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# COVID-19 Testing Supplies One Year into the Pandemic

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## Abstract

The COVID-19 pandemic has caused massive disruptions in global supply chains, including those required to effectively respond to and contain its spread. A group of products subject to these changes include those required to test for this disease. Being able to accurately diagnose patients relies on a suite of consumable materials to both collect samples from patients and analyze them in the laboratory. This paper presents information on the state of the domestic market for swabs, viral transport medium, RNA extraction kits, serology consumables, diagnostic reagents, plastic consumables, and diagnostic instruments one year into the pandemic. Changes to the state of the domestic manufacturing base in response to the pandemic is discussed, along with shifts in trade for each testing product and general factors that impact continued availability.

U.S. International Trade Commission

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# Introduction

COVID-19 has and continues to disrupt the normal functioning of society. Millions of Americans have been stricken by this pandemic, including the hundreds of thousands who have perished to date.[1] Several treatments have been devised to help support recovery, but an overall return to normal is unlikely before the majority of the population can be vaccinated.[2] Even then, the global nature of the pandemic necessitates continued vigilance for new strains and other factors that would cause the virus to persist. Testing for COVID-19 will, therefore, remain critical, as it provides important information to healthcare workers and public health authorities regarding both who has the disease and who might have been exposed.[3]

In a hospital setting, it is important to know the condition of each patient in order to implement the appropriate safety procedures. Hospitals would ideally test all admitted persons and healthcare workers to confirm their COVID-19 status.[4] If they test positive, the appropriate treatment regimens and support can be given to increase their chance of survival and recovery, while minimizing spread. If they do not test positive, they can be kept in a separate treatment area to lower the risk of transmission.[5] The pandemic has not stopped other medical emergencies or conditions that require treatment at a hospital, making it is imperative that non-COVID-19 patients be protected from a complicating illness.

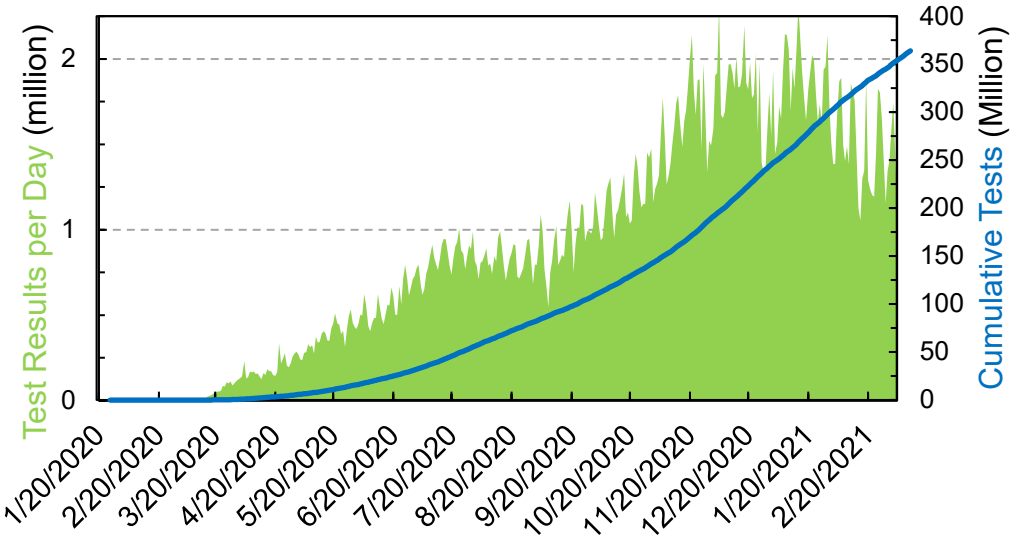
The general public is also protected by the proliferation of testing. The key to stopping widespread transmission of a communicable disease is to prevent people from coming into contact with the agent. Testing the populace to determine who might have been exposed helps identify which people need to undergo quarantine to limit the probability that they will transmit COVID-19 to others.[6] Once that is accomplished, the transmission chain can be broken, and further spread of the disease can be halted. The ability to achieve those goals relies on the availability of testing supplies.

The overall market for COVID-19 testing supplies is driven by the need to rapidly screen large segments of the population and deliver test results. The data shows demand for laboratory COVID-19 tests rising from less than ten thousand tests completed per month in February 2020 to approximately two million per day by the end of the year (figure 1).[7] While daily demand slackened somewhat in the new year, correlating with the introduction of vaccines, the overall order of magnitude of demand for testing supplies remains on the scale of millions per day. Maintaining the availability of testing supplies will

[1] Miller and Wu, "Coronavirus in the U.S.," December 2, 2020.
[2] CDC, "Potential Treatments," November 30, 2020; Whitten, "Why a COVID-19 Vaccine," November 4, 2020.
[3] AdvaMed, written submission to the USITC in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 14.
[4] Johns Hopkins Medicine, "Hospital and Emergency Care" (accessed December 2, 2020); Smith, "California Urges," November 30, 2020.
[5] CDC, "Triaging Sick Patients," September 11, 2020; Jewett, "Some Hospitals," September 10, 2020.
[6] CDC, "Contact Tracing for COVID-19," updated February 25, 2021.
[7] The COVID Tracking Project, "National Data" (accessed March 1, 2021). This data represents tests completed at laboratories and does not necessarily capture point-of-care tests completed, which may have approached 4 million per day during the referenced increase. Industry representatives, telephone interview by USITC staff, March 25, 2021.

continue to be critical for managing and abating the damage caused by the pandemic until vaccine deployment is complete, if not beyond that point.

**Figure 1**: U.S. COVID-19 tests completed by March 7, 2021




Source: The COVID Tracking Project, "National Data" (accessed March 26, 2021).
Note: Test counts are based on the data provided by individual states and territories; tracking by this source ceased on March 7, 2021; additional information on each location's methods is available at: The COVID Tracking Project, "About the Data" (accessed March 1, 2021).

Testing for COVID-19 encompasses many different components that are produced, transported, and used semi-independently. While the commonly used term *test kit* implies a complete product that one uses to obtain a diagnosis, the reality is more complicated.[8] All of the presently approved COVID-19 tests rely on myriad supply chains that provide different physical products. Most of the materials used in COVID-19 testing are disposable, requiring a constant influx of new material. The specific manufacturers and suppliers involved in this global value chain will, in part, depend on the specific type of test employed and the configuration of the approved test.[9] Similarly, the distribution channels will vary depending on the product, with some moving directly to medical and laboratory end-users and others through distributors.[10]

The need for widespread testing has led to a substantial increase in demand for many products needed to carry out COVID-19 tests.[11] However, the extent of demand varies depending on the type of test, the number of approved configurations, and the extent to which products are also used in different applications. Some products, like swabs and viral transport medium, have experienced major increases in demand that have overwhelmed supply, while supplies of other products like serology consumables were able to be re-directed from other applications to meet demand. Products such as COVID-19-

[8] Pfeiffer, "Despite Early Warnings," May 12, 2020; AdvaMed, "Principles for Preparedness," June 29, 2020, 9.
[9] Industry representatives, telephone interview by USITC staff, September 8, 2020.
[10] Industry representatives, telephone interviews with USITC staff, September 17, 2020; Government Officials, telephone interview by USITC staff, September 9, 2020.
[11] USITC, "COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges (Pub. 5145)," December 2020, 147.

specific biologics didn't exist before the pandemic and therefore, there was a lag before supply was able to ramp up to meet demand. Substantial barriers for any constituent product could pose a risk to meeting the overall testing demand.[12]

The objective of this paper is to provide details on the testing supplies required to continue mitigating the COVID-19 pandemic. First, an overview of the different forms of tests is provided. Subsequent sections provide details on the current state of individual testing supplies (i.e., swabs, viral transport medium [VTM], serology consumables, RNA extraction kits, biologics, plastic consumables, and instruments). For each, details on their composition is provided, followed by information on the current state of the U.S. industrial base and trade and how the market has evolved to reach that state over the past year of the pandemic. Finally, overarching issues are identified and discussed along with a look to maintaining the capability to respond to pandemics in the future.

# Types of Tests

The ultimate goal of a COVID-19 test is to look for evidence that a person is or was infected with the virus. There are multiple pathways to obtaining this information through the different configurations of a COVID-19 test.[13] Overall, COVID-19 testing should be viewed as a process, split into two distinct parts: (1) sample collection and (2) sample analysis. The equipment and consumables will be different for each stage of the testing procedure and, to a certain degree, the type of test employed. When bottlenecks are identified within the wider discussion of *test kits*, it typically means a limitation in a specific product or products that are key to one or both testing phases.[14] To better understand how shortages in a given product may affect specific tests, this section provides details of how those tests are performed and the consumables they require.

The goal of sample collection is to obtain material from a patient that contains the markers of this specific coronavirus and preserve it until it can be analyzed. As COVID-19 is a respiratory disease, markers of an active case can be found most commonly in saliva, lung excretions, and mucus. Evidence of past infection is found in the patient's blood, necessitating a blood draw. Regardless of method, the sample is collected by medical personnel, placed in a protected container, and transported to a laboratory for processing and analysis.[15]

The sample is analyzed in the laboratory for the presence of COVID-19 markers. The samples arriving for testing undergo different procedures depending on the marker that is being looked for, but the overall scheme is largely the same. The samples are exposed to a chemical probe that activates when it comes into contact with one of the virus's markers. The activated probe's fluorescence indicates a positive result, which is detected by a laboratory instrument.[16]

Some COVID-19 tests allow healthcare facilities to directly process and test a sample within 15 to 30 minutes using laboratory equipment that is already available.[17] Presently, several such "point-of-care"

[12] For example: Rose, "Coronavirus Testing Machines," May 28, 2020.
[13] FDA, "Coronavirus Testing Basics" (accessed November 16, 2020).
[14] Pfeiffer, "Despite Early Warnings," May 12, 2020.
[15] CDC, "Specimen Collection," updated February 26, 2021.
[16] Extance, "Explainer," July 6, 2020.
[17] NIH, "NIH Delivering New COVID-19 Testing Technologies," July 31, 2020.

tests have been granted an Emergency Use Authorization (EUA) by the FDA.[18] They work similarly to the way a normal laboratory test would function, only with one sample at a time and using the specific laboratory consumables for a given analyzer. Alternatively, tests have been developed that do not require a machine to analyze samples, which generally work in a similar manner as a pregnancy test.[19] A sample is deposited on a card or other test strip, and other liquid reagents are added and react with the sample for several minutes. If COVID-19 biomarkers are present, they will display a visible result on the test card, such as a distinct colored line.[20]

The accuracy of a COVID-19 test is measured by two parameters, the sensitivity and specificity. Test sensitivity describes how often a positive case is correctly identified, while specificity describes how often a negative case is correctly identified. As a result, a negative test does not definitively confirm that there is no active infection, nor does a positive test confirm infection one hundred percent of the time. Rapid tests are typically less accurate by these measures than their laboratory counterparts.[21]

To confirm that the test has been completed properly, positive and negative controls are analyzed alongside the patient's sample. The positive control is a sample known to contain the COVID-19 biomarker and will always return a positive result if the test protocol was performed correctly. Similarly, the negative control is a sample know not to contain any COVID-19 biomarkers, meaning it will provide a negative result if the protocol was performed correctly. An incorrect positive control indicates that the negative diagnoses cannot be trusted, while an incorrect negative control indicates the positive diagnoses cannot be trusted; in each case, the test must be performed again.

Whether they are performed in a separate laboratory or at the point-of-care, tests can broadly be split into three types based on the specific viral marker they're looking for: (1) nucleic acid and (2) antigen tests, which look for the presence of the virus directly, and (3) antibody tests, which detect the body's immune response to the virus.[22] Specifics for each type of test are discussed in the following sub-sections. While the specific protocol will vary depending on the laboratory, supplies on hand, and the approved protocol they are following, the general outlines provided below provide an overview of the major steps and procedures that are involved.

# Nucleic Acid Tests

Nucleic acid tests are used to determine if a person was infected with COVID-19 at the time they provided a sample.[23] This method looks for the genetic material (RNA) of this specific virus.[24] Viral RNA will only be present during an active infection, and the test will not reveal if the subject has had the virus

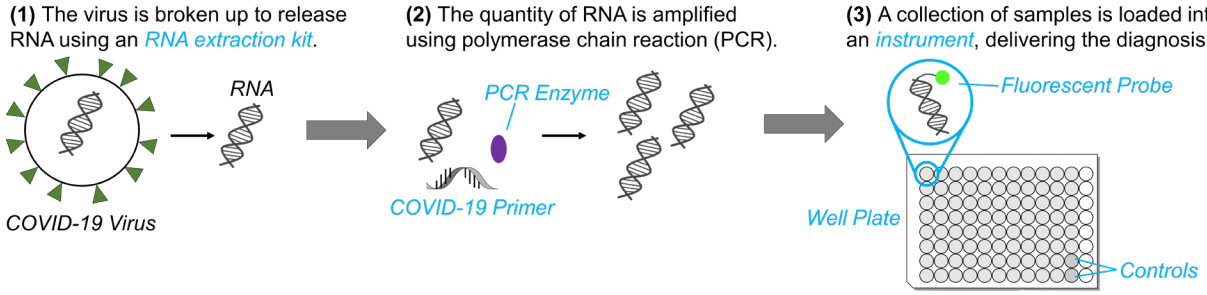
[18] An EUA permits the FDA Commissioner to authorize the use of an unapproved medical product, or an unapproved use of an approved product, if the Secretary of HHS makes the requisite declaration of a public health emergency and other required criteria are met. FFDCA §§ 564(a) and (b), 21 U.S.C. §§ 360bbb-3(a) and (b).
[19] Industry representatives, telephone interview by USITC staff, September 8, 2020.
[20] BioMedomics, "COVID-19-19 IgM/IgG Rapid Test" (accessed November 20, 2020).
[21] Wan and Sun, "Trump Administration's New Rapid Coronavirus Tests," September 29, 2020.
[22] FDA, "Coronavirus Testing Basics" (accessed November 16, 2020).
[23] Other terms for this type of test include *molecular tests* and (*rt-*)*PCR tests*.
[24] RNA stands for ribonucleic acid. RNA performs the same function for COVID-19 as DNA does for humans insofar as it carries the genetic information of the virus.

and since recovered.[25] The majority of approved protocols are laboratory based, but there are examples of approved point-of-care variants. In each case, the general steps will be the same in concept for the completion of the test.

