specific sectors, to the extent data are available.

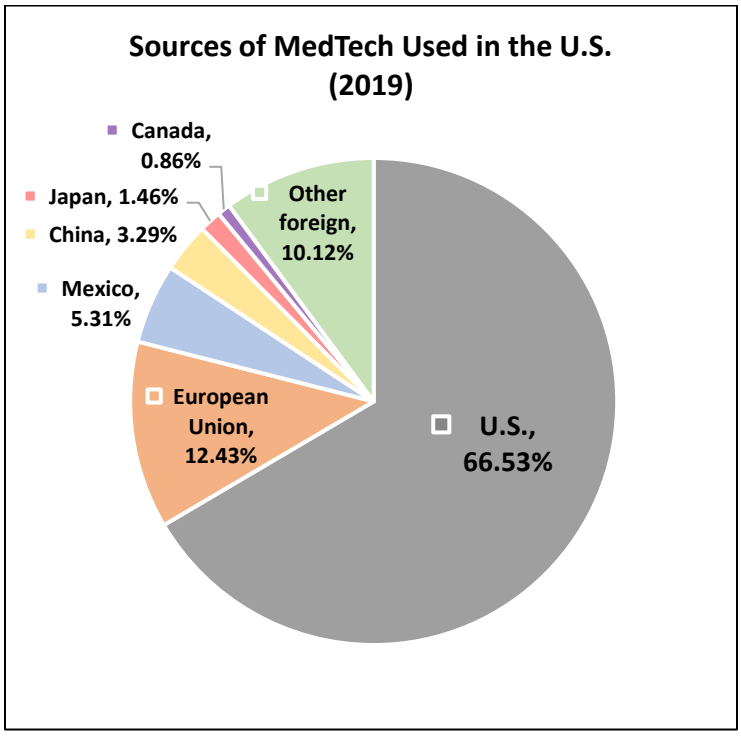
4. Outline ways we can better prepare for public health emergencies, including COVID-19, and how the U.S. government can help our industry further accelerate deployment of critical medical technologies so they reach patients and health care providers who need them the most.

Overview of the U.S. Medical Device & Diagnostics Industry, and Import Dependence

The complexity and diversity of the medical technology industry must be understood in order to implement effective policies. The World Health Organization counts two million kinds of medical technologies spread over 22,000 type categories. Innovation is rapid, with new medtech products replacing current products about every 18-24 months. The industry is global, with American companies providing patients access to the highest quality devices and diagnostics in nearly all of the UN's 195 countries.

The U.S. makes up over 40 percent of the over $400 billion global market for medical technology, though medtech represents only about 5.2 percent of total U.S. national health expenditures. Two-thirds of all medical technology used in the U.S. is manufactured domestically. The remaining one-third is imported. However, medtech overseas trade is balanced, with annual imports approximately equal to exports at about $60 billion each. Our largest source of imported medtech is the European Union (12.5 percent of overall consumption), while imports from Mexico account for just over five percent and China accounts for 3.3 percent, as can be seen in the chart below:

Two-thirds of medical technologies consumed in the United States are manufactured domestically; the remaining one-third is imported.



Sources: Annual Survey of Manufacturers (Census), U.S. Customs trade data, Fitch Data Solutions

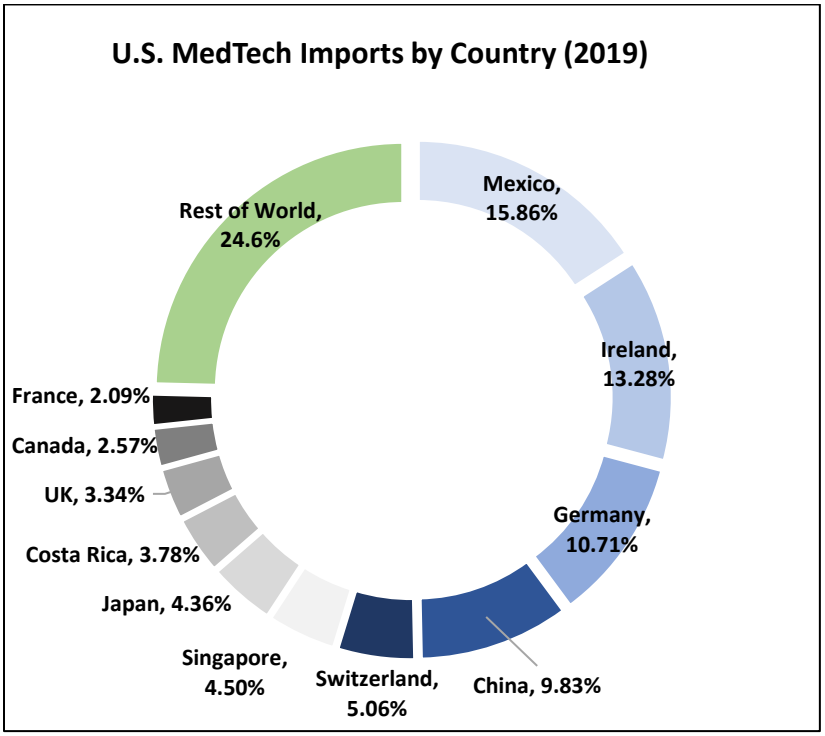
Data from the above pie chart are also represented in the table below, with corresponding dollar values of imports from each region:

Sources of Finished MedTech Products Consumed within the U.S. (2019)		
Country	**Value**	**% share of U.S. market**
U.S.	$ 121,557,752,703	66.53%
European Union	$ 22,712,173,513	12.43%
Mexico	$ 9,699,602,334	5.31%
China	$ 6,009,590,382	3.29%
Japan	$ 2,668,777,897	1.46%
Canada	$ 1,574,671,795	0.86%
Other foreign	$ 18,492,782,195	10.12%

Sources: Annual Survey of Manufacturers (Census), U.S. Customs trade data, Fitch Data Solutions

Looking at medtech imports as a group, U.S. overseas suppliers are diverse. While the European Union as a whole accounts for the largest share of U.S. imports, at the national level Mexico is the largest supplier. Mexico makes up 5.3 percent of the U.S. market, but 16 percent of imports, as represented in the chart below; China makes up 3.3 percent of the U.S. market, but 10 percent of imports.

Mexico accounts for 16% of U.S. medtech imports while China accounts for 10%



Sources: U.S. Customs trade data, Fitch Data Solutions

The types of medical technology imported into the U.S. are also diverse. While imports from Mexico and China span a broad range, about half of the imports from Ireland are artificial joints, as seen in the chart below:

Sources of U.S. MedTech Imports (2019)			
Country	**Import Value**	**% Share**	**Top Product Categories**
Mexico	$ 9,699,602,334	15.86%	Catheters and syringes; a wide variety of electrical-surgical instruments
Ireland	$ 8,119,458,111	13.28%	Hip and knee implants
Germany	$ 6,550,259,552	10.71%	MRI machines and CT scanners; electrical-surgical instruments
China	$ 6,009,590,382	9.83%	Patient aids such as hearing aids and wheelchairs; otherwise imports are diversified
Switzerland	$ 3,092,468,860	5.06%	Orthopedic implants
Singapore	$ 2,754,623,640	4.50%	Ventilators; diagnostic reagents
Japan	$ 2,668,768,858	4.36%	Physical examination equipment
Costa Rica	$ 2,308,939,194	3.78%	Catheters, drains, and bougies

Source: U.S. Customs trade data

Drilling down into specific COVID-19 related medical products, our import dependence is greater for certain types of products, such as latex gloves (72% come from Malaysia), gowns (44% come from China), and ventilators (60% are produced outside the U.S.). It's challenging to parse out historical U.S. import dependence on certain supplies like N95 masks, due to their aggregation with other products under individual tariff codes. It's worth noting that while China accounts for most of the world's face mask supply, N95 masks make up only 3% of China's mask production. (Source: Bain & Co).

U.S.-China Trade:

U.S.-China trade in medical technology is balanced. In 2019, U.S. medtech imports from China totaled $6 billion, whereas U.S. exports to China totaled $5.9 billion. The U.S. imports a wide variety of medical technologies from China, which for the most part contain low- to medium-technological content. Examples include wheelchairs, hearing aids and surgical gowns. On the other hand, the U.S. mostly exports to China advanced and innovative medical technologies.

The U.S. is the largest foreign supplier in China's medical technology market, with sales having robustly increased over the past five years, due in part to China's aging population and increased health care spending by the government and patients. However, China's government in recent years has been providing different forms of support to domestic medical technology manufacturers at the expense of U.S. and foreign manufacturers. For example, China's regulatory processes tend to grant some categories of locally-produced products a more expeditious approval time than imports. In addition, during the past year, Chinese government

entities (mainly provincial) – which are the largest purchasers of medical devices in China's health care system – have implemented a procurement scheme that makes it more difficult for multinational companies to compete with domestic firms. Over time, these preferential policies could significantly blunt growth in sales by U.S. medtech firms in China, leading to unbalanced U.S.-China medtech trade.

Industry Response to COVID-19

Throughout the year, AdvaMed and AdvaMedDx have been in constant contact with our companies and others supporting providers on the front lines in responding to the pandemic. Our companies have fully mobilized, demonstrating a firm commitment to supporting our nation's COVID-19 response, patient care and public health. They moved quickly to institute policies to protect employees from the virus while ramping up manufacturing to maximize production of critical products. Innovation and collaboration are happening at an unprecedented, rapid pace. At the same time, the industry faces severe cost pressures in the U.S. and other countries. As health care systems grapple with the financial impact of COVID, they are seeking ways to lower costs, including on their purchases of medical technology.

AdvaMed has also been working very closely with the government here and elsewhere to ensure our companies' work to save lives can continue as smoothly as possible without interference – to ensure rapid FDA Emergency Use Authorizations for essential products, for example, and to open global supply chains, lift import tariffs, and oppose export limits. The association and our member companies have been engaged at high levels with the White House task force, HHS, FDA, CDC, FEMA, DHS, DOD, Congress, and other key officials, and we commend all their hard work.

The COVID-19 pandemic has caused an unprecedented surge in demand for critical medical products (including ventilators, personal protective equipment, and diagnostic tests) that was well beyond any reasonable projection during manufacturers' previous-year planning, even incorporating levels for unforeseen demand spikes, as manufacturers do. Since the very start of the pandemic, almost overnight, AdvaMed's member companies refocused their operations − expanding production capacity and partnerships to develop and manufacture the medical technologies that are critical to our country's fight against this pandemic, including as follows:

Ventilators:

Ventilator production capacity in the U.S. increased over ten-fold from approximately 700 U.S. ventilators per week pre-COVID to roughly 10,000 a week by the end of the second quarter, based on data from seven AdvaMed member companies that are leaders in respiratory care. As of this submission, it appears that U.S. supplies of ventilators have stabilized, and hospitals are well equipped to deal with ventilation needs going into the fall.

It's important to note that to meet this challenge our companies continue to rely on complex global supply chains. For our companies that compete on the global stage, it is critical for them to have robust supplier networks and manufacturing hubs around the world. Ventilators are extremely complex products with upwards of 1,700 separate component parts, and often rely on

complex software. Given the vast diversity of component parts needed, approximately 60 percent of global ventilator supply is produced outside the U.S., including the EU and Asia. Notwithstanding this complex and interdependent global supply chain, which has been tested throughout the pandemic, our members report that they have been able to stay on top of demand.

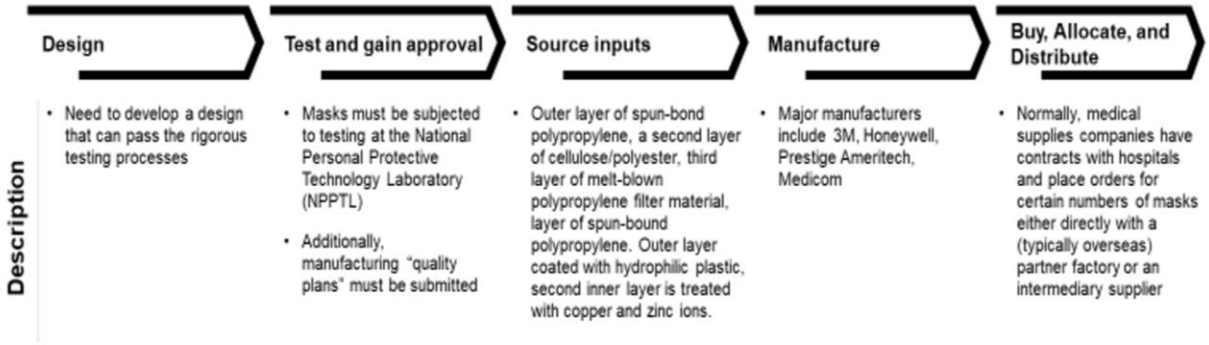
To support this effort, AdvaMed launched in May an online platform called VentConnect to help connect ventilator companies with additional component suppliers for scale-up of production and distribution. We subsequently expanded that platform – now the MedDeviceNetwork – to include other complex medical technologies needed in the fight against COVID-19 and future health care emergencies.

Personal Protective Equipment:

Looking at personal protective equipment (PPE), it's important to consider the wide range of technologies and supplies that come under this category. Generally, for COVID-19, PPE refers to surgical and N95 masks, gloves, gowns and face shields. Today, we know production of PPE is topping 100% capacity. Manufacturers have added third shifts, running existing PPE production lines 24/7, and repurposing production lines that typically make other products to make PPEs. They've hired new workers and retrained existing workers to focus exclusively on PPE development. One AdvaMed member company has announced plans to quadruple global output of N95 respirator masks to 2 billion per year by December, and triple production for the U.S. market to more than 95 million per month.