The first step for completing a nucleic acid test is to recover material from the patient. This is typically accomplished using a swab to collect mucus from the nose or back of the throat. The swab is then placed in a sterile plastic tube, which usually contains viral transport medium. Viral transport medium preserves the sample during transportation to the lab by preventing the RNA from degrading. Alternatively, a small number of nucleic acid tests only require a saliva sample and no swab.[26]

Once the sample arrives at the laboratory, personnel can begin processing it to ultimately render a diagnosis (figure 2). The first step is to isolate any viral RNA, which is accomplished using a set of consumable laboratory materials called an RNA extraction kit. An RNA extraction kit does this by breaking apart the virus particles to release the RNA and separating the RNA from everything else in the sample. Because the amount of RNA in a typical sample is very small, the next step of the test is to amplify it. Enzymes (called polymerases) and nucleic acids (called primers) are used to multiply the amount of viral genetic biomarkers in a sample through a polymerase chain reaction (PCR).[27] The primers are specifically designed to interact with and amplify the COVID-19 RNA, making them a unique consumable.

**Figure 2**: Nucleic acid test procedure




Source: Brunning, "Periodic Graphic," June 25, 2020; diagram created by author; some images derived from the public domain image repository Open Clipart (DNA, single strand DNA, and well plate).
Note: features are not to scale; testing supplies are marked with blue text; RNA does not typically exist as a double helix, but that shape is used here for clarity of concept.

The final step of the nucleic acid test is to use an instrument to detect the amplified viral genetic material. This is accomplished by adding another reagent called a probe. For a nucleic acid test, this is a fluorescent dye that will bind to the viral genetic material. A laboratory instrument will then detect the probe's fluorescence to confirm a positive diagnosis, while a negative diagnosis will not show this signal.

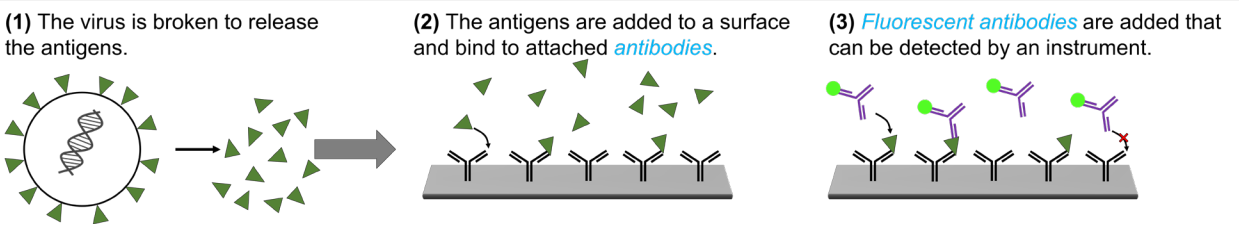
[25] USITC, hearing transcript in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 22–23 (testimony of Susan Van Meter, AdvaMed).
[26] FDA, "Coronavirus (COVID-19) Update," August 15, 2020.
[27] Hagen, "COVID-19 Testing FAQs," August 19, 2020.

# Antigen Tests

Antigen tests are largely similar to nucleic acid tests in most regards. They provide the same information, namely whether or not someone is currently infected with COVID-19. The method of collection is the same, as are the materials required. The primary difference is that a different biomarker is being tested for—antigens—which are the proteins coating the surface of the COVID-19 virus. This creates an altered workflow in the laboratory compared to nucleic acid tests, but the overarching structure remains the same.

The laboratory procedure begins by isolating the antigens from the rest of the sample (figure 3). This is accomplished by chemically breaking apart the virus particles and separating out the antigen proteins. Unlike a nucleic acid test, amplification of the biomarker is not required. The proteins are then added to a testing platform (e.g., a well plate) that is coated with antibodies that bind to the antigens. A fluorescent probe attached to a separate antibody is then added, which binds to any antigens caught by the first antibodies. The resulting fluorescence is then detected by an instrument to confirm either a positive diagnosis.

**Figure 3**: Antigen test procedure




Source: Brunning, "Periodic Graphics," June 25, 2020; diagram created by author; some images derived from the public domain image repository Open Clipart (DNA).
Note: features are not to scale; testing supplies are marked with blue text; RNA does not typically exist as a double helix, but that shape is used here for clarity of concept.

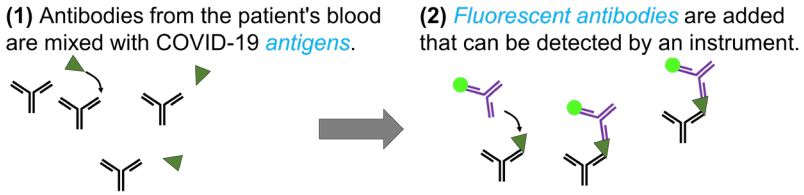
# Antibody Tests

The final type of COVID-19 test is substantially different from the other two. Antibody tests cannot distinguish between active and former infections because their target biomarkers—antibodies—will be present in both conditions. The targets are also different, as they are produced by the human body as part of the immune response to infection rather than being constituents of the invading virus. An antibody is a complex assemblage of proteins made by the immune system that selectively target viral antigens. The antibodies produced in response to different viruses are all different, meaning one can differentiate between them to gauge a patient's exposure to a given infectious agent. Antibody tests are also used to determine immunity levels, as quantitative antibody tests can measure the immune response to vaccine administration.

Collecting a sample for antibody testing is different than for the other two types of tests. Antibodies are found in the patient's blood, necessitating a blood draw using standard laboratory equipment, including needles and blood collection vials. In the laboratory, antibody tests work by doing the reverse of an antigen test. Antibodies separated from the patient's blood are added to a testing environment that

already contains viral proteins (figure 4). If there are COVID-19 antibodies in the sample material, they will bind to these proteins. In the next step, a fluorescent probe (e.g., another antibody) is introduced into the testing environment that binds to the antigen-antibody complex. The resulting fluorescence will be detectable by a laboratory instrument to confirm the diagnosis.

**Figure 4**: Antibody test procedure




Source: Brunning, "Periodic Graphics," June 25, 2020; diagram created by author.
Note: features are not to scale; testing supplies are marked with blue text.

# U.S. Markets for Testing Supplies

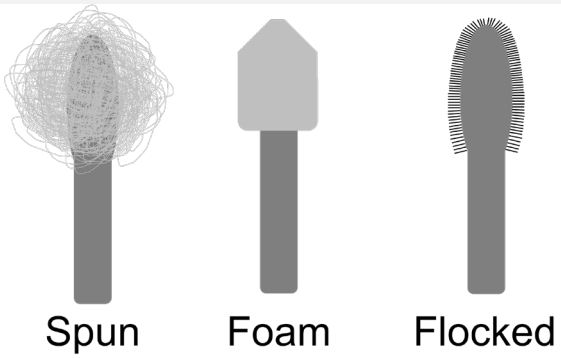
The following sub-sections provide details about the state of the market for COVID-19 testing supplies. Each product is first described, which is followed by a discussion of the U.S. industrial base and trade situation for it. Most products were, at one point during the pandemic, subject to shortages that posed a risk to continued testing availability. Products like swabs, VTM, RNA extraction kits, and plastics exhibited rising demand that required additional capital investments to mitigate and saw increased trade in the interim. Laboratory instruments, in contrast, are part of a global value chain that cannot adapt by simply increasing manufacturing in one country. Serology consumables, the needles and tubes required to draw blood, are unique insofar as their demand did not exceed supply throughout the pandemic.

## Swabs

Swabs are integral for COVID-19 testing, as they are used to collect material from the patient that bears the genetic and antigen biomarkers that can be detected in the laboratory. The most accurate tests use long nasopharyngeal swabs, which are capable of collecting material deeper within the nasal passages, where there are typically higher virus concentrations. There are three primary types of swabs that can be used for collecting samples for COVID-19 testing (figure 5).[28] In each case, the materials used in the swab head and stick have to be entirely synthetic (i.e., plastic) to prevent any inadvertent biological contamination of the sample. The simplest is the spun polyester variant, which is analogous to a standard cotton swab. The second type of swab employs a foam tip instead of individual fibers. The final form is a flocked swab, comprised of fibers attached to the plastic stick in controlled configurations.

[28] Industry representatives, telephone interview by USITC staff, August 20, 2020.

**Figure 5**: Types of swabs.




Source: created by author.
Note: features are not to scale.

While all swab types are currently in use for detecting COVID-19, of the three, flocked swabs are generally preferred for COVID-19 testing. The configuration of the fibers allows for more efficient sample collection, as they are capable of holding-on to more material.[29] Additionally, flocked swabs more completely release that material in the laboratory. As swabs are disposable and can only be used once, continued availability is necessary to respond to the pandemic.

# Swabs U.S. Industrial Base

The domestic industrial base for producing testing swabs before the pandemic was somewhat limited. There was only one domestic manufacturer of medical grade flocked swabs—Puritan Medical Products Company LLC (Puritan) of Guilford, Maine.[30] Their pre-pandemic capacity was reportedly insufficient to meet demand stemming from increased testing, as the market for flocked swabs increased by over three hundred percent in the first several months of the pandemic.[31] Puritan started working to increase production by building new facilities and manufacturing capacity for both foam and flocked swabs. This investment, enabled by funds disbursed through the Defense Production Act and CARES Act, was targeted to double production to over 100 million total swabs per month.[32] By March 2021, that target had been exceeded, and foam and flocked swab output exceeds 200 million per month, mitigating earlier bottlenecks.[33]

Some companies have bolstered the domestic industrial base by switching from making other types of swabs. Microbrush, with manufacturing in Grafton, Wisconsin, pivoted from making flocked swabs for dental applications to swabs for COVID-19 testing in a period of ninety days, producing millions of units per week by fall 2020.[34] Similarly, cotton swab producer U.S. Cotton switched part of the company's

[29] Puritan, "Why Flocked Swabs," August 26, 2013.
[30] Puritan currently holds a U.S. patent on flocked swabs, following a legal battle with Copan-Italia. Copan, "Summary Judgement," September 10, 2018; Puritan, "Puritan's Products" (accessed November 19, 2020); PRWEB, "Puritan Wins," November 15, 2018.
[31] AdvaMed, written submission to the USITC in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 19.
[32] DOD, "DOD Details $75 Million," April 29, 2020; DOD, "DOD Awards $51.15 Million," July 31, 2020.
[33] Industry representatives, telephone interviews by USITC staff, March 19 and 25, 2021.
[34] Hauer, "A Grafton Company," October 1, 2020.

existing manufacturing lines to accommodate the synthetic materials needed for diagnostic swabs and was able to produce millions of swabs per week.[35] It is also possible to manufacture swabs via 3D printing, as some companies like FormLabs in Millbury, Ohio, have done under FDA EUAs.[36]

The primary challenge to increasing swab production is sourcing and standing up the manufacturing equipment, which is unique to the intellectual property of the producer and usually has to be custom made.[37] This capital includes the machines and molds used to create and join individual swab components (i.e., the head, stick, and agent that binds them together), and their overall throughput determines the total production capacity. Packaging is also a challenge for increasing the swab supply. The swab packaging process requires automated machines to substantially increase output.[38] If they do not possess in-house capacity, swab manufacturers often rely on third-party packaging companies.

Firms initially expanded their capacity in part by using non-standard sources of capital to speed up the process of equipment acquisition. Puritan, for example, formed a new partnership with General Dynamics Bath Iron Works and other firms to help produce forty new machines.[39] Funds from the Defense Department helped bring these new capabilities to bear. Microbrush had to procure new production equipment and molds to expand their capacity as well, although partnerships with Proctor and Gamble and the Cleveland Clinic helped speed this process.[40] By March 2021, capital constraints had partially been alleviated, and manufacturers were able to return to relying on traditional sources of production equipment.[41]

An increase in swab production capacity has necessitated an increase in employment. It can take several hundred people to fully staff a production line, even after upgrading to a more automated process.[42] Onboarding was initially hindered by the necessity of training in smaller groups due to the pandemic and the availability of labor.[43] However, the contained training capacity issue has reportedly been dealt with, and the number of people employed in swab manufacturing has almost tripled since the pandemic began.[44]

Access to raw materials is not reportedly a bottleneck for swab production. Raw materials, primarily plastic resins, are typically sourced from domestic sources, and those orders have not been stymied by the pandemic.[45] The quantities required are also quite small for producing swabs at scale. For example, one pound of plastic resin can be used to create tens of thousands of swabs.[46]

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[35] Esposito, "Gaston County Company Develops Synthetic Swab," April 22, 2020.
[36] Lininger, "Concordance Partners with NW Ohio Company," April 20, 2020; FDA, "3D Printing," August 3, 2020.
[37] Industry representatives, telephone interview by USITC staff, August 20, 2020.
[38] Industry representatives, telephone interviews by USITC staff, August 20, September 17, and October 2, 2020 and April 2, 2021.
[39] Milliken, "BIW Signs Contract to Build Swab Machines," May 7, 2020.
[40] Reinke, "From Dental Tools to Test Swabs," October 8, 2020; Cleveland Clinic, "Cleveland Clinic, P&G, and Microbrush Collaborate" (accessed November 19, 2020).
[41] Industry representatives, telephone interview by USITC staff, March 19, 2021.
[42] Industry representatives, telephone interviews by USITC staff, August 20 and September 17, 2020.
[43] Shanker, "Swabs, Stat!," March 25, 2020.
[44] Industry representatives, telephone interview by USITC staff, March 19, 2021.
[45] Industry representatives, telephone interviews by USITC staff, August 20, September 17, and October 2, 2020.
[46] Industry representatives, telephone interviews by USITC staff, October 2, 2020.

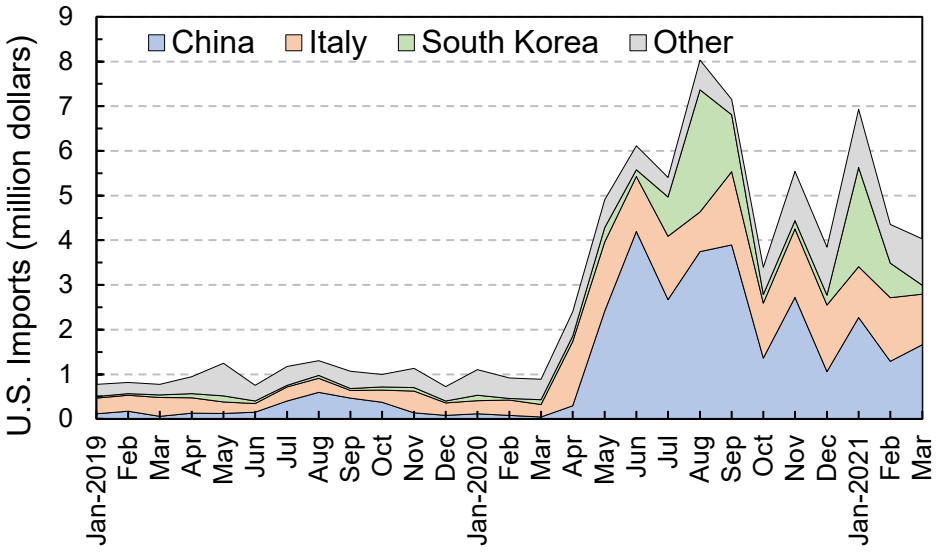
The overall situation for domestic swabs production has substantially improved compared to pre-pandemic capabilities. The large spike in testing demand during November 2020 to January 2021 put a strain on swabs supplies, but the continuing investments in new capacity were able to better accommodate that shock than earlier spikes in testing demand.[47] Some manufacturers anticipate that capacity becoming permanent to support greater overall (i.e., not exclusively COVID-19) testing. Some also anticipate being able to export swabs once current investments are fully realized.