The complexity of the manufacturing process for masks is instructive, as the filtering property of the masks is a function of a multi-layered structure made of non-woven fabric – most commonly polypropylene. The fabric is "melt-blown" in order to obtain fibers of a small diameter in a random pattern that can trap small particles. The fibers are electrically charged so that particles are attracted while the air passes through (using "electret treatment"). N95 respirators have a similar production process, with the filtering enhanced through high-efficiency, melt-blown, electret non-woven material, involving higher-tech machines and increased production costs. Non-woven fabric has been the main bottleneck in the value chain.

How the N95 Mask Value Chain Works



Source: Bain & Company

The manufacturing acceleration we've seen to date is a major undertaking when you consider that the machines used to manufacture melt-blown fabric in N95 masks costs about $4 million and requires roughly four months of lead time. And while much is said about our country's reliance on China for PPE, N95 masks make up only 3% of China's face mask production.

Finally, as we assess the medical technology industry's mobilization efforts, it's important to recognize the role of innovative partnerships and new technologies that have contributed to supporting the fight against the pandemic. Nontraditional players outside of health care have entered the market and partnered with medical device companies to expand capacity for manufacturing. On the innovation side, companies have also come forward with new technologies to decontaminate PPE to maximize supplies.

Syringes:

The U.S. market for syringes (with or without needles) was about $2.7 billion in 2019 (Source: Fitch Data Solutions). Syringes manufactured in the U.S. account for just over 70% of the domestic market (about $2 billion), while imports account for nearly $750 million. U.S. exports of the devices are slightly higher, at about $900 million. The largest suppliers of imports are the EU ($255 million), Mexico ($125 million) and China ($110 million).

Diagnostic Tests (*see "Annex" for additional information beyond this summary*):

In vitro diagnostics (IVD) companies produce advanced diagnostic tests and technologies that facilitate early detection of disease and guide appropriate treatments to improve the quality of patient care and public health. More specifically, manufacturers develop and produce IVD tests and the instruments, or platforms, on which the tests are performed, as well as the collection devices used to collect and transport the patient specimens to be tested.

Similar to the overall medtech market, the U.S. makes up over 40% of the global IVD market – or about $24 billion out of the $57 billion global market. (Figures exclude glucose testing.) Primary consumers in the U.S. include the approximately 158,000 Clinical Laboratory Improvement Amendments (CLIA)-certified domestic clinical labs across the country. Over 300 manufacturing sites in the U.S. and ~730 globally produce IVD instruments intended for the U.S. market.[i] Additionally, ~950 sites in the U.S. and ~2,100 globally manufacture IVD instruments and reagents intended for U.S. market.[ii]

In the fight against COVID-19, there are several IVD tests most relevant, including molecular, next generation sequencing, and antigen tests that diagnose an active infection, and serology (antibody) tests that identify those who have been infected in the past, even after the virus is no longer detectable. The range of use cases for these tests include support for surveillance, contact tracing, and vaccine and therapeutic development efforts. As effective vaccines and therapeutics become available, IVD testing will continue to be a critical part of determining how best to prioritize treatment and vaccine delivery, and the efficacy of these efforts. (See the Annex to this pre-hearing brief for more information on COVID-19 tests and use cases.)

Manufacturers of these commercial tests have increased coronavirus testing capacity, speed, and throughput since the early days of public sector testing to guide patient care and protect public health. Public health and reference laboratories were among the first test developers to launch COVID-19 molecular testing in early 2020. These efforts were massively augmented by the arrival on the market of commercial tests manufactured at scale, including those run on high-throughput instruments/platforms – manufactured by IVD companies – capable of running hundreds of tests in 1-4 hours. Furthermore, IVD companies are providing rapid, point-of-care molecular, antigen and serology tests to the market. These tests provide results in minutes.

As of Sept. 5, leading IVD companies have manufactured and shipped over 150 million molecular COVID-19 tests to U.S. public health, reference, and hospital laboratories, and other sites across the country. Manufacturers have also increased the supply of instruments/platforms to labs. These IVD industry efforts have enabled laboratories across the country to have run more than 87 million molecular tests as of Sept. 5. The magnitude of IVD industry mobilization to develop and manufacture at scale COVID-19 testing is unparalleled, reflecting the tremendous demand for testing across the country and industry's commitment to the nation's response.

The highly specialized expertise needed to manufacture key components of tests and testing platforms, including those that require handling of active virus and patient samples, is evident in an intricate and complex global supply chain that has been leveraged, maximized, and augmented during the pandemic.

Beyond tests that diagnose active or past COVID-19 infections, IVD makers have also ramped up manufacturing of tests critical to the care of many coronavirus patients. These include hemostasis (blood clotting/balance) tests such as D-dimer, essential to facilitate patient evaluation and management of the significant coagulopathies that can result from COVID infection, and arterial blood gas (ABG) tests, which are critical to evaluating and monitoring respiratory function in patients who may require ventilators to help them breathe. Reliable supply of hemostasis and ABG tests, and the analyzers on which each are run, is essential to the care of many hospitalized COVID patients. One major global manufacturer of D-dimer and ABG tests experienced increases in U.S. demand of 57% and 18%, respectively, from March through August, compared with the same period in 2019. By leveraging global supply chains (68% U.S.; 16% EU; 10% Canada; 5% Mexico; <2% other, including China), and bolstering U.S. manufacturing, the company was able to significantly increase production of hemostasis and ABG analyzers, tests and related consumables to assure plentiful supply in the U.S. and globally.

IVD manufacturers are adapting to what they are learning about the virus and its impact on patients, in real time, while also providing instruments/platforms on which the IVD tests are run. Rapid development of tests and supply chain ramp-up are being accomplished by manufacturers of scale and experience with FDA, aided in part by capital provided by government.

Critically, all types of COVID-19 tests across all modalities – laboratory-based and point-of-care testing – need to be leveraged to support patient care and public health. This requires the full efforts of testing suppliers and laboratories – including public health, independent, hospital, health system, and reference laboratories. It also requires the efforts of health care providers across the continuum of care, including those at urgent care sites as well as non-traditional

testing sites like skilled nursing facilities. In short, the entire testing ecosystem is required to address testing needs in this pandemic.

The ongoing experience of manufacturers of IVD tests during the COVID-19 pandemic provides critical insight into the capability of industry, when faced with a new pathogen, to rapidly develop and manufacture at scale quality tests that are essential front-line tools in the fight against the virus.

Supply Chain Challenges & Considerations

The complexity, resiliency, and variety of the supply chains for medical devices and IVD tests and technologies need to be appreciated by policy makers who call for strengthening the supply chains. The sources of medical technology supplies include both domestic and overseas manufacturing by U.S. companies, as well as firms in other countries that also manufacture medical technology products in the U.S. and overseas. As noted above, two-thirds of all medtech used in the U.S. is manufactured domestically. Further, state and federal stockpiles have also been a source of supply. These sources are all essential to meeting America's needs.

The U.S. imports medical technologies from many countries. The sources of components for medical technologies are also widespread, with multiple competitive offerings mitigating the risk of a shortage. Medical technology manufacturers also usually make up a relatively small percentage of the global demand for certain components, such as circuit boards and monitors, which means a surge in demand will not overwhelm the supply chain.