# Swabs Trade

There are several foreign flocked swab producers that reportedly sell to consumers in the United States. These include European Producer Copan-Italia and several Asian firms, such as Noble Bio in South Korea.[48] The swabs appropriate for diagnostic use are imported under HTSUS subheading 5601.22.[49] This tariff line covers waddings of man-made textile materials, meaning there are unrelated products captured within its statistics.[50] However, there are clear shifts in trade under this heading as a result of the pandemic (figure 6). Monthly imports under this heading averaged $840,000 from 2010–2019, which increased to circa $5 million per month between April and May 2020. This shift correlates with the pandemic timeline within the United States. Imports peaked over the summer, but then began declining in fall 2020 and into early 2021.[51] As the overall scale of demand for testing supplies has not slackened, this is likely evidence that U.S. producers are better able to meet domestic demand. Both increased capital investments and market shifts are likely responsible for the overall decline in swab imports and reliance on foreign manufacturers.

[47] Industry representatives, telephone interview by USITC staff, March 19, 2021.
[48] Yoon and Park, "…," March 9, 2020; Lee, "…," April 18, 2020; Boo, "…," April 28, 2020.
[49] This subheading received a new breakout statistical reporting number in response to the pandemic, 5601.22.0050, for flocked swabs. However, no imports were recorded under this line by the time this paper was written. USITC, Harmonized Tariff Schedule of the United States (2021).
[50] The normal trade relations duty rate is 6.3 percent, but that has been supplemented by a 25 percent Section 301 tariff since September 24, 2018. Petitions for Section 301 exceptions specifically for swabs have been received by the Office of the U.S. Trade Representative, as have objections to those petitions. Exceptions have not been granted to date. USTR, "Request for Comments," responses 0583, 0708, 0715, 0780, 0782, 0786, and 0790 (accessed November 20, 2020).
[51] Industry representatives, telephone interview by USITC staff, April 2, 2021.

**Figure 6**: U.S. imports of other articles of wadding of man-made fibers




Source: USITC DataWeb/USDOC for HTSUS subheading 5601.22 (accessed February 26, 2021).
Note: this HTSUS statistical reporting number contains products other than swabs.

There were also shifts in the source country for some imports under this tariff line. Historically, China and Italy accounted for the majority of imported swabs, with imports from both countries substantially increasing in spring 2020. The bulk of the increase came from China, despite Copan Italia being a primary source of flocked swabs globally. South Korea also strongly entered the U.S. market during summer 2020 after a decade of being a minor source, accounting for much of the non-Italian and -Chinese import balance. This trend tracks with activity by South Korean producers in response to the pandemic, although the imports from South Korea returned to previous levels by the end of the year.

# Viral Transport Medium

The purpose of VTM is to preserve a patient's sample as it is transported to the laboratory. Essentially, VTM is a buffered salt solution with preservatives to prevent bacterial or fungal growth.[52] Such contaminants can degrade the COVID-19 biomarkers before testing is complete. VTM is dispersed to testing sites as part of a larger overall group of testing supplies. It comes packaged in the specimen collection tube, pre-loaded by the manufacturer. The health care worker need only deposit the swab containing the patient's sample into the tube, submerge the swab head with the VTM, and seal the tube to complete the sample collection procedure. On average, each test requires approximately three milliliters of VTM.[53]

[52] Buffered means that chemicals are added to maintain a constant acidity. CDC, "Preparation of Viral Transport Medium" (accessed November 19, 2020).
[53] LABline, "OSU Wexner Medical Center Creates," April 13, 2020.

# VTM U.S. Industrial Base

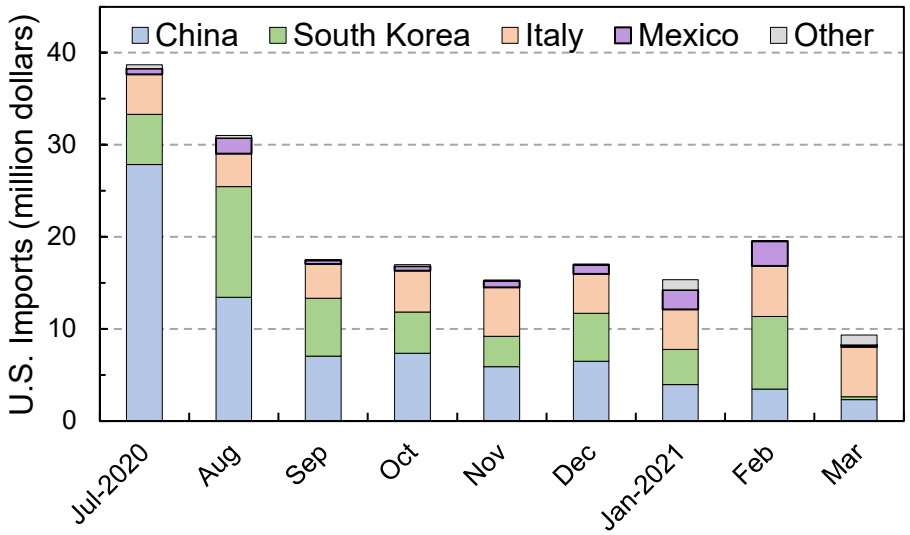
There are multiple firms within the United States that are capable of manufacturing VTM. However, the United States reportedly did not have the domestic capacity to meet demand for viral transport medium, early in the pandemic.[54] Some firms have been able to scale up production of VTM using existing facilities. Hardy Diagnostics (Santa Maria, California), for example, increased its output of VTM from several hundred tubes per week to approximately half a million tubes.[55] Similarly, Teknova (Hollister, California) has increased its output to an order of magnitude greater than pre-pandemic levels by increasing capacity utilization and boosting staffing.[56] Additional production capacity is also planned to come online to supplement the existing domestic industrial base. Thermo Fisher was able to start building a new facility on a government contract in Lanexa, Kansas, supplementing the company's existing production of eight million tubes per week.[57] Smaller organizations and laboratories had also begun making their own VTM, which the FDA had temporarily decided not to restrict in light of the pandemic.[58] As a result of these factors and production increases, the availability of VTM has substantially improved by March 2021.[59]

# VTM Trade

A specific tariff line was added for VTM in response to the COVID-19 pandemic. Trade data are available under HTSUS statistical reporting number 3821.00.0010 from July 2020, and such data reveals the primary sources of VTM imported by the United States during the pandemic (figure 7).[60] As with swabs, the bulk of VTM imports originate from China, South Korea, and Italy, which tracks with the observation that swabs and other collection materials often share suppliers. With no trade data before July 2020, it is difficult to draw conclusions about the state of the import market before the pandemic and the subsequent response.[61] However, it is clear that total imports of VTM have substantially decreased, by approximately 50 percent, between July and September. These import levels were largely maintained through the end of the year, which indicates there was a substantial rise in demand for foreign product in the early stages of the pandemic that has since abated as more U.S. capacity has come online.

[54] Market demand has been such that alternative products like saline have been used to expand testing capacity. Saline solution is a sterile solution of water and salt. Industry representatives, telephone interviews by USITC staff, September 17 and September 22, 2020; FDA, "FAQs on Viral Transport Media" (accessed November 19, 2020).
[55] Hardy Diagnostics, "Hardy Diagnostics Increases Manufacturing," May 6, 2020.
[56] Teknova, "Teknova Scales up Production," September 10, 2020; Chadwell, "Teknova Hiring," July 3, 2020.
[57] Thermo, "Thermo Fisher Scientific Officially Opens," August 28, 2020.
[58] For example: Smith et al, "Large-Scale in-House Production," 2020; FDA, "Enforcement Policy," July 2020.
[59] Industry representatives, telephone interviews by USITC staff, March 19 and 25, 2021.
[60] The normal duty rate is 5 percent, and no Section 301 tariffs apply. USITC, Harmonized Tariff Schedule of the United States (2021).
[61] The overall subheading, 3821.00, is a large basket category predominantly composed of non-VTM products, making analysis of trade volumes before the new breakout difficult.

**Figure 7**: U.S. imports of viral transport medium




Source: USITC DataWeb/USDOC for HTSUS statistical reporting number 3821.00.0010 (accessed February 26, 2021).

# Serology Consumables

The materials required to collect a sample for an antibody test are the same as for any diagnostic test based on a blood draw. A lab technician requires: an alcohol swab to disinfect the patient's skin, a needle, a collection tube, and, in some cases, a rubber tourniquet to make it easier to find a vein.[62] The protocol for collection is itself routine for a blood draw procedure, and the infrastructure used for laboratory sample collection is the same as for non-COVID-19 tests. A laboratory technician has multiple options when choosing needles for collecting a blood sample. Needles can be of the traditional type, wing sets, or self-closing safety varieties. The ultimate choice depends on the preference of the medical facility or practitioner, and any can be used for a COVID-19 test.[63]

The plastic tubes used for blood draws are unique to that purpose and cannot be substituted. For example, the tubes used for the other types of COVID-19 tests are not compatible with this application. Serology tubes must have an internal vacuum to help facilitate the blood draw, which requires unique manufacturing and external seals. This impedes the stockpiling of serology tubes, as the internal vacuum only holds for at most two years. There are approximately five variants of serology tubes, all of which could be used for COVID-19 testing. However, the preferred options are the serum separation variants, because they allow for the cleanest analysis.[64] These tubes come pre-loaded with chemicals that aid sample processing in the laboratory by providing a cleaner separation of the COVID-19 antibodies from the rest of the blood serum.

[62] The alcohol swabs and tourniquets require somewhat different inputs and follow different supply chains than other products discussed in this paper, so the focus of this section is on the needles and collection tubes only.
[63] Industry representatives, telephone interview by USITC staff, September 14, 2020.
[64] Industry representatives, telephone interview by USITC staff, September 14, 2020.

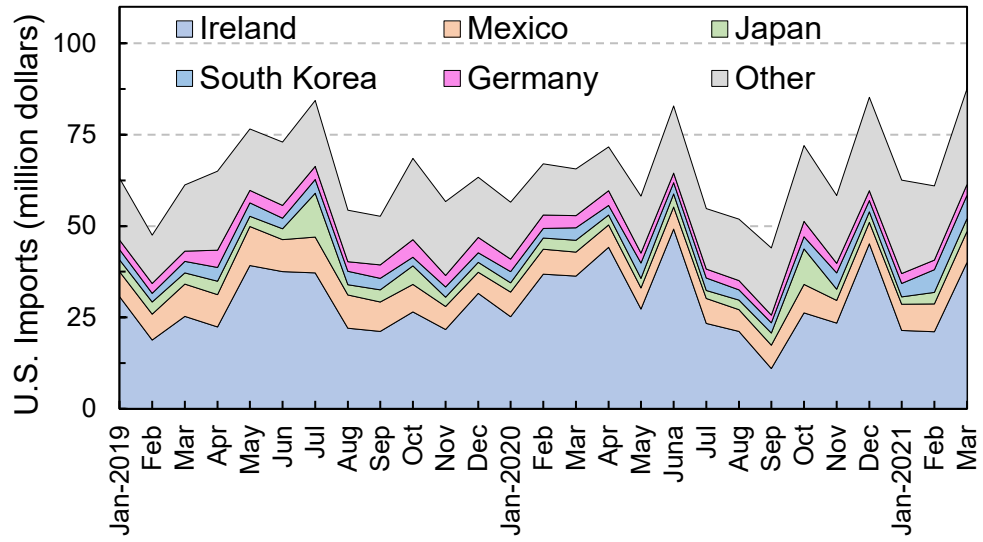
# Serology Consumables U.S. Industrial Base

Companies within the United States are reportedly able to produce needles and serology tubes in substantial quantities. Enough materials are produced every year for several billion blood tests.[65] In response to the pandemic, these firms were able to ramp-up production between February and March 2020, but had to subsequently decrease their output as the countervailing downturn in regular medical procedures substantially depressed overall demand. This excess capacity is still available, should the need arise, which is enough to enable circa 100 million tests per month.[66]

# Serology Consumables Trade

While the majority of U.S. blood draw consumables are produced domestically, there are foreign suppliers that supplement that capacity. A substantial fraction of needle imports originate from Europe (Figure 8), while caps for serology tubes are often sourced from India.[67] There was an issue sourcing the specialized caps for blood collection tubes from a specific supplier during the first several months of the pandemic, but that has since subsided.[68] Trade in needles has largely remained constant throughout the pandemic, and other bottlenecks in the global supply chain have not been reported at this time.

**Figure 8**: U.S. imports of needles




Source: USITC DataWeb/USDOC for HTSUS subheading 9018.32 (accessed March 26, 2021).

[65] Industry representatives, telephone interview by USITC staff, September 14, 2020.
[66] USITC, hearing transcript in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 85–86, (testimony of Susan Van Meter, AdvaMed).
[67] Serology caps and tubes are covered under broader laboratory consumable HTSUS subheadings, of which they are a minor component, and are not presented here. Industry representatives, telephone interview by USITC staff, September 14, 2020.
[68] Industry representatives, telephone interview by USITC staff, September 14, 2020.

# RNA Extraction Kits

Preparing samples for analysis in the laboratory requires many different pieces of consumable equipment. An RNA extraction kit is used by the majority of nucleic acid test protocols to isolate and purify the COVID-19 genetic material.[69] These kits are not a single, unique product, but are sets of consumable plastic laboratory materials (small centrifuge tubes, filters, and collection vials) and chemical reagents (solutions for breaking the virus apart and purification) assembled by a manufacturer. Each kit has enough materials to process several dozen samples.

The use of RNA extraction kits is not exclusive to COVID-19 testing, meaning that a market existed pre-COVID-19 that could start to meet the demand spurred by the pandemic.[70] The overall market for RNA extraction kits has substantially grown since the beginning of the pandemic. Total demand, previously on the scale of hundreds of thousands per month, rose to tens of millions per month in the fall of 2020.[71] Supplies were scarce at the beginning of 2020 during the early stages of the pandemic, but the situation has substantially improved by early 2021 as additional production capacity came online.[72]

# RNA Extraction Kit U.S. Industrial Base

There are reportedly six international firms with facilities in the United States that produce RNA extraction kits for the domestic market.[73] For example, Promega (Madison, Wisconsin) and Qiagen (based in Germany with U.S. manufacturing in Germantown, Maryland) are both producers that provide extraction kits for approved COVID-19 tests.[74] Companies have responded to the pandemic by generally working to increase production levels by at least an order of magnitude.[75] Qiagen, for example, had increased production from several hundred thousand per month to millions by mid-2020.[76] Promega has also reportedly increased output by boosting capacity utilization at its present facilities.[77] These efforts earlier in the pandemic have helped clear the backlog for RNA extraction kits, and tens of millions of units were being produced by March 2021.[78]

Domestic manufacturers typically rely on raw materials primarily sourced from other producers within the United States, with one substantial exception. Chemicals used to release RNA from the inside of the

[69] AdvaMed, written submission to the USITC in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 19–20; U.S.
[70] Government Officials, telephone interview by USITC staff, September 9, 2020.
[71] USITC, hearing transcript in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 24–25 (testimony of Susan Van Meter, AdvaMed).
[72] Government Officials, telephone interview by USITC staff, September 9, 2020; Industry representatives, telephone interviews by USITC staff, March 19, 2021.
[73] AdvaMed, written submission to the USITC in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 19; U.S.
[74] Taylor, "Qiagen Aims for 50-Fold Jump," May 7, 2020; York, "Meeting Customer Needs," March 30, 2020.
[75] AdvaMed, written submission to the USITC in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 19–20; U.S; Industry representatives, telephone interviews by USITC staff, August 25, September 8, and September 22, 2020.
[76] Taylor, "Qiagen Aims for 50-Fold Jump," May 7, 2020.
[77] York, "Meeting Customer Needs," March 30, 2020.
[78] Industry representatives, telephone interviews by USITC staff, March 19, 22, and 25, 2021.

virus—guanidine thiocyanate and guanidine hydrochloride—were not initially available from domestic sources in the quantity (i.e., tons instead of kilograms) required to meet demand for extraction kits.[79] One of the few facilities globally that could manufacture at this scale is a German-owned company in China, forcing firms to diversify their supply chains as they respond to the pandemic.[80] Firms have since been able to navigate and adjust their value chains in response to this constraint, which has included a doubling of domestic production such that these chemicals are no longer a bottleneck.[81]

# RNA Extraction Kit Trade

The U.S. manufacturing base for RNA extraction kits is supplemented by multiple producers overseas. Some of the world's largest producers are based in Europe, including Qiagen and Roche.[82] Roche provides an alternative set of products, also with production in Germany.[83] Production overseas has ramped up in response to the pandemic, as it has in the United States.[84] Imports of RNA extraction kits are captured under a new HTSUS breakout, statistical reporting number 3822.00.5095 (figure 9).[85] However, other products are also covered under this heading, obfuscating the RNA extraction kit component. The available data since July 2020 shows stable demand until December, when imports substantially increased. This shift was primarily driven by imports from Lithuania, which had heretofore been a minor supplier for the products under this statistical reporting number, which may indicate non-pandemic or non-testing supply factors at play. That temporary spike  has since decreased.

[79] Production capacity of these chemicals has reported been offshored in previous years due to U.S. regulations on chemical manufacturing. Industry representatives, telephone interviews by USITC staff, August 25 and September 22, 2020; USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 118 (testimony of Susan Van Meter, AdvaMed).

[80] These chemicals are imported under statistical reporting number 2925.29.9000 and are subject to an additional 25 percent duty under the Section 301 tariff heading 9903.88.03. Exemptions for these chemicals from Section 301 tariffs have been petitioned for, but have not been granted to date. USTR, "Request for Comments," response 0975 (accessed November 20, 2020). USITC, Harmonized Tariff Schedule of the United States (2021).

[81] Industry representatives, telephone interview by USITC staff, March 22, 2021.

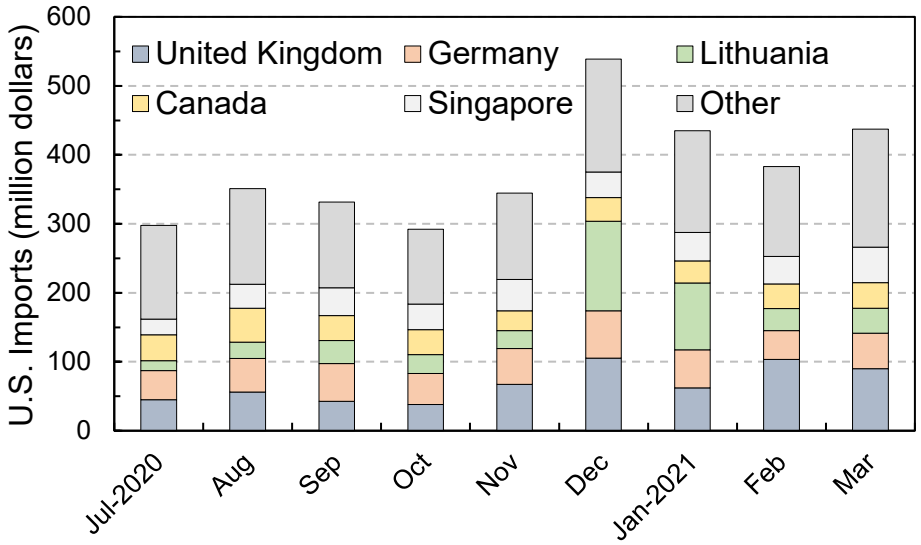
[82] Krieger, "Coronavirus: California Testing Hamstrung," March 15, 2020.

[83] Industry representatives, telephone interviews by USITC staff, August 28, September 8, and September 22, 2020.

[84] Herper, "Shortage of Crucial Chemicals," March 10, 2020.

[85] This tariff line has column 1 duty rate of free and no Section 301 tariffs apply. This subheading contains multiple products, making analysis of import trends before the new breakout difficult.

**Figure 9**: U.S. imports of other diagnostic or laboratory reagents




Source: USITC DataWeb/USDOC for HTSUS statistical reporting number 3822.00.5095 (accessed February 26, 2021).
Note: this HTSUS statistical reporting number contains products other than RNA extraction kits.

# Biologics

Each type of COVID-19 test requires access to different laboratory reagents for producing a diagnosis. These are specialized materials that are designed to interact with the COVID-19 biomarkers or provide other information that, as a group, are referred to in this paper as biologics. These include the primers used in nucleic acid tests and the specific fluorescent probes used in all three types of COVID-19 tests. These biologics are also variant-specific, meaning new versions have to be created to ensure accurate diagnoses. Fortunately, developing these modified versions are reportedly much easier than starting from scratch, largely precluding the long development times experienced at the beginning of the pandemic.[86] The main bottleneck in that scenario is identifying the variants before they become widespread among the population.[87]

Controls can also be classified under this category of testing supplies.[88] Positive controls must be curated and approved for use in a given protocol because of the presence of viral biomarkers. In contrast, the negative control can be any sample of human tissue that is known to be free of COVID-19 material. Only one of each control is required to confirm a batch of samples that are analyzed concurrently, which for highly automated machines means several hundred diagnoses can be made per unit of control material.

[86] Industry representatives, telephone interview by USITC staff, March 19, 2021.
[87] Industry representatives, telephone interview by USITC staff, March 22, 2021.
[88] Government Officials, telephone interview by USITC staff, September 10, 2020.

# Biologics U.S. Industrial Base

While the United States does have an advanced biomedical manufacturing ecosystem, the industrial base for COVID-19-specific reagents did not exist prior to the pandemic. In order to producer the primers, probes, and other materials, the pathogen must be identified, and the proper reagents developed before production can begin.[89] This research and development stage takes time to complete and requires access to curated virus samples, which is why COVID-19 tests were not instantaneously available in early 2020.[90] As a result, the demand for tests caused by the pandemic created an immediate deficit between what industry was able to manufacture and the new market that was created.

There are now multiple producers in the United States that are able to supply COVID-19 biologics for the domestic market. For example, Roche, Promega, Qiagen, Becton Dickinson (BD), Thermo Fisher Scientific, and IDT all manufacture components for laboratory nucleic acid and antigen tests at U.S. facilities.[91] Domestic production of COVID-19 biologics has reportedly ramped-up through increased capacity utilization rather than the installation of new capital.[92] Despite these efforts, multiple COVID-19 biologics suffered shortages early in the pandemic.[93]

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[89] The manufacturing process for biologics varies depending on the type, and individual manufacturers typically do not provide all of the laboratory reagents for a given test. The DNA primers and probes used in nucleic acid tests are chemically synthesized sequentially from individual nucleotides in the sequence required for detecting a specific target (a nucleotide is one of the four chemical bases used to make DNA). Antibodies, in contrast, are produced in living systems, either with cultured cell lines or in a whole organism, like a mouse. In each of those cases, the target protein (i.e., antigen) is introduced into the living system, and the system's immune system produces the antibodies, which are then harvested. Both DNA and antibodies are isolated and purified after synthesis. This prevents any unwanted by products or materials contaminating the final test. The pure materials can then be chemically functionalized with fluorescent markers, depending on the end-use for the specific reagent. The final product is typically encapsulated within its own plastic vial for storage and transport, allowing materials to be assembled from different producers as needed to provide the complete suite of testing reagents needed by a specific laboratory protocol. Surat, "Industrial Production of Antibodies" (accessed November 23, 2020).

[90] USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 80–81 (testimony of Susan Van Meter, AdvaMed); Industry representatives, telephone interview by USITC staff, September 8, 2020.

[91] The CDC is also a domestic producer and packager of reagents, but only for state public health laboratories. CDC shipments include primers, probes, and control samples. This manufacturing takes place at CDC facilities managed by their Division of Scientific Resources in Georgia. Industry representatives, telephone interviews by USITC staff, August 25, August 28, and September 22, 2020; Integrated DNA Technologies, "SARS-CoV-2 Probes and Other COVID-19 Research Reagents" (accessed September 29, 2020); Sable-Smith, "Promega Helping Supply materials for COVID-19 Tests," March 18, 2020; Duvernay, "Eugene Facility Part of Company's Efforts," March 17, 2020. CDC, "Diagnostic Test for COVID-19 Only," July 15, 2020; Government Officials, telephone interview by USITC staff, September 9, 2020.

[92] Industry representatives, telephone interview by USITC staff, August 25, 2020.

[93] FDA, "Medical Device Shortages" (accessed October 20, 2020); GAO, "COVID–19 (GAO-20-701)," September 21, 2020, 34–37, 197; Industry representatives, telephone interview by USITC staff, September 22, 2020.

In addition to traditional laboratory tests, multiple firms produce materials for rapid tests, such as Abbott Laboratories and BD.[94] These firms have increased production capacity for this market segment in response to the pandemic. Abbott Laboratories had announced plans for a new facility to help meet the demand for rapid tests.[95] BD, as another example, has received funding from the federal government to increase capacity for this market segment.[96] However, the deployment of rapid tests has not necessarily decreased demand for traditional laboratory tests. By their nature, laboratory tests are more conclusive, meaning rapid tests are often accompanied by a laboratory test to confirm a diagnosis, although rapid tests do still fulfill a critical niche where large numbers of tests need to be completed or tests need to be completed quickly.[97]

Issues can arise in the domestic reagent supply chain for multiple reasons. Stockpiling COVID-19 biologics is often difficult, as the materials used in testing only have a shelf life on the order of one year.[98] Biologics are also not generally substitutable, meaning if a laboratory relies on a particular manufacturer that has an production issue, they can cannot easily switch to a different provider.[99] These products can also become contaminated, as happened with early CDC testing supplies, which can take weeks for the manufacturer to correct.[100] Sourcing inputs for manufacturing has reportedly not been an issue, as most are available from and sourced from U.S. companies, and manufacturers also try to maintain multiple sources.[101]

Investments in additional capacity were able to alleviate or prevent some bottlenecks as the pandemic progressed. Producers of biologics were able to weather the larger increase in demand experienced at the end of 2020.[102] In 2021, demand has reportedly leveled-off and a new steady state was achieved by March. Part of this is attributable to the introduction of vaccines and the shifts of some laboratories, such as academic labs, no longer performing COVID-19 testing. Of the different test variants, demand for antibody tests declined more rapidly than nucleic acid tests.[103]

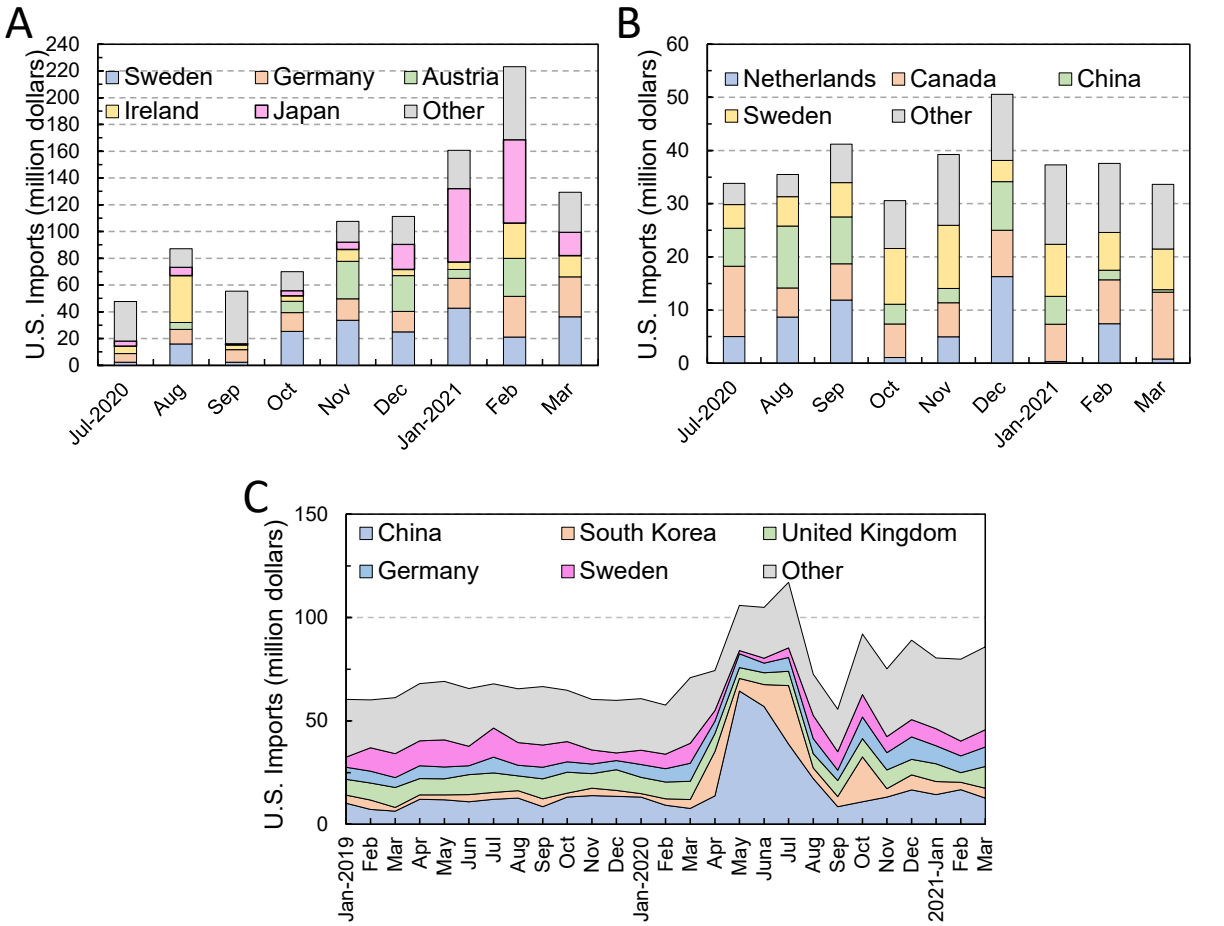
# Biologics Trade

There are non-U.S. producers of all biologics used in COVID-19 testing. Companies like Qiagen and Roche with U.S. manufacturing sites have locations in Europe to supply that market locally. Trade is captured under different statistical reporting numbers, depending on the type of test.[104] Materials for nucleic acid tests are imported under 3822.00.5050, antigen tests under 3822.00.1090, and antibody tests under