Notwithstanding the tremendous efforts of medtech manufacturers to date, some bottle necks, trade barriers and other impediments that strain supply chains for critical COVID-19 technologies remain. For example, based on data from individual companies' self-reporting, FDA announced in August that the potential exists for the U.S. to experience supply shortages for gloves, gowns, N95 respirators, as well as specimen collection devices (including swabs), specimen transport devices and extraction reagent used in certain diagnostic tests. While there is no single cause for the ongoing supply challenges, we've observed a number of leading stressors that have contributed to this dynamic, as follows:

- **Unabated Demand:** As the pandemic continues in the U.S. and around the world, including major hot spots such as India and Latin America, the demand for some critical medical supplies remains at unprecedented levels. As record levels in demand continue, industry is constantly working to build capacity and tap into new supplies while maintaining their usual product lines for other technologies necessary to care for non-COVID patients. As with the other areas of the health care ecosystem, including hospitals, medtech supply chains must adapt with potential regional demand spikes globally, which may occur from time to time, until efficacious vaccines or meaningful therapeutics are widely available.

- **Logistics:** Government lockdown measures in some geographies, including restrictions in the movement of people and factory operations – and those impacting component

suppliers as well – have impeded the movement of critical medical products and components throughout the global supply chain and created bottlenecks, particularly at the onset of the pandemic when restrictions first came into place.

- **Transport:** As we move into colder weather, we anticipate even greater demand for medical technologies used to address COVID. Medical technology manufacturers rely on the cargo capacity of commercial passenger flights to move products and their components. The massive decrease in passenger flights and insufficient staffing at airports – by airlines, Customs and Border Protection (CBP), and FDA – to clear medical products in a timely manner due to the ongoing COVID-19 pandemic undermines our ability get products to health care workers and patients who need them in a timely manner. Compounding these challenges are the skyrocketing transport costs associated with ground, air and sea travel. While we appreciate the acceleration of cargo delivery through Project Airbridge, broader federal engagement to incentivize and compel passenger and freight airlines – particularly those receiving recovery funds – to quickly and safely move to prioritize the transport of medical supplies is urgently needed.

- **Export Controls:** Another source of supply chain disruption has come from governmental interference with exports. Many countries, including the U.S., have restricted the export of COVID-19 technologies such as PPE (and inputs), coronavirus tests, and ventilators. The U.S. Chamber of Commerce has a useful dashboard which tracks global government policies linked to COVID-19, including export controls. AdvaMed members have reported that export restrictions in geographies and countries such the EU, India, Taiwan, and China, in particular, disrupted their supply chains for PPE and ventilators.

- **State-based Inventory Requirements:** While well intentioned, overly aggressive and uncoordinated inventory requirements – for PPE and other supplies – on hospitals by states have the potential to further exacerbate supply distribution and allocation challenges. We would encourage a more thoughtful approach that could best be achieved through public-private partnerships to help states better set supply requirements for hospitals. Such partnerships could help drive products to facilities that have greater need, based on their case load and hospitalizations.

- **Shortages vs. Allocation Considerations:** Another factor worthy of greater examination is differentiating between actual supply shortages and allocation issues. There are occasions when public-private collaborations around prioritization of allocation, such as in the case of ventilators, was effective and appropriate.

- **Substandard & Counterfeit Products:** The proliferation of substandard or questionable medical supplies during the pandemic, particularly in the realm of PPE, has created additional delays and impeded supplier efforts. Additional scrutiny of packaging, vendors, and paperwork/contracts create an additional layer of bureaucracy and increase costs for PPE purchasers, which include medical device companies that use PPE for their factory workers and employees.

- **Trade Disputes:** Measures imposed during trade disputes have the potential to increase supply-chain costs through higher tariffs, making our industry less competitive vis a vis key markets including China, Europe, Japan, and many others. While most of the COVID-related products directly covered by this ITC investigation no longer face Section 301 import tariffs, some inputs do. AdvaMed member companies source components and semi-finished products from all over the world, including China, to complete the manufacturing process of medical technologies here at home for domestic use or export. Shifting the source of inputs for finished medical technologies also involves costs. FDA has regulations affecting changes to input used in manufacturing medical technology. Depending on the risk classification of the product and the use of the component being changed, FDA may require a supplemental submission to the FDA. If this were to occur, changes in sourcing could lead to delays of several months to possibly a year, as this would require identifying a suitable alternative, notifying FDA, inspecting and validating the specific manufacturing process (e.g., installation, performance, operations), and submitting supplemental registration data. Even if a company believes its product with a new component would not need specific FDA approval, the firm would still be required to use resources to validate that the component from the new source meets specifications, which can also take several months.

- **Lack of purchase orders:** Many companies were willing to expand production of needed supplies but could not get specific commitments for those supplies. Government could focus on identifying items that are over- or under-supplied; providing clear guidance to private companies on what to produce and where it will be needed most; providing purchase orders; removing regulatory barriers related to ramping up production; and connecting with needed end users.

Policy Recommendations for Better Preparedness

In recognition of the complex global supply chains for medical technologies and the ongoing challenges our industry faces as we navigate the pandemic, AdvaMed would like to put forward the following recommendations, which would support the U.S. medical technology industry as it continues to mobilize and fight the pandemic, and also to prepare for future events:

- **Store sufficient supplies** in the Strategic National Stockpile (SNS) to meet any initial surge in demand from any future health care crisis. The U.S. government should enhance and ensure adequate funding for the SNS. The SNS should reflect the latest science and the kind of technologies we now know are needed to tackle a pandemic. In addition, federal, state, and provider stockpile expiry dates should be appropriately managed; the private sector can assist with this effort. Reforms to the SNS should also take into consideration the PPE and medical supplies necessary to prepare for subsequent waves of the virus that may occur until we have a meaningful therapeutic, and widespread efficacious vaccines. The government should begin preparing for and envisioning the investments and infrastructure necessary to provide vaccinations on a mass scale. We are

concerned that manufacturing capacity for injection devices (i.e. needles and syringes) is not being addressed alongside vaccine development.

Regarding testing, the SNS should have adequate supply of diagnostic testing equipment, materials, and supplies, as it is critical to have the ability to rapidly test and diagnose patients who are sick or have been exposed to a pathogen. While it is not possible to stockpile diagnostic tests for an unknown pathogen, certain tests can be stockpiled that can help rule out other infections. For example, annually, the stockpile could ensure it has flu tests available to rule out flu if a new pathogen causes similar respiratory symptoms. We recommend stockpiling the equipment necessary to process IVD tests – such as test instruments, analyzers and other capital equipment – to rapidly scale up diagnostic testing infrastructure and help to ensure prompt testing of samples in communities that may not have an existing lab or testing infrastructure. In addition, medical supplies used in sample collection, transport and processing of IVD tests should be considered for the SNS. These include swabs, collection tubes, lancets, transport medium/tubes, and reagents such as DNA/RNA extraction kits, which are generally not specific to particular tests/pathogens.