[94] Abbott Laboratories, "An Update," August 14, 2020; Crain's Chicago Business, "Abbott Labs Cleared," August 26, 2020; BD, "BD Launches," July 6, 2020.
[95] Murphy, "Abbott Laboratories Plans Expansion," May 28, 2020.
[96] DOD, "DOD and HHS Invest $24.3M," July 31, 2020.
[97] Industry representatives, telephone interviews by USITC staff, March 19, 2021.
[98] Industry representatives, telephone interview by USITC staff, September 21, 2020.
[99] Industry representatives, telephone interviews by USITC staff, August 25, August 28, and September 22, 2020.
[100] Government Officials, telephone interview by USITC staff, September 9, 2020; CNN, "Early CDC Test Kits," June 25, 2020; Chen et al, "Key Missteps at the CDC," February 28, 2020; Sarata, "Development and Regulation of Domestic Diagnostic Testing," March 9, 2020.
[101] Industry representatives, telephone interviews by USITC staff, August 20, August 28, September 17, September 21, and September 22, 2020.
[102] Industry representatives, telephone interviews by USITC staff, March 19 and 22, 2021.
[103] Industry representatives, telephone interview by USITC staff, March 22, 2021.
[104] New breakouts were provided for antibody and nucleic acid reagents in response to the pandemic.

3002.15.0010 (figure 10).[105] The sources for each product are largely similar, primarily countries in Europe and Asia with developed biomedical sectors.

**Figure 10**: U.S. imports of laboratory materials




Source: USITC DataWeb/USDOC for HTSUS statistical reporting numbers 3002.15.0010. 3822.00.1090, and 3822.00.5050 (accessed February 26, 2021).
Note: (A) antibody, (B) nucleic acid, and (C) antigen reagents; these HTSUS statistical reporting numbers contain products other than COVID-19 materials.

Import data for nucleic acid and antibody biologics since July 2020 show demand on the order of tens of millions of dollars per month.[106] Between July and the end of the year, imports of antibody biologics generally increased by 2- to 3-fold. Imports of nucleic acid biologics were largely stable, but they temporarily spiked in early 2021. The data for these statistical reporting numbers indicate that the U.S. manufacturing base for these reagents has not been able to increase capacity over the period enough to overcome the need for imported material.

[105] All of these tariff lines have a column 1 duty rate of free and no Section 301 tariffs apply. USITC, Harmonized Tariff Schedule of the United States (2021).
[106] Import data for antibody and nucleic acid tests are only available through new breakouts after July 2020. Previously, their inclusion under basket subheadings complicates analysis before this timeframe.

Long-term data is available for antigen biologics, which show a temporary spike in imports by value from April to August 2020 compared to the baseline trend, with the bulk of the increase attributable to Chinese imports. This has declined from a peak in summer 2020, although the overall magnitude of antigen biologics imports is still elevated compared with the 2019 status quo. Unlike the other two reagents, the data for antigen biologics indicates the U.S. industrial base has been able to increase production somewhat to meet the increased demand.

# Plastic Consumables

Myriad plastic products are required to obtain a COVID-19 test result. Disposable plastic vials are used to transport samples from the testing site to the laboratory. Pipette tips are required to move small volumes of liquid during laboratory analysis. Small tubes are necessary at various processing stages in the laboratory. Plastic well plates are used to run assays. All of these materials are specifically made for laboratory or medical use due to the exacting specifications required for delivering an accurate diagnosis.

Laboratory plastics need to be manufactured to be free of RNase and DNase. RNases and DNases are enzymes that break down nucleic acids. Their presence would interfere with the ability of a COVID-19 test to detect the virus' genetic material, potentially leading to a false negative result.[107] The requirements for maintaining an RNase- and DNase-free production environment means that there are currently few producers with those capabilities in the United States.[108] Ramping-up plastic production, was reportedly hindered by the difficulty in bringing new capacity online that meets these requirements, and these requirements are reportedly still slowing capital investment.[109]

In addition to not having readily available substitutes with non-medical plastics, multiple plastic laboratory pieces are specific to certain instruments and protocols. Pipette tips, for example, are specially designed for diagnostic applications on specific instruments. Their shape is often specialized for use with one type or make of instrument, requiring unique molds and manufacturing lines.[110] All diagnostic pipette tips additionally require a filter, not unlike one used in a cigarette, to prevent contamination between samples; this precludes the use of the non-filtered tips, which are much more common.[111] As a result, pipette tips for automated machines experienced early shortages and continued supply chain difficulties throughout the pandemic.[112]

[107] Thermo Fisher Scientific, "How to Maintain an RNase-free Lab" (accessed November 25, 2020).
[108] For example, all workers in these environments must maintain rigorous personal protective equipment use to avoid contaminating products. Industry representatives, telephone interviews with USITC staff, September 21 and November 16, 2020.
[109] AdvaMed, written submission to the USITC in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 20; Industry representatives, telephone interviews by USITC staff, March 19, 2021.
[110] Industry representatives, telephone interview by USITC staff, November 16, 2020.
[111] Industry representatives, telephone interviews by USITC staff, September 21 and November 16, 2020.
[112] Industry representatives, telephone interviews by USITC staff, September 21 and September 22, 2020, and March 19, 2021.

# Plastic Consumables U.S. Industrial Base

There are multiple firms that produce plastic testing products within the United States, although they provide capacity for different products.[113] Some firms produce plastics as part of their primary business, while others produce them as a secondary activity to support their other products, offering complete solutions like tubes filled with viral transport medium.[114] Multiple domestic producers have increased production in response to the pandemic. California-based Hologic, for example, ramped up production and increased employment, in part with government funds.[115] Thermo Fisher has similarly invested in new production capacity for vials, pipettes, and other plastic consumables in New York and California, in addition to other global locations.[116] There is less overall investment in new plastic production in spring 2021 than there was earlier in the pandemic and fewer companies are reportedly entering the market.[117]

There are certain bottlenecks associated with producing the multiple plastic products used in COVID-19 testing, and they are, collectively, predicted by industry to remain a risk into the future.[118] The ability to increase production cannot happen instantaneously due to the unique capital required to make plastic medical consumables. Laboratory and medical grade plastics often require complex molds, powerful hydraulic presses, and other automated production equipment.[119] Molds for pipette tips can require several months (16–20 weeks) to source, often from abroad. The producers of the molds reportedly had their capacity fully booked early in the pandemic, although this is less of an issue in 2021.[120] The availability of automated production equipment has also been an issue, and standing up a new production line is taking anywhere from 8–14 months.[121]

While not all plastic products are critically vulnerable, a subset of products could create substantial issues. For example, the demand for well plates has exceeded supply.[122] Pipette filters continue to be a bottleneck for the testing supply chain as their capacity is reportedly constrained. There is only one domestic manufacturer, Porex, of the filters required for plastic pipette tips.[123] This has contributed to the overall and continuing global shortage of pipette tips.[124] Additionally, unique capital is often required to load the pipette tips with the filters, the acquisition of which will take time as equipment manufacturers are similarly booked. Other raw materials, such as plastic resins, have not reportedly

[113] Industry representatives, telephone interviews by USITC staff, September 21, and November 16, 2020.
[114] Industry representatives, telephone interview by USITC staff, August 20, 2020.
[115] DOD, "DOD, HHS Award $7.6 Million," July 27, 2020; Foo, "San Diego Company," August 6, 2020.
[116] Thermo, "Thermo Fisher Scientific Expands," September 15, 2020.
[117] Industry representatives, telephone interview by USITC staff, March 22, 2021.
[118] Industry representatives, telephone interviews by USITC staff, August 28, 2020, and March 19 and 25, 2021; Government Officials, telephone interview by USITC staff, September 9, 2020.
[119] Industry representatives, telephone interviews by USITC staff, September 21 and November 16, 2020.
[120] Industry representatives, telephone interview by USITC staff, March 22, 2021.
[121] Industry representatives, telephone interviews by USITC staff, March 19 and 22, 2021.
[122] Industry representatives, telephone interviews by USITC staff, March 19 and 22, 2021.
[123] More information on Porex's products can be found here: Porex, "Liquid & Sample Handling" (accessed November 24, 2020). Industry representatives, telephone interviews by USITC staff, September 21 and November 16, 2020.
[124] Wu, "'It's Like Groundhog Day'," August 15, 2020; Industry representatives, telephone interview by USITC staff, November 16, 2020.

been a substantial bottleneck for industry, with the exception of disruptions caused by winter weather in early 2021.[125] Not every plastic product has been so affected as pipette tips, and some portions of the laboratory plastics industry report a general leveling-off in demand.[126]

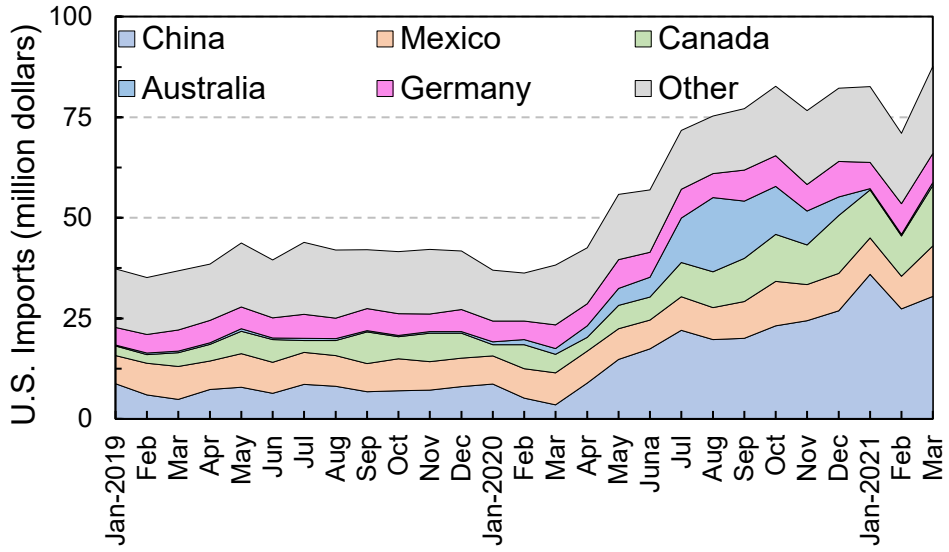
# Plastic Consumables Trade

Plastic consumables used in medical laboratories are globally produced, which supplements U.S. manufacturing capacity.[127] In general, testing supply providers report sourcing consumables from the most readily available source, which can be either domestic or imported.[128] The most relevant HTSUS subheading for plastic consumables relevant to COVID-19 is 3926.90.9910 (figure 11).[129] Imports by quantity under 3926.90.9910 grew steadily during 2010–2019, at an average rate of 7.0 percent per year. In terms of value, however, imports for the first nine months of 2020 alone exceed total imports for 2019 ($491 versus $484 million).

The increase in demand started between April and May and remained elevated throughout the end of the year. The major source countries remained largely the same, with the bulk of the increase occurring due to greater Chinese imports. The notable exception is Australia, which was a minor player before the pandemic but has since risen to account for a substantial portion of imports. The consistently elevated levels of imports through the end of the year indicates that the U.S. industrial base has not been able to increase capacity in response to the pandemic in sufficient quantities to meet domestic demand.

[125] Industry representatives, telephone interview by USITC staff, November 16, 2020, and March 19 and 25, 2021.
[126] Industry representatives, telephone interview by USITC staff, March 22, 2021.
[127] Government Officials, telephone interview by USITC staff, September 9, 2020. However, raw materials for plastic products are not always available in the same grades as used in the United States. Reportedly, U.S. producers use higher grade USP Class VI resins that are not generally available from China. Industry representatives, telephone interview by USITC staff, November 16, 2020.
[128] Industry representatives, telephone interview by USITC staff, August 28, 2020.
[129] The column 1 general rate of duty for this statistical reporting number is 5.3 percent. An additional 7.5 percent tariff was implemented under Section 301 tariff line 9903.88.15. USITC, Harmonized Tariff Schedule of the United States (2021). Multiple firms have petitioned U.S. Trade Representative for section 301 duty suspensions on several plastic laboratory consumables. An exclusion for the statistical reporting number covering these products has been granted. USTR, "Request for Comments," responses 0574, 0580, 0590, 0583, 0669, 0726, 0806, and 0827 (accessed November 20, 2020).

**Figure 11**: U.S. imports of laboratory plastics




Source: USITC DataWeb/USDOC for HTSUS statistical reporting number 3926.90.9910 (accessed February 26, 2021).
Note: this HTSUS statistical reporting numbers contain products other than COVID-19 testing supplies and is not necessarily inclusive of all plastic products used for COVID-19 testing.

# Instruments

Chemical analysis instruments are required to read the result of test assays and deliver a final diagnosis. Laboratory instruments represent the maximum total testing capacity within the United States. Each instrument can only run a certain number of tests per day. Once that threshold is met, additional tests cannot be performed, just as if the supplies of any consumable product were depleted.

The total throughput of a laboratory will depend on the equipment and instruments that are available. The largest and most automated machines in commercial and public health laboratories are capable of analyzing a batch with hundreds of samples within 1–4 hours.[130] The more automated the process is, the more samples can be run at the same time. However, those capabilities are less common than less automated and smaller batch laboratory workflows. The most numerous are small analyzers used for point-of-care testing, of which there are tens of thousands currently operating in the United States.[131]

The basic operating principles of the instrument will be largely the same for the bulk of laboratory tests, regardless of target. A sample is loaded into a small container, such as a well-plate. That assembly is then loaded into a chamber within the instrument. A monochromatic light source (i.e., single color) illuminates each sample in turn, and a detector looks for light emission from the fluorescent probes. If a

[130] AdvaMed, written submission to the USITC in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 14.
[131] Industry representatives, telephone interview by USITC staff, September 22, 2020; USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 22 (testimony of Susan Van Meter, AdvaMed).

signal is detected, it means a biomarker is present and a positive diagnosis is assigned, while no signal indicates a negative diagnosis.

# Instruments U.S. Industrial Base

Scientific instrument manufacturing is more dependent on a global value chain than other testing supplies. A company is unlikely to have all of the components required to build an instrument produced in a single location or even the same country. For example, specialty parts or electronics may be produced elsewhere, imported to the United States, and then assembled into the final product.[132] Thus, while there is domestic manufacturing, overall capacity depends on industry outside of the United States.

Producers have reportedly ramped-up production in response to the pandemic.[133] However, they now have little excess capacity with which to further expand.[134] Manufacturing instruments that are able to diagnose COVID-19 usually requires a lead-time of six months from the date when the order is placed until it is delivered.[135] Expanding further would require certifying new parts suppliers, which would also take time, and the pre-pandemic supply chain was reportedly at its limit and backup inventory had been depleted.[136] However, these earlier issues have dissipated, and by early 2021 laboratory instrumentation capacity, especially for nucleic acid tests, has substantially increased.[137]

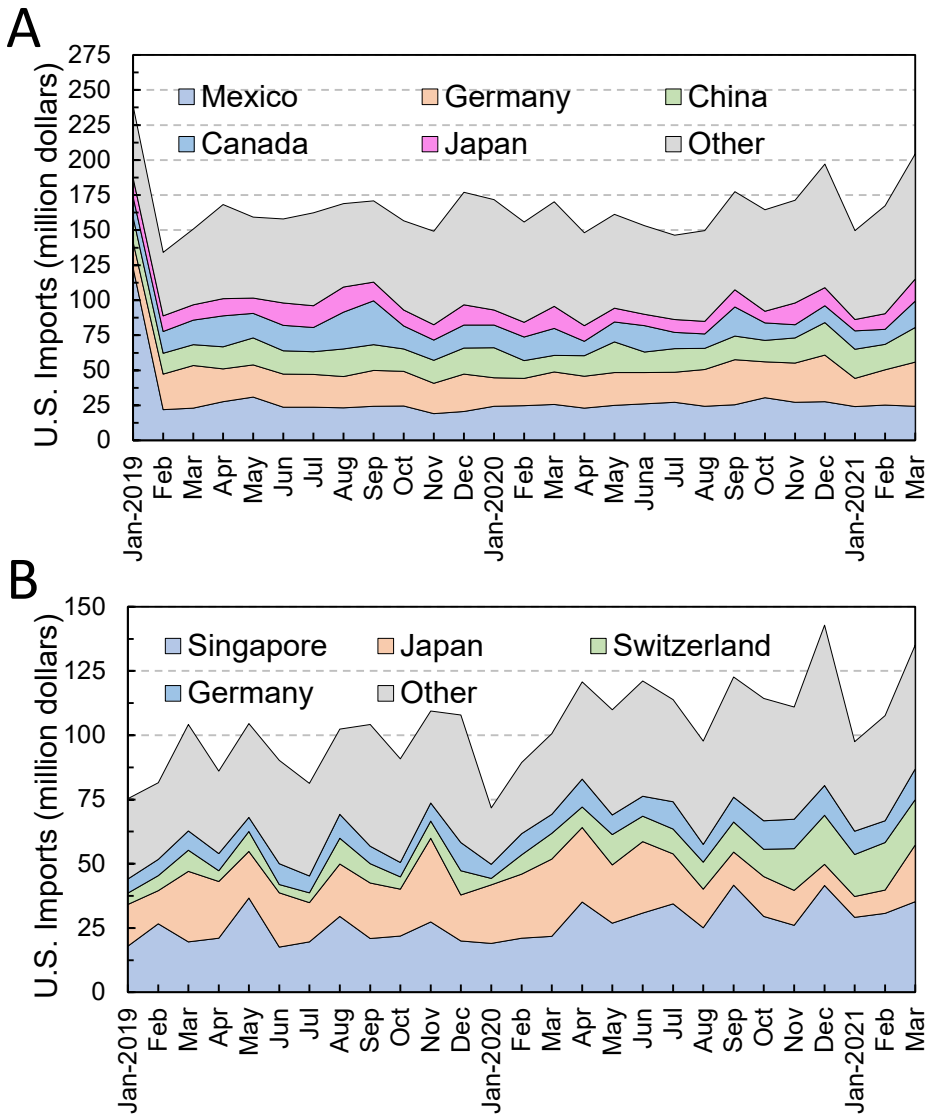
# Instruments Trade

The trade in diagnostic instruments encompasses both complete units and parts that are assembled within the United States.[138] Firms reportedly rely on manufacturing facilities in nations with advanced biomedical industries, including Switzerland, Japan, Canada, and Malaysia.[139] Some of the relevant

[132] Industry representatives, telephone interview by USITC staff, September 22, 2020; USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 93 (testimony of Susan Van Meter, AdvaMed).
[133] Industry representatives, telephone interview by USITC staff, September 22, 2020.
[134] Crow, "US Lab Giant Warns," July 21, 2020.
[135] USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 117 (testimony of Susan Van Meter, AdvaMed); AdvaMed, written submission to the USITC in connection with investigation no. 332-580, *COVID-19 Related Goods*, September 23, 2020, 20.
[136] Industry representatives, telephone interview by USITC staff, September 14, 2020.
[137] Industry representatives, telephone interview by USITC staff, March 25, 2021.
[138] Relevant HTSUS statistical reporting number likely include 8479.90.9496 (other parts) and 9027.50.40 (optical chemical analysis instruments. Both have a column 1 duty rate of free and a 25 percent Section 301 tariff under subheading 9903.88.01. USITC, Harmonized Tariff Schedule of the United States (2021). Petitions for Section 301 exceptions specifically for instrument parts (8479.90.9496) have been received by the Office of the U.S. Trade Representative but have not been granted to date. USTR, "Request for Comments," responses 0574, 580, 0583, 0590, 0658, and 0726 (accessed November 20, 2020). Petitions for Section 301 exceptions specifically for instruments (9027.50.40) have been received by the Office of the U.S. Trade Representative but have not been granted to date. USTR, "Request for Comments," responses 0373, 0583, 0590, and 0658 (accessed November 20, 2020).
[139] Industry representatives, telephone interviews by USITC staff, August 28, September 21, and September 22, 2020; USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 116–117 (testimony of Susan Van Meter, AdvaMed).

instruments trade will be captured under two tariff lines: 8479.90.9496 for parts (including some pipette tips) and 9027.50.40 for complete instruments (figure 12). Trade under both headings has remained relatively constant throughout 2020 with pre-pandemic levels. The slight increase visible in the complete instruments trade data is consistent with an overall year-over-year increase of 8.5 percent since 2010. Combined, this data may reflect the perspective that global capacity remains near maximum capacity. However, these are large categories that contain non-COVID-19-relevant materials, whose trends may be lost within the macro dataset.

**Figure 12**: U.S. imports of instruments and parts




Source: USITC DataWeb/USDOC for HTSUS statistical reporting number 8479.90.9496 and subheading 9027.50.40 (accessed February 26, 2021).
Note: parts (A) and complete instruments (B); these HTSUS statistical reporting numbers contain products other than COVID-19 testing supplies and are not inclusive of all instruments and components thereof used for COVID-19 testing.

# General Issues

Domestic firms have reported several issues that cut across multiple products and types of testing consumables. The issues highlighted below are either former bottlenecks that have been resolved during the pandemic or bottlenecks that continue to affect the ability of the United States to continue providing COVID-19 test results.[140]

## Market Acceptance

While new capacity by existing producers is able to directly begin feeding demand for testing supplies, new entrants have reported some difficulty in shipping their products, regardless of demand. Some manufacturers new to the medical diagnostic sector report excess capacity that is not being used because of caution in the medical supply chain regarding new producers.[141] This is the result of some medical providers receiving poor quality goods early in the pandemic from previously unused sources, which makes them hesitant to accept supplies from companies they haven't dealt with before.[142]

Issues around market acceptance persisted until late 2020. The surge in testing demand between November and January created a scramble for additional resources that allowed new entrants better access to the market.[143] Some firms report being able to clear their stockpiled resources, although the previous issues did lead to a production stoppage and other disruptions that could have better served domestic demand had it been continually been utilized. These manufacturers report entering a new steady state into 2021 after new business relationships were able to mature.[144]

## Sterility

Testing supplies must be sterile and free of biological contaminants. Sterile materials decrease the likelihood of contamination, to protect the patient, to preserve the samples in transit, and to prevent erroneous test results. In general, all of the testing consumables discussed in preceding sections must be sterile before they can contribute to meeting the demand for testing.

There are two primary mechanisms for sterilizing testing consumables: gamma radiation and ethylene oxide. Gamma radiation involves sending product through a specialty chamber, where a radioactive source kills microorganisms as the goods pass through, not unlike a more powerful airport x-ray machine.[145] Ethylene oxide is a gas that sterilizes materials upon contact.[146]

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[140] See USITC Publication 5145 for additional bottlenecks that were encountered by industry, including development time, regulatory approval, and substitutability.
[141] Industry representatives, telephone interview by USITC staff, September 17, 2020.
[142] Industry representatives, telephone interview by USITC staff, September 17, 2020.
[143] Industry representatives, telephone interview by USITC staff, April 2, 2021.
[144] Industry representatives, telephone interview by USITC staff, April 2, 2021.
[145] Steris, "Gamma Irradiation Processing" (accessed November 25, 2020).
[146] CDC, "Ethylene Oxide "Gas" Sterilization" (accessed November 25, 2020).

While some manufacturers possess in-house gamma sterilization capacity, many manufacturers must contract with third-party providers for bulk ethylene oxide sterilization.[147] However, there are only two domestic firms, Steris and Sterigenics, that can currently provide this service. This is also complicated by the pre-pandemic shuttering of multiple facilities in Georgia and Illinois by environmental agencies due to emissions concerns.[148] New ethylene capacity is unlikely to come online in the short term, given the substantial capital required and levels of permitting required. Access to this capacity has largely remained a bottleneck for producers of testing supplies, and substantial competition continues to exist for domestic sterilization capacity.[149] Alternatives, such as electron-beam sterilization, are currently being evaluated for suitability by some manufacturers.[150]

# Transportation

Trade is a barrier to acquiring testing supplies insofar as biomedical devices are part of a global value chain.[151] The primary bottleneck for sourcing imported testing products or raw materials early in the pandemic had been the ability to find transportation.[152] Companies reportedly had to rely on air freight to rapidly meet demands. However, with the decline in both personal and commercial flights due to the pandemic, there was substantial competition for booking the remaing air capacity.[153] This situation resulted in supply chain difficulties and substantially increased costs for importers during the early months of the pandemic.[154] The situation had improved by the one year point, such that access to transportation capacity was less of an issue.[155] However, a new bottleneck emerged at the ports. Several U.S. port facilities have experienced substantial congestion, delaying the offloading and processing of containers.[156] This has also been complicated by COVID-19 outbreaks at some ports that decrease the workforce available to offload ships.[157]

[147] Industry representatives, telephone interviews by USITC staff, September 14, September 17, and October 2, 2020.
[148] Industry representatives, interviews with USITC staff, September 17 and September 28, 2020; USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 118 (testimony of Abby Pratt, AdvaMed); Baichwal, "Illinois EPA," October 2, 2018; Cobb County Government, "Latest on Sterigenics" (accessed November 25, 2020).
[149] Industry representatives, telephone interviews by USITC staff, March 19, 2021.
[150] For additional information on electron beam sterilization, see: E-Beam Services, "How Does," December 16, 2015.
[151] USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 151 (testimony of Prashant Yadav, Center for Global Development) and 159, 189–191 (testimony of Lori Wallach, Public Citizen).
[152] Industry representatives, telephone interview by USITC staff, September 21 and September 22, 2020.
[153] USITC, hearing transcript in connection with investigation no. 332-580, COVID-19 Related Goods, September 23, 2020, 19 (testimony of Abby Pratt, AdvaMed).
[154] Industry representatives, telephone interview by USITC staff, September 22, 2020.
[155] Industry representatives, telephone interviews by USITC staff, March 19 and 22, 2021.
[156] Leonard, "4 Charts Show," February 16, 2021.
[157] Industry representatives, telephone interview by USITC staff, March 25, 2021.

# Competition with Influenza Testing

One concern reported during early stages of the pandemic was that the availability of testing supplies would be further strained by the onset of flu season. Flu and COVID-19 present with similar symptoms, and it is necessary to distinguish from them in a clinical setting to ensure the proper care is provided to each patient. Given how widespread influenza is in a typical year, this would mean many more people presenting with symptoms justifying the use of testing supplies. Because the tests for each disease use the same types of consumables, there would be an increased overall demand for testing supplies during flu season, which will further strains supply chains. The effect could be similar to delays experienced by industry as a result of hurricanes and wildfires earlier in 2020.[158]

This scenario did not transpire. The 2020–2021 flu season was much milder than in typical years. This can largely be attributed to COVID-19 precautions—masks and social distancing—limiting the transmission of influenza.[159] Some portions of the testing supply industry do anticipate that COVID-19 testing will become part of repertory infection diagnostic panels in the future, maintaining some level of demand for disease-specific supplies into the future, especially if variants remain prevalent globally.[160] However, that persistent demand would not tax supply chains close to the extant as the sudden onset of the pandemic.