- **Maintain resilient supply chains** so that medtech companies can efficiently access the components and raw materials they need to ramp up production, and the U.S. can continue to supply patients and providers here and around the world. In recognition of the global nature of medical technology supply chains, the U.S. government should work to maintain open trade in medical supplies by minimizing export restrictions and working with trading partners to limit barriers in the flow of goods. Forced localization and onshoring efforts can be disruptive, and make U.S. companies less competitive globally.

- **Support Robust Allocation Strategies** through careful planning on how to get crucial medical supplies to those most in need. It is critical to coordinate across states, the federal government, and manufacturers to streamline the various purchasing entities to avoid a situation where each is working in a vacuum to secure their own product directly. Initially, this dynamic inflated demand, drove prices up, and provided an avenue for sub-quality product to be purchased by those that don't understand the market. When used in collaboration with industry, mechanisms under the Defense Production Act, such as voluntary agreements, can contribute to efficient allocation, especially by locating critical resources and assigning priorities to "hot spots" and other identified needs as they arise. Other public-private partnerships can help support shipment prioritization by private industry that aims to address the nation's most pressing public health needs. Through leveraging of predictive analytics for where an increase in COVID-19 infection is anticipated, for example, the federal government can add important insight to already robust IVD test shipment prioritization.

- **Invest in America's people, R&D, and facilities** to support a strong domestic medical technology industry that will continue to meet the needs of U.S. patients and health care providers. Public-private partnerships and strategic incentives to bolster additional manufacturing capacity should be the model for longer-term measures to prepare for future pandemics.

- **Sustain Federal Investment for Diagnostic Innovation**, building upon recent federal stimulus funding, which has launched the National Institute of Health's new Rapid Acceleration of Diagnostics (RADx) initiative. The initiative is aimed at speeding innovation, development and commercialization of COVID-19 testing technologies. The RADx program is investing in early innovative technologies to speed development of rapid and point-of-care COVID-19 testing. The investment in diagnostics required to address pandemics exceeds that which the private sector can bear entirely on its own. Establishing and sustaining through robust funding important programs such as RADx is an important complement to the Biomedical Advanced Research and Development Authority (BARDA). BARDA provides significant support to IVD manufacturers to advance and accelerate the development of emergency diagnostic tests. Innovation should be fully embraced to ensure a broad range of testing, from those that enable advanced surveillance, facilitate triaging of patients based on their potential risk for deterioration, and beyond. Bolstering support for these important programs will help ensure the country and diagnostics manufacturers are ready for future outbreaks of novel pathogens.

Conclusion

Let's prepare for the next phase of this pandemic and beyond by planning now. AdvaMed, AdvaMedDx and our member companies are committed to working with Congress and the Administration to ensure the continued supply of essential medical supplies while continuing to look for ways to engage outside industries in the production of essential medical products. As we look to the next phase of the pandemic, where reopening will require vast infrastructure and investment for testing, vaccines (needles/syringes), PPE and other equipment, we are eager to look at solutions that will support this effort.

Our industry will continue to support our nation's response to the pandemic through increased production of needed products, and coordination with public health authorities and government agencies. As policymakers evaluate new laws, we encourage them to preserve this vibrant domestic manufacturing sector, and the robust and resilient supply chains that enable this sector to support and protect American frontline health care workers. We stand ready to engage with policymakers on steps aimed at accomplishing this important goal.

Ralph F. Ives

ANNEX
The IVD Industry & COVID-19 – Supplemental Information

IVD Industry Overview

Manufacturers develop and produce IVD tests and the instruments, or platforms, on which the tests are performed[iii], as well as the collection devices used to collect and transport the patient specimens to be tested. More specifically:

- ***In Vitro* Diagnostic (IVD) Tests** – An IVD is a medical test, developed by manufacturers for the commercial market, that examines specimens (e.g., blood, tissue, nasal mucus, etc.) taken from the human body, as well as data derived from specimens, in order to screen or diagnose patients for diseases or other conditions, monitor and prevent disease, and help determine appropriate treatments and cures.

- **Patient sample/specimen collection and transport** – IVD companies develop and manufacture devices that collect patient samples, i.e. a nasal swab, and transport media that allows for safe handling and transfer of samples for testing.

- ***In Vitro* Diagnostic Test Kit** – 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 hundreds of tests, with an average of about 100 tests in a test kit.

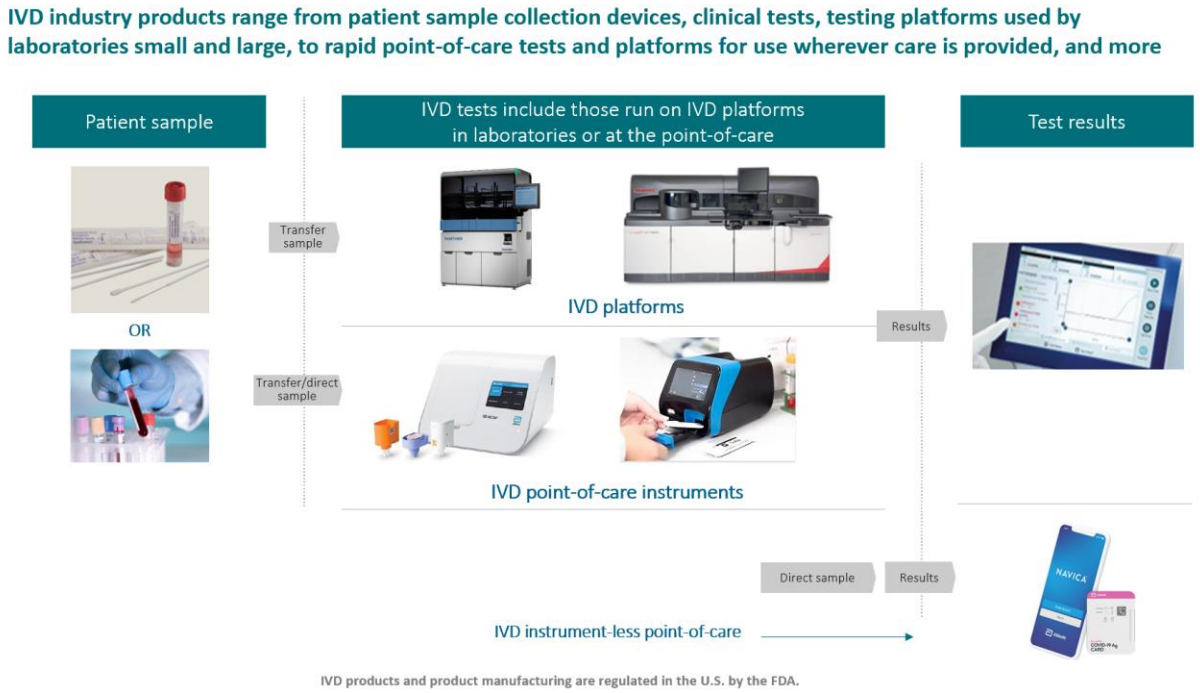
- **IVD Instruments or Platforms** – IVD tests are run on instruments/platforms. Unlike manual tests developed by some laboratories (see below) that may take significantly longer to return a result, IVD tests generally can return results in 1-4 hours or less.