# Other Disasters

While the availability of raw materials was not an issue for a majority of testing supplies throughout the pandemic, the 2021 winter storm in Texas substantially disrupted supply chains. The loss of power in the aftermath of that event shut down local industry.[161] Due to the concentration of petrochemical sites in the region, this impacted the availability of plastic resins, leading to a 10- to 14-day gap in supplies.[162] These resins are used in manufacturing laboratory plastics and sample collection equipment, meaning a sustained shortfall in resins impacts the entire testing process. While the shutdown was temporary and the disruption has been mitigated, this situation highlights a potential risk that must be considered when evaluating supply chain resiliency.

# Incomplete Information

One bottleneck reported by some segments of industry was an incomplete understanding of the available production capacity by those in the U.S. government responding to the pandemic. A more general survey or compilation of knowledge about the core technical capabilities and how they could be applied to producing pandemic-related goods was reportedly incomplete or missing.[163] This includes a lack of insight into the raw material inputs required for various goods and the ability to ensure

[158] Industry representatives, telephone interview by USITC staff, September 21, 2020.
[159] Ries, "Why the Flu Season," February 11, 2021; Industry representatives, telephone interview by USITC staff, March 22, 2021.
[160] Industry representatives, telephone interview by USITC staff, March 22, 2021.
[161] Industry representatives, telephone interviews by USITC staff, March 19, 2021.
[162] Industry representatives, telephone interviews by USITC staff, March 22 and April 2, 2021.
[163] Industry representatives, telephone interview by USITC staff, April 2, 2021.

manufacturers were able to source what they needed to ramp production or safeguard supply chains. Some firms were also reticent to initially engage with the government, over uncertainty about how authorities like the Defense Production Act would impact their business or the longevity of potential funding.[164]

# Conclusion

Continued access to COVID-19 testing will depend on the United States' ability to source the myriad testing supplies required to deliver a diagnosis. The primary barrier experienced during the pandemic was not having enough production capacity to meet the spike in demand. It took upwards of a year to increase production levels to a point where testing consumables were no longer in short supply. This is a similar issue with all aspects of the COVID-19 response: the U.S. healthcare system was not designed to handle this kind of event and reconfiguring it required substantial new investments and time to resolve.[165]

Tests were initially scarce due to the need to develop the required diagnostic tools, without which it was not possible to begin production. While that necessary development time took place, the need for testing only grew as the virus spread, increasing the baseline demand that manufacturers would have to meet. This was followed by shortages due to existing manufacturing capacity being generally not configured to instantaneously scale to meet demand. The need for swabs provides such an example. The existing manufacturing capacity was insufficient to meet the spike in demand, necessitating investment in new manufacturing capital. That capital takes time to bring online and, until it is, the products it manufactures will be subject to a bottleneck.

The initial shortfalls in certain testing supplies enabled new companies to enter the market. However, these entities reportedly relied on elevated prices created by the spike in demand to sustain themselves. The market is already starting to shift in the other direction, as some industry sources report that some augmented production capacity is going unused.[166] Non-traditional manufacturers may not continue to be viable after the pandemic, and it is likely many new entrants will cease to exist under more normal conditions.[167]

Trade is a component of acquiring testing supplies insofar as biomedical devices are part of a global value chain. The present configuration of this supply chain does not necessarily contain all of the nodes required to produce a test result in a given country, let alone at the volumes required. Laboratory instruments provide examples of this condition, as primary manufacturing of multiple components occurs overseas. Increasing the maximum capacity for testing thus relies on a supply chain that cannot easily be moved or expanded.

Imports of testing supplies by the United States have generally increased in response to the pandemic. However, it has neither been universal nor sustained. Imports of some products like plastic products have substantially increased and remained above pre-pandemic levels throughout 2020, while others

[164] Industry representatives, telephone interview by USITC staff, April 2, 2021.
[165] Hannah, "One Way to Build," February 16, 2021; MIT SHASS Communications, "What Has the Pandemic Revealed," April 5, 2021.
[166] Industry representatives, telephone interview by USITC staff, March 25, 2021.
[167] Industry representatives, telephone interview by USITC staff, March 19 and 22, 2021.

like swabs spiked in the summer and subsequently decreased to previous levels. This scenario may become more common as additional U.S. manufacturing capacity comes online through the capital investment that has taken place throughout the year. Post-pandemic, these investments may mean a lower overall level of imports compared to pre-pandemic levels, as they are able to meet the bulk of domestic demand and U.S. consumers have adopted their laboratory protocols to use them. Some level of imports will likely remain as medical consumers may choose to maintain a diverse supply chain to avoid potential bottlenecks of critical materials during future such events. Some portions of industry note that countries have, in general, become more amendable to onshoring critical capacity in response to the pandemic, which may indicate a new trade paradigm for certain products in the future.[168]

The demand for testing supplies will continue to evolve over the next year. As vaccines continue to be deployed, the demand for testing supplies will naturally decrease with the number of new or serious cases. The second year of the pandemic is showing this trend already, with a general decrease in the number of tests completed per day. Evan after vaccine rollout, there are several areas where testing supplies will continue to have a market. Rapid testing at public locations like airports; screening populations as schools, universities, manufacturing sites, and offices re-open; self-testing with home-based kits; and point-of-care testing in developing countries without high-throughput laboratory capacity will likely continue for the foreseeable future and maintain demand.[169] Antibody tests can be shifted to monitoring vaccine efficacy by quantifying a person's immune response over time, especially as the world is facing the emergence of new COVID-19 variants.[170] If new variants do become substantially more virulent and not mitigated by existing vaccines, it is likely another rapid increase in testing demand would follow additional outbreaks.[171]

It is important to keep in mind that COVID-19 is neither the first nor last global pandemic. It is thus important to use the lessons learned during the past year to plan for the next one. For multiple industry players, this has led to a new look at supply chains and supply chain weaknesses and, in some instances, diversifying with new domestic and international sources.[172] This may engender greater onshoring of capacity or stockpiling certain products in the future. While some industry players do not anticipate such dramatic shortfalls in the near future, keeping reserve or easily re-configurable capacity available in case of emergency will likely be a critical component for mitigating future outbreaks or novel pandemics.[173] As some in industry have suggested, a more thorough understanding of U.S. production capabilities by public agencies could mitigate that issue and allow for more rapid deployment of resources next time.[174]

[168] Industry representatives, telephone interview by USITC staff, March 22, 2021.
[169] Industry representatives, telephone interviews by USITC staff, March 19, 22, and 25 and April 2, 2021.
[170] Industry representatives, telephone interviews by USITC staff, March 19, 22, and 25, 2021.
[171] Industry representatives, telephone interview by USITC staff, April 2, 2021.
[172] Industry representatives, telephone interviews by USITC staff, March 22 and April 2, 2021.
[173] Industry representatives, telephone interview by USITC staff, March 19, 22, and 25, 2021.
[174] Industry representatives, telephone interview by USITC staff, April 2, 2021.

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# Appendix A
# Data Tables for Figures

**Table A.1** U.S. COVID-19 tests completed by March 7, 2021

| Date | Test Results per Day | Cumulative Test Results |
|---|---|---|
| February 1, 2020 | 0 | 8 |
| March 1, 2020 | 96 | 6,651 |
| April 1, 2020 | 123,021 | 1,306,569 |
| May 1, 2020 | 285,823 | 6,970,758 |
| June 1, 2020 | 419,427 | 18,617,830 |
| July 1, 2020 | 729,493 | 35,690,419 |
| August 1, 2020 | 817,592 | 61,567,531 |
| September 1, 2020 | 796,530 | 87,045,460 |
| October 1, 2020 | 1,016,972 | 114,796,431 |
| November 1, 2020 | 1,160,138 | 151,506,495 |
| December 1, 2020 | 1,494,046 | 199,966,644 |
| January 1, 2021 | 1,545,537 | 255,795,456 |
| February 1, 2021 | 1,507,545 | 313,394,628 |
| March 1, 2021 | 1,154,440 | 355,138,357 |

Note: See Figure 1. Only data for the first of each month is provided.

**Table A.2** U.S. imports of other articles of wadding of man-made fibers (million dollars)

| Date | China | Italy | South Korea | Other |
|---|---|---|---|---|
| January 2019 | 0.12 | 0.35 | 0.03 | 0.28 |
| February 2019 | 0.17 | 0.36 | 0.03 | 0.25 |
| March 2019 | 0.06 | 0.42 | 0.06 | 0.24 |
| April 2019 | 0.13 | 0.35 | 0.10 | 0.38 |
| May 2019 | 0.13 | 0.26 | 0.14 | 0.73 |
| June 2019 | 0.15 | 0.19 | 0.06 | 0.35 |
| July 2019 | 0.41 | 0.31 | 0.04 | 0.42 |
| August 2019 | 0.60 | 0.31 | 0.07 | 0.33 |
| September 2019 | 0.47 | 0.17 | 0.04 | 0.39 |
| October 2019 | 0.37 | 0.27 | 0.07 | 0.28 |
| November 2019 | 0.14 | 0.49 | 0.08 | 0.43 |
| December 2019 | 0.08 | 0.28 | 0.05 | 0.32 |
| January 2020 | 0.11 | 0.29 | 0.12 | 0.58 |
| February 2020 | 0.08 | 0.34 | 0.04 | 0.46 |
| March 2020 | 0.05 | 0.28 | 0.11 | 0.46 |
| April 2020 | 0.30 | 1.43 | 0.12 | 0.54 |
| May 2020 | 2.41 | 1.55 | 0.32 | 0.62 |
| June 2020 | 4.20 | 1.23 | 0.15 | 0.54 |
| July 2020 | 2.67 | 1.41 | 0.88 | 0.43 |
| August 2020 | 3.75 | 0.89 | 2.73 | 0.67 |
| September 2020 | 3.89 | 1.64 | 1.27 | 0.34 |
| October 2020 | 1.36 | 1.23 | 0.19 | 0.61 |
| November 2020 | 2.72 | 1.53 | 0.19 | 1.10 |
| December 2020 | 1.06 | 1.49 | 0.22 | 1.07 |
| January 2021 | 2.27 | 1.13 | 2.22 | 1.30 |
| February 2021 | 1.29 | 1.42 | 0.78 | 0.87 |
| March 2021 | 1.66 | 1.13 | 0.20 | 1.03 |

Note: See Figure 6.

**Table A.3** U.S. imports of viral transport medium (million dollars)

| Date | China | South Korea | Italy | Mexico | Other |
|---|---|---|---|---|---|
| July 2020 | 27.86 | 5.46 | 4.32 | 0.64 | 0.41 |
| August 2020 | 13.44 | 12.03 | 3.58 | 1.68 | 0.29 |
| September 2020 | 7.03 | 6.30 | 3.71 | 0.38 | 0.11 |
| October 2020 | 7.36 | 4.47 | 4.50 | 0.49 | 0.15 |
| November 2020 | 5.88 | 3.31 | 5.31 | 0.71 | 0.10 |
| December 2020 | 6.48 | 5.22 | 4.25 | 0.98 | 0.10 |
| January 2021 | 3.95 | 3.81 | 4.34 | 2.12 | 1.14 |
| February 2021 | 3.47 | 7.86 | 5.50 | 2.67 | 0.08 |
| March 2021 | 2.33 | 0.29 | 5.42 | 0.19 | 1.08 |

Note: See Figure 7.

**Table A.4** U.S. imports of needles (million dollars)

| Date | Ireland | Mexico | Japan | South Korea | Germany | Other |
|---|---|---|---|---|---|---|
| January 2019 | 30.74 | 6.83 | 3.19 | 2.80 | 2.65 | 16.88 |
| February 2019 | 18.85 | 7.04 | 3.36 | 2.38 | 2.65 | 13.24 |
| March 2019 | 25.33 | 8.84 | 2.99 | 3.21 | 2.75 | 18.10 |
| April 2019 | 22.43 | 8.83 | 3.65 | 3.76 | 4.77 | 21.57 |
| May 2019 | 39.20 | 10.63 | 2.82 | 3.73 | 3.40 | 16.82 |
| June 2019 | 37.54 | 8.73 | 2.99 | 2.92 | 3.42 | 17.39 |
| July 2019 | 37.20 | 9.82 | 12.00 | 3.76 | 3.54 | 18.02 |
| August 2019 | 22.08 | 9.08 | 2.78 | 3.66 | 2.66 | 14.04 |
| September 2019 | 21.22 | 7.98 | 3.33 | 3.20 | 3.65 | 13.30 |
| October 2019 | 26.52 | 7.55 | 5.06 | 2.34 | 4.78 | 22.28 |
| November 2019 | 21.67 | 6.32 | 2.51 | 2.80 | 3.17 | 20.24 |
| December 2019 | 31.61 | 5.78 | 2.66 | 2.66 | 4.19 | 16.43 |
| January 2020 | 25.17 | 6.77 | 2.52 | 3.11 | 3.35 | 15.61 |
| February 2020 | 36.82 | 6.82 | 3.09 | 2.60 | 3.70 | 14.01 |
| March 2020 | 36.35 | 6.49 | 3.29 | 3.40 | 3.33 | 12.75 |
| April 2020 | 44.21 | 6.13 | 2.67 | 2.61 | 4.05 | 12.01 |
| May 2020 | 27.30 | 5.78 | 2.65 | 4.18 | 2.69 | 15.55 |
| June 2020 | 49.14 | 6.05 | 3.65 | 3.04 | 2.57 | 18.44 |
| July 2020 | 23.41 | 6.76 | 2.20 | 3.46 | 2.45 | 16.48 |
| August 2020 | 21.18 | 5.94 | 2.65 | 2.75 | 2.58 | 16.77 |
| September 2020 | 11.05 | 6.36 | 3.37 | 2.74 | 2.13 | 18.33 |
| October 2020 | 26.23 | 7.77 | 9.75 | 3.31 | 4.19 | 20.75 |
| November 2020 | 23.50 | 6.21 | 3.03 | 4.45 | 2.59 | 18.56 |
| December 2020 | 45.16 | 5.81 | 2.90 | 3.09 | 2.69 | 25.54 |
| January 2021 | 21.42 | 7.17 | 2.04 | 3.70 | 2.69 | 25.57 |
| February 2021 | 21.11 | 7.56 | 3.18 | 6.17 | 2.67 | 20.27 |
| March 2021 | 40.11 | 8.45 | 3.51 | 6.35 | 3.01 | 26.19 |

Note: See Figure 8.