  Platforms/instruments are devices that can be designed for use in small and large clinical laboratories, often with easy to follow and automated workflows, and integrated software, to perform accurate, reliable diagnostic testing. Small, point-of-care instruments can be used by providers in non-laboratory settings, providing results in minutes.

  When considering IVD production scale-up and laboratory testing capacity, it is critical to understand the placement of IVD instruments in laboratories needed to run the tests across the U.S. IVD tests must be allocated to where instruments that match with those tests are located. While not universally the case, commercial tests typically have technical features and biochemistry unique to each manufacturer, so that specialized tests developed by a single manufacturer generally are suited to run on platforms also developed by that same manufacturer. The tests on these platforms all complement one another, because platform placement in hospitals and labs across the country and around the world is widespread.

  Point-of-care testing can be made widely available, virtually anywhere patients seek care, from emergency departments, doctor's offices, clinics, pharmacies and in some cases even in

the home setting. More point-of-care tests are expected to reach the market in the coming weeks and months. These tests compliment testing done in laboratories and help make access to testing more widely available.



In response to the COVID-19 global pandemic, it is essential that all types of COVID-19 diagnostic testing across all laboratory and point-of-care settings are fully leveraged to ensure clinicians have all the tools available to them to best care for patients and the public health.

COVID-19 Test Development and FDA Authorization: Accelerated Processes; Proposed Refinements

IVD manufacturers typically require 3-5 years to bring a test to market, as the process requires securing appropriate samples of the pathogen, research and development of a quality test, undertaking clinical studies to support the validation of the test, bringing the test through the U.S. FDA for approval or clearance, and manufacturing the test at scale for the commercial market. During this pandemic, however, the diagnostics industry has been able to demonstrate a dramatically increased pace of research, development, and manufacturing to bring quality products to market in just months.

Since mid-March, over 130 commercial IVD tests for COVID-19 so far have received FDA Emergency Use Authorizations (EUAs), permitting these tests to be deployed to laboratories, hospitals, and other testing sites across the country.

The FDA EUA pathway has been a critical component of the U.S. response to the COVID-19 pandemic. This pathway enabled new and novel diagnostic tests, developed in record time, to be

widely utilized for patients in need and public health. The FDA provided support and clarity to test developers by putting forth EUA templates for different types of tests and through frequent open-door sessions to provide updates and clarity on agency policy. Further, the overall EUA process has facilitated manufacturers' modifications and updates to EUAs to support innovative changes to tests, including those changes precipitated by limitations in testing supplies. One such example is the FDA's flexibility in allowing updates to EUAs to allow use of alternate forms of swabs for the collection of patient samples, transport media to safely contain specimens for delivery to laboratories for testing, and other necessary aspects of a test system. In addition, FDA provided an Emergency Use Notification pathway to allow vendors to implement assays ahead of actual EUA submissions. Vendors were able to use this pathway to offer tests and unlock supply availability for collection devices.

AdvaMed and AdvaMedDx, reflecting on collective experience with the EUA pathway thus far, have developed regulatory and legislative recommendations to streamline and improve the EUA pathway, including through an expedited provision of EUA templates to test developers. Further, AdvaMed and AdvaMedDx recommend the leveraging of the clinical data, or Real World Evidence, being generated during this emergency to ensure that product advancements made during this public health emergency can be fully utilized to support longer term and broader uses, via subsequent premarket submissions for devices. In addition, in the case of a test – where FDA has already determined as part of the EUA process that the test qualifies for waived status[iv] – the agency should not have to repeat that assessment if the same test is submitted for a subsequent premarket submission after the emergency is over.

Further, the current pandemic has amply demonstrated that delays in access to patient viral samples can impede rapid development of testing capabilities. It has also shown the dangers of relying on one sole source for the development of initial tests. As FDA recently explained, "Typically, with an emerging health threat, the Centers for Disease Control and Prevention (CDC) is the first developer of a diagnostic test in the U.S…. CDC has first access to viral samples that other test developers do not."[v] For COVID-19, viral samples became commercially available to private sector test developers in late February. FDA has recommended that, and AdvaMed concurs, "In the future, making viral samples available earlier to commercial developers will be crucial to deploying tests quickly."[vi]

AdvaMed and AdvaMedDx have proposed legislative changes that would direct the Secretary to establish a streamlined process for manufacturers and other test developers to access patient viral samples, to complement CDC development efforts and ensure diversification of testing development and capacity.

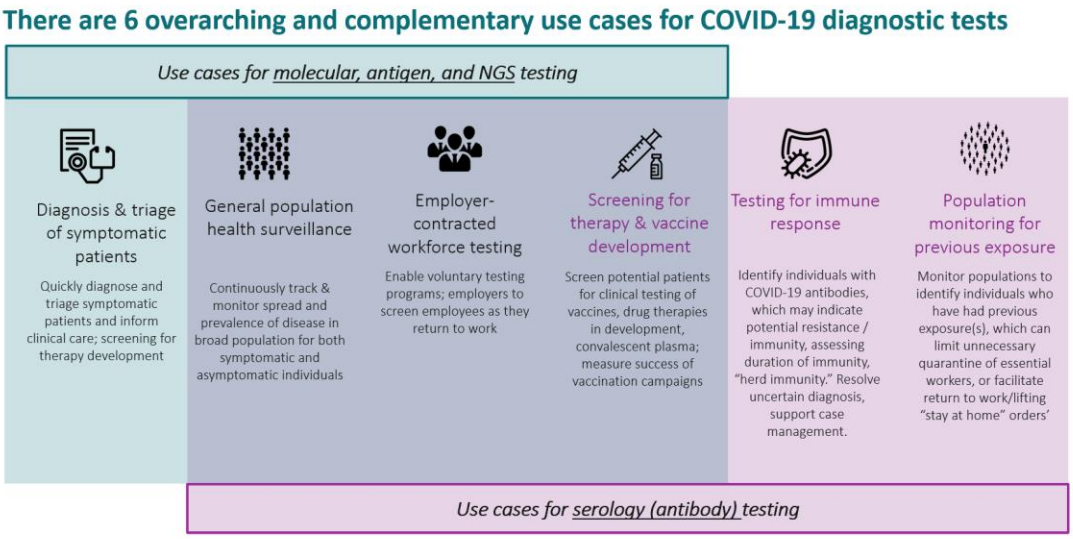
Main Types of COVID Diagnostic Tests: Key Patient and Public Health Use Cases

AdvaMed and AdvaMedDx urge policy makers to ensure all types of COVID-19 diagnostic testing across lab and point-of-care settings are fully leveraged to ensure clinicians have all of the tools available to them to best care for patients and the public health.

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

- *Molecular tests*: The most widely leveraged type of COVID test, these highly sensitive tests are run in laboratories, or on small instruments at the site of patient care. They detect cases of active infection using nasal swab or oral swab/oral fluid patient samples.
- *Next Generation Sequencing (NGS) tests*: A type of molecular test, these detect active infection using nasal swab samples and provide detailed information on genetics of a pathogen.
- *Antigen tests*: These tests detect cases of active infection at the point of care or in laboratories with a nasal swab or oral swab/oral fluid patient sample. Somewhat less sensitive than molecular tests, antigen testing is being increasingly deployed at the point-of-care.
- *Serology (Antibody) tests*: Using blood samples, these laboratory or point-of-care tests identify people who have been infected, for whom an immune response has been detected. They provide understanding of disease prevalence across communities and are critical to the development of effective employment of therapeutics and vaccines.

The use cases for these tests are wide ranging. The illustration below provides more specific demonstrations of the way in which IVD COVID-19 tests are being actively employed in response efforts.

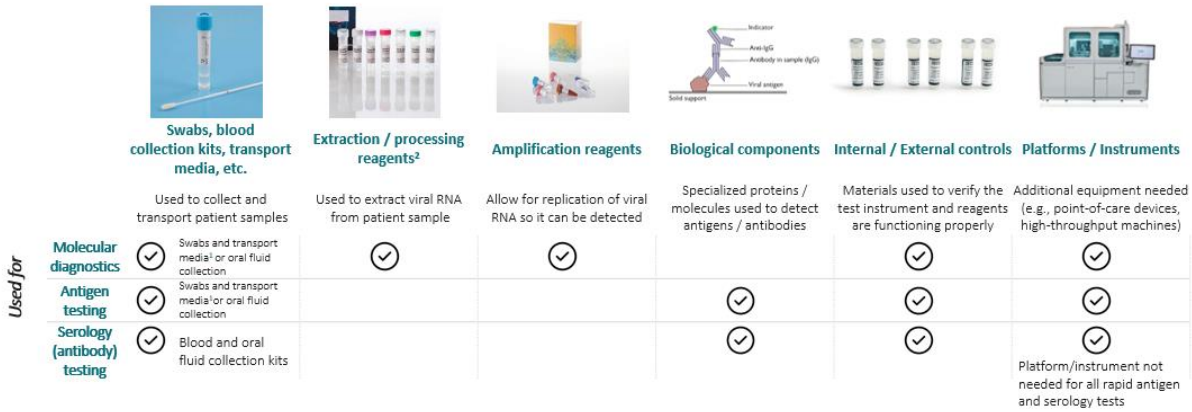


IVD Industry Manufacturing Mobilization; Tests, Test Kits, Platforms - Key Facets of IVD Supply Chain

The many components of IVD instruments/platforms, IVD tests and test kits are sourced from a multitude of entities across the U.S. and globally. These components are highly specialized, requiring significant expertise, including for handling active virus and patient samples.

The illustration below provides a high-level depiction of the key and necessary components required for molecular, antigen and serology (antibody) COVID-19 tests.

Various components are needed to perform each type of COVID-19 diagnostic test



Used for	Swabs, blood collection kits, transport media, etc.	Extraction / processing reagents[2]	Amplification reagents	Biological components	Internal / External controls	Platforms / Instruments
	Used to collect and transport patient samples	Used to extract viral RNA from patient sample	Allow for replication of viral RNA so it can be detected	Specialized proteins / molecules used to detect antigens / antibodies	Materials used to verify the test instrument and reagents are functioning properly	Additional equipment needed (e.g., point-of-care devices, high-throughput machines)
Molecular diagnostics	✓ Swabs and transport media[1] or oral fluid collection	✓	✓		✓	✓
Antigen testing	✓ Swabs and transport media[1] or oral fluid collection			✓	✓	✓
Serology (antibody) testing	✓ Blood and oral fluid collection kits			✓	✓	✓ Platform/instrument not needed for all rapid antigen and serology tests

Specialized expertise is required to make these components, and companies generally focus on offering a selection of the above.

Prior to the pandemic, IVD supply chains were well established and included an array of suppliers skilled at producing key components critical for the development and manufacturing at scale of quality IVDs and IVD platforms/instruments. Manufacturers strove to ensure resilience and redundancy.

By early 2020, as the number of COVID-19 cases skyrocketed, the sheer magnitude of the demand for COVID-19 testing created strains in the system.

IVD manufacturers and suppliers responded rapidly to augment manufacturing by building new lines, hiring new skilled staff, running lines around the clock, securing additional sources of raw materials or other components, and in some cases beginning manufacturing for the first time of a component previously secured through a supplier. In short, IVD manufacturers have taken, and continue to take, significant measures to maximize operations to allow for continuity of supplies during the pandemic, striving to meet this unprecedented demand.

Many leading IVD manufacturers have been provided support for these efforts through the Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response-led Biomedical Advanced Research and Development Authority (BARDA). BARDA has provided significant support to IVD manufacturers to advance and accelerate the development of emergency diagnostic tests. Further, the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) initiative, aimed at speeding innovation, development and commercialization of COVID-19 testing technologies, has also provided support to manufacturers striving to meet demand. The investment in diagnostics required to

address pandemics exceeds that which the private sector can bear entirely on its own. AdvaMed and AdvaMedDx strongly support bolstering important programs such as RADx, and ensuring the country and diagnostics manufacturers are ready for future outbreaks of novel pathogens.

Examples of Key IVD Supply Chain Components Relevant to COVID-19

Swabs / Transport Media

Both molecular (including NGS) and antigen testing principally use nasal swab patient samples. Early in the pandemic, a shortage of nasal pharyngeal (NP) (upper throat) swabs used to secure specimens from patients for testing, as well as transport media used to safely contain and transport swabs to laboratories for testing, hindered response. Some estimates are that the demand for NP swabs rose by 300 percent early in the pandemic. Initially, only NP swabs and viral transport media were authorized by the FDA for COVID-19 specimen collection and transport. A very small number of manufacturers in the U.S. and globally produced the NP swab. Since then, FDA provided guidance on alternate collection methods, including broadening the range of swabs and specimen types that can be validated and used with FDA EUA tests. FDA also took steps regarding the type of device that can be used to transport patient samples.

Considering the supply challenges, traditional manufacturers including IVD manufacturers have taken critical steps to rapidly scale up production of swabs in the U.S. and overseas to meet demand – more than doubling capacity in some cases. One IVD company has made an investment in a small U.S.-based company to support their swab production while also laying the groundwork to establish their U.S.-based swab manufacturing plant to increase supply. Further, a number of non-traditional manufacturers have adapted their infrastructure and technologies to manufacture swabs (which requires validation prior to use), adding to the national supply. Increased manufacturing capacity and availability of alternatives has led to increased access to swabs and other collection supplies across the board. Further steps could be taken to support domestic swab manufacturing, including through increased funding for the Strategic National Stockpile for the purchase of swabs and greater clarity for suppliers on how to most efficiently engage with the multiple federal government agencies that have been serving pivotal roles in maximizing swab production and allocation. Presently, health care providers and IVD manufacturers rely on both domestic and overseas supplies to meet demand.

Extraction Reagents

Extraction reagents are a key component in molecular testing. These reagents are specialized materials used to draw out the pathogen's RNA or DNA from the patient sample. Extraction reagents are not specific to any particular pathogen. That is, extraction reagent used for COVID-19 molecular testing can also be used for other types of molecular testing. There are about six major manufacturers of extraction reagent globally, most with some manufacturing in the U.S.

Early in the pandemic, with demand for molecular COVID testing climbing dramatically, the supply chain for extraction reagent was strained. One of the world's largest manufacturers of extraction reagent ramped up production astronomically since January, increasing its monthly production in the U.S. and OUS by 20 times its typical monthly production from January to June

of this year. The U.S. augmentation was achieved by focusing on increasing production of a single type of extraction reagent that could be used across manual and automated platforms, and building an automated line at an existing manufacturing facility and running the line 24 hours a day. That same company expects to double its monthly production over the second half of the year. The pace and scale of manufacturing of extraction reagent was extraordinary. It was chiefly held back from even greater advances due to the inability of raw material providers in the U.S. and globally, save for one in Asia, to provide in sufficient quantity a key ingredient critical to production of extraction reagent.

Importantly, as it pertains to supply of extraction reagent for COVID-19 testing, of the over 145 million molecular tests that have been shipped to U.S. laboratories since mid-March, ~95% of these tests either include extraction reagents in the test kit or they are bundled in with the shipments in the quantity needed.

Instruments/Platforms

Small- and mid-size platforms utilized by laboratories to run clinical tests from many IVD manufacturers have consistently been available on the market in the U.S. throughout the pandemic. The largest high-throughput platforms, capable of running hundreds or more samples within 1-4 hours, represent a significant capital expenditure for laboratories and are most typically built to the specifications of a laboratory at the time of purchase. These platforms are built by hand by highly skilled professionals to exacting standards critical to ensuring the patient tests will be analyzed with absolute precision. It is not uncommon for a duration of 4-6 months from the time an order for such a platform is placed to when it would be installed by the manufacturer on site at the laboratory. Orders placed early in the pandemic for the largest high-throughput instruments/platforms are now resulting in deliveries. Several leading IVD manufacturers house instrument/platform manufacturing outside of the U.S. Manufacturing sites in the U.S. and outside of the U.S. are subject to FDA inspection and oversight.

Consumables: Precision plastics

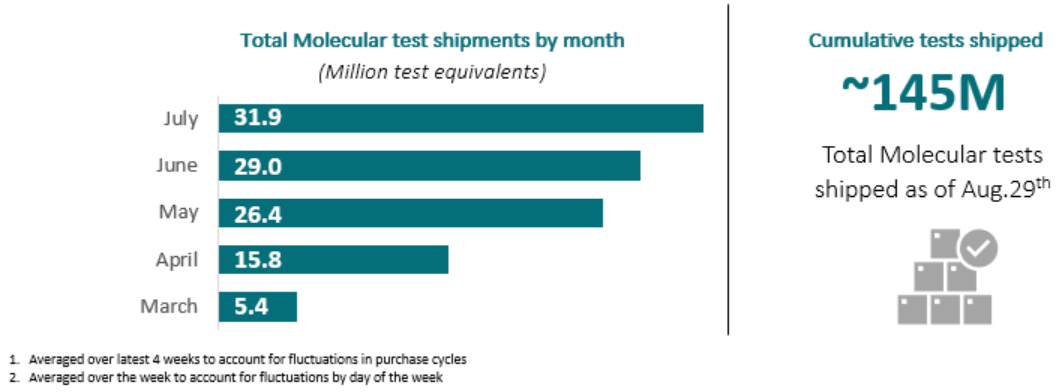
IVD companies and laboratories are reporting challenges procuring some precision plastics used to run tests on instruments/platforms, such as pipettes and plastic trays that fit precisely into instruments/platforms. While IVD companies do not manufacture these consumables, some are included in test kits, though most of these plastics are procured directly by laboratories. Shortages in these supplies can have a negative downward impact on laboratory capacity. Some IVD companies have explored the potential to secure a partnership with a non-scientific precision plastics manufacturer in hopes such a firm could transition to making scientific grade plastics. The challenges of ensuring manufacturing sites are DNA- and RNA-free has left few options, even among world renowned manufacturers of precision plastics unaccustomed to the requirements of scientific plastic production. In short, IVD manufacturers are seeking new partnerships to ameliorate the precision plastics shortage while traditional scientific plastics manufacturers continue their ramp-up.

AdvaMed COVID Testing Supply Registry: Supporting Federal/State Policy Makers' COVID Response

In July, AdvaMed and AdvaMedDx publicly launched a comprehensive, COVID-19 Diagnostics Supply Registry to help state and federal governments in their pandemic responses. The Registry is a partnership between AdvaMed and 13 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 account for about 95% of the molecular tests shipped in the U.S.

The Registry provides real-time, actionable data on molecular and serology (antibody) COVID-19 testing supplies shipped to hospital, public health, and reference laboratories within the U.S. These data are delivered via weekly reports to U.S. Department of Health and Human Services leadership and, increasingly, to state policy makers in furtherance of the IVD industry's effort to support our nation's COVID-19 response. Public editions of the weekly Registry reports are available here. Efforts are underway to include antigen testing data in the Registry. Further, the Registry aims to support collaboration with laboratories and other public health stakeholders to optimize access to all platforms of COVID-19 testing so that any potential shortages are identified and addressed quickly.

The *Sept. 4, U.S. COVID-19 Diagnostic Supply Registry National Report* shows that since the beginning of the pandemic, Registry participants have manufactured and shipped over 145 million molecular diagnostic tests to laboratories and other settings throughout the U.S. On average, these companies ship a collective 1.2 million tests each day. These figures demonstrate the massive mobilization of the IVD industry.



This supply of tests has enabled U.S. laboratories to run over 80 million COVID-19 molecular tests nationwide, to date. IVD manufacturers will continue with their commitment to providing increasing supply of IVD tests and technologies to laboratories to bolster testing capacity.

For serology (antibody) testing, Registry participants have the capacity to manufacture 100 million tests per month for the U.S. market.

While antigen testing data is not yet reported out by the Registry, public statements by the few companies that have secured EUAs for point-of-care antigen testing suggest that, by late fall, over 100 million tests will be manufactured and shipped across the U.S. Three of the EUAs require a small, portable instrument for testing while the fourth is instrumentless. These point-of-care tests compliment laboratory-based testing and will enhance access to testing.

To improve our nation's response to COVID-19 it is essential that all types of COVID-19 diagnostic testing across all laboratory and point-of-care settings are fully leveraged to ensure clinicians have all the tools available to them to best care for patients and the public health.

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[i] FDA Establishment Registration and Device Listing, 2018

[ii] FDA Establishment Registration and Device Listing, 2018

[iii] Some point-of-care tests do not require an instrument, or platform. These instrumentless tests provide a visual result. A non-COVID example of a point-of-care test that can be used in the home setting is a home pregnancy test.

[iv] Waiver under the Clinical Laboratory Improvement Amendments (CLIA) allows for point-of-care tests to be used in non-laboratory settings.)

[v] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expedites-review-diagnostic-tests-combat-covid-19.

[vi] *Id.*