**Table A.5** U.S. imports of other diagnostic or laboratory reagents (million dollars)

| Date | United Kingdom | Germany | Lithuania | Canada | Singapore | Other |
|---|---|---|---|---|---|---|
| July 2020 | 44.87 | 42.23 | 14.27 | 37.68 | 22.82 | 135.97 |
| August 2020 | 56.17 | 48.73 | 23.71 | 49.22 | 34.72 | 138.62 |
| September 2020 | 42.84 | 54.73 | 33.20 | 36.03 | 40.57 | 124.05 |
| October 2020 | 38.25 | 44.56 | 27.52 | 36.36 | 37.06 | 108.24 |
| November 2020 | 67.11 | 51.98 | 25.89 | 29.07 | 45.27 | 125.13 |
| December 2020 | 105.34 | 68.50 | 129.85 | 34.20 | 37.48 | 163.29 |
| January 2021 | 62.22 | 55.34 | 96.54 | 32.00 | 41.36 | 147.52 |
| February 2021 | 103.30 | 41.77 | 32.19 | 35.44 | 40.04 | 130.40 |
| March 2021 | 90.10 | 51.55 | 35.97 | 37.20 | 51.29 | 171.12 |

Note: See Figure 9.

**Table A.6** U.S. imports of antibody reagents (million dollars)

| Date | Sweden | Germany | Austria | Ireland | Japan | Other |
|---|---|---|---|---|---|---|
| July 2020 | 2.23 | 6.47 | 0.00 | 5.51 | 3.95 | 29.49 |
| August 2020 | 15.97 | 10.83 | 5.27 | 35.03 | 6.23 | 13.83 |
| September 2020 | 2.37 | 9.29 | 0.04 | 3.52 | 0.92 | 39.25 |
| October 2020 | 25.30 | 14.04 | 8.56 | 3.99 | 3.87 | 14.17 |
| November 2020 | 33.68 | 16.05 | 27.96 | 8.91 | 5.46 | 15.44 |
| December 2020 | 25.00 | 15.20 | 26.82 | 4.66 | 18.72 | 20.81 |
| January 2021 | 42.61 | 22.40 | 6.55 | 5.56 | 54.90 | 28.67 |
| February 2021 | 21.17 | 30.40 | 28.40 | 26.37 | 62.31 | 54.46 |
| March 2021 | 36.32 | 29.83 | 0.00 | 15.82 | 17.50 | 29.84 |

Note: See Figure 10A.

**Table A.7** U.S. imports of nucleic acid reagents (million dollars)

| Date | Netherlands | Canada | China | Sweden | Other |
|---|---|---|---|---|---|
| July 2020 | 5.02 | 13.21 | 7.17 | 4.43 | 3.99 |
| August 2020 | 8.69 | 5.45 | 11.64 | 5.52 | 4.21 |
| September 2020 | 11.87 | 6.85 | 8.77 | 6.46 | 7.23 |
| October 2020 | 1.09 | 6.31 | 3.69 | 10.52 | 8.96 |
| November 2020 | 4.95 | 6.42 | 2.71 | 11.85 | 13.30 |
| December 2020 | 16.28 | 8.72 | 9.17 | 3.97 | 12.42 |
| January 2021 | 0.34 | 6.99 | 5.23 | 9.81 | 14.92 |
| February 2021 | 7.44 | 8.23 | 1.83 | 7.11 | 12.99 |
| March 2021 | 0.78 | 12.58 | 0.45 | 7.66 | 12.17 |

Note: See Figure 10B.

**Table A.8** U.S. imports of antigen reagents (million dollars)

| Date | China | South Korea | United Kingdom | Germany | Sweden | Other |
|---|---|---|---|---|---|---|
| January 2019 | 10.15 | 4.03 | 7.63 | 5.79 | 4.86 | 27.93 |
| February 2019 | 7.24 | 4.46 | 8.32 | 5.67 | 11.33 | 23.16 |
| March 2019 | 6.34 | 1.87 | 9.64 | 4.76 | 11.60 | 27.04 |
| April 2019 | 12.09 | 2.17 | 7.87 | 6.20 | 12.02 | 27.65 |
| May 2019 | 11.83 | 2.44 | 7.73 | 5.74 | 13.15 | 28.21 |
| June 2019 | 10.92 | 3.48 | 9.67 | 4.23 | 9.46 | 27.93 |
| July 2019 | 12.16 | 3.28 | 9.47 | 7.57 | 14.07 | 21.34 |
| August 2019 | 12.75 | 3.47 | 7.16 | 5.18 | 10.94 | 26.04 |
| September 2019 | 8.54 | 3.75 | 9.70 | 5.62 | 10.75 | 28.30 |
| October 2019 | 13.17 | 1.95 | 10.16 | 5.00 | 9.70 | 24.91 |
| November 2019 | 13.94 | 3.59 | 6.94 | 4.70 | 6.78 | 24.49 |
| December 2019 | 13.54 | 2.89 | 9.99 | 4.41 | 3.73 | 25.34 |
| January 2020 | 13.17 | 1.70 | 7.80 | 6.29 | 6.92 | 24.91 |
| February 2020 | 9.30 | 3.02 | 8.14 | 6.39 | 7.03 | 23.81 |
| March 2020 | 7.73 | 4.20 | 8.82 | 8.78 | 9.61 | 31.71 |
| April 2020 | 13.75 | 21.44 | 8.79 | 5.90 | 5.19 | 19.33 |
| May 2020 | 64.52 | 6.03 | 5.20 | 6.79 | 1.46 | 21.89 |
| June 2020 | 57.00 | 10.58 | 5.68 | 4.68 | 2.41 | 24.58 |
| July 2020 | 38.80 | 28.26 | 6.91 | 6.73 | 4.62 | 31.76 |
| August 2020 | 22.08 | 5.21 | 6.94 | 7.28 | 11.16 | 19.96 |
| September 2020 | 8.54 | 4.93 | 7.66 | 5.04 | 8.99 | 20.54 |
| October 2020 | 10.96 | 21.69 | 8.84 | 10.47 | 10.86 | 29.23 |
| November 2020 | 13.13 | 4.12 | 9.03 | 8.41 | 7.67 | 32.79 |
| December 2020 | 16.68 | 7.28 | 7.49 | 10.83 | 8.33 | 38.41 |
| January 2021 | 14.42 | 6.24 | 8.65 | 8.67 | 8.18 | 34.24 |
| February 2021 | 16.81 | 3.55 | 4.66 | 8.11 | 7.07 | 39.70 |
| March 2021 | 12.68 | 4.82 | 10.47 | 9.41 | 8.39 | 40.01 |

Note: See Figure 10C.

**Table A.9** U.S. imports of laboratory plastics (million dollars)

| Date | China | Mexico | Canada | Australia | Germany | Other |
|---|---|---|---|---|---|---|
| January 2019 | 8.72 | 6.98 | 2.38 | 0.29 | 4.38 | 14.50 |
| February 2019 | 5.98 | 7.87 | 2.15 | 0.34 | 4.67 | 14.16 |
| March 2019 | 4.86 | 8.18 | 3.45 | 0.38 | 5.24 | 14.71 |
| April 2019 | 7.29 | 7.12 | 4.09 | 0.39 | 5.58 | 14.01 |
| May 2019 | 7.84 | 8.37 | 5.59 | 0.64 | 5.35 | 15.90 |
| June 2019 | 6.34 | 7.74 | 5.66 | 0.35 | 5.03 | 14.42 |
| July 2019 | 8.55 | 7.98 | 2.99 | 0.49 | 6.01 | 17.89 |
| August 2019 | 8.10 | 7.63 | 3.75 | 0.45 | 5.10 | 16.97 |
| September 2019 | 6.77 | 6.96 | 7.86 | 0.36 | 5.50 | 14.61 |
| October 2019 | 6.98 | 7.95 | 5.47 | 0.38 | 5.37 | 15.44 |
| November 2019 | 7.13 | 7.10 | 7.07 | 0.40 | 4.37 | 16.08 |
| December 2019 | 8.03 | 7.10 | 6.21 | 0.35 | 5.50 | 14.54 |
| January 2020 | 8.70 | 6.99 | 2.73 | 0.70 | 5.22 | 12.62 |
| February 2020 | 5.17 | 7.32 | 5.97 | 1.22 | 4.67 | 11.93 |
| March 2020 | 3.46 | 7.99 | 4.59 | 1.48 | 5.88 | 14.83 |
| April 2020 | 8.88 | 7.97 | 3.46 | 2.80 | 5.49 | 13.96 |
| May 2020 | 14.79 | 7.64 | 5.76 | 4.21 | 7.16 | 16.24 |
| June 2020 | 17.38 | 7.20 | 5.69 | 4.92 | 6.21 | 15.56 |
| July 2020 | 22.00 | 8.33 | 8.58 | 11.05 | 7.14 | 14.63 |
| August 2020 | 19.73 | 7.94 | 8.89 | 18.50 | 5.97 | 14.29 |
| September 2020 | 20.02 | 9.18 | 10.69 | 14.25 | 7.74 | 15.21 |
| October 2020 | 23.17 | 10.99 | 11.73 | 11.89 | 7.67 | 17.23 |
| November 2020 | 24.40 | 9.01 | 9.88 | 8.42 | 6.57 | 18.38 |
| December 2020 | 26.88 | 9.27 | 14.45 | 4.60 | 8.77 | 18.23 |
| January 2021 | 35.92 | 9.05 | 12.00 | 0.32 | 6.47 | 18.83 |
| February 2021 | 27.36 | 8.14 | 10.00 | 0.39 | 7.62 | 17.49 |
| March 2021 | 30.45 | 12.57 | 15.07 | 0.68 | 7.23 | 21.63 |

Note: See Figure 11.

**Table A.10** U.S. imports of instrument parts (million dollars)

| Date | Mexico | Germany | China | Canada | Japan | Other |
|---|---|---|---|---|---|---|
| January 2019 | 123.26 | 18.22 | 17.82 | 14.53 | 13.41 | 51.36 |
| February 2019 | 22.03 | 25.24 | 14.98 | 15.41 | 11.15 | 45.28 |
| March 2019 | 23.14 | 30.39 | 14.75 | 17.57 | 10.99 | 53.86 |
| April 2019 | 27.57 | 23.47 | 15.64 | 22.21 | 12.14 | 67.20 |
| May 2019 | 30.98 | 23.01 | 19.22 | 17.50 | 10.83 | 57.83 |
| June 2019 | 23.79 | 23.57 | 16.61 | 18.23 | 15.89 | 59.99 |
| July 2019 | 23.62 | 23.37 | 16.31 | 17.27 | 15.46 | 66.28 |
| August 2019 | 23.34 | 22.30 | 19.55 | 26.32 | 17.93 | 59.36 |
| September 2019 | 24.43 | 25.50 | 18.43 | 31.26 | 13.22 | 58.02 |
| October 2019 | 24.51 | 24.83 | 15.91 | 16.43 | 11.28 | 63.78 |
| November 2019 | 19.21 | 21.63 | 16.32 | 14.35 | 10.90 | 66.74 |
| December 2019 | 20.57 | 26.75 | 18.50 | 16.49 | 14.41 | 80.20 |
| January 2020 | 24.37 | 20.29 | 21.49 | 16.15 | 10.80 | 78.56 |
| February 2020 | 24.81 | 19.34 | 12.69 | 16.98 | 10.35 | 71.56 |
| March 2020 | 25.74 | 23.10 | 11.88 | 19.26 | 15.58 | 74.60 |
| April 2020 | 22.99 | 22.73 | 14.78 | 10.17 | 11.29 | 66.15 |
| May 2020 | 25.05 | 23.29 | 21.86 | 14.32 | 9.71 | 67.09 |
| June 2020 | 26.21 | 22.29 | 14.67 | 18.64 | 8.24 | 63.09 |
| July 2020 | 27.30 | 21.36 | 16.73 | 11.71 | 9.12 | 60.05 |
| August 2020 | 24.30 | 26.41 | 14.96 | 10.28 | 9.08 | 64.69 |
| September 2020 | 25.39 | 32.11 | 16.84 | 20.95 | 12.25 | 69.90 |
| October 2020 | 30.56 | 25.41 | 15.45 | 12.50 | 8.15 | 72.48 |
| November 2020 | 27.15 | 27.98 | 18.04 | 9.30 | 15.62 | 73.17 |
| December 2020 | 27.67 | 33.30 | 23.00 | 12.06 | 12.86 | 88.29 |
| January 2021 | 24.09 | 20.22 | 20.68 | 13.07 | 8.11 | 63.44 |
| February 2021 | 25.26 | 25.19 | 18.17 | 10.73 | 11.00 | 77.07 |
| March 2021 | 24.42 | 31.53 | 24.71 | 18.66 | 15.83 | 89.13 |

Note: See Figure 12A.

**Table A.11** U.S. imports of instruments (million dollars)

| Date | Singapore | Japan | Switzerland | Germany | Other |
|---|---|---|---|---|---|
| January 2019 | 17.92 | 16.22 | 4.41 | 5.52 | 31.19 |
| February 2019 | 26.59 | 12.97 | 5.78 | 6.34 | 29.78 |
| March 2019 | 19.58 | 27.42 | 8.23 | 7.56 | 41.38 |
| April 2019 | 21.06 | 22.08 | 4.11 | 6.70 | 32.11 |
| May 2019 | 36.71 | 18.09 | 7.76 | 5.50 | 36.46 |
| June 2019 | 17.55 | 21.08 | 3.32 | 8.02 | 40.21 |
| July 2019 | 19.66 | 15.25 | 3.80 | 6.53 | 36.06 |
| August 2019 | 29.56 | 20.40 | 10.00 | 9.22 | 33.26 |
| September 2019 | 20.91 | 21.63 | 7.43 | 6.83 | 47.43 |
| October 2019 | 21.83 | 18.28 | 4.73 | 5.69 | 40.33 |
| November 2019 | 27.30 | 32.67 | 6.63 | 7.02 | 35.74 |
| December 2019 | 19.92 | 17.90 | 9.41 | 11.03 | 49.56 |
| January 2020 | 19.00 | 22.82 | 2.42 | 5.51 | 22.03 |
| February 2020 | 21.01 | 24.94 | 7.55 | 8.23 | 27.68 |
| March 2020 | 21.77 | 30.01 | 10.08 | 7.31 | 31.43 |
| April 2020 | 35.12 | 29.04 | 7.96 | 10.89 | 37.75 |
| May 2020 | 26.86 | 22.67 | 11.79 | 7.71 | 40.84 |
| June 2020 | 30.79 | 27.80 | 9.89 | 7.73 | 44.95 |
| July 2020 | 34.42 | 19.39 | 9.68 | 10.65 | 39.69 |
| August 2020 | 25.07 | 15.00 | 10.56 | 6.92 | 40.13 |
| September 2020 | 41.72 | 12.79 | 11.78 | 9.67 | 46.74 |
| October 2020 | 29.46 | 15.56 | 10.56 | 11.17 | 47.60 |
| November 2020 | 26.04 | 13.56 | 16.24 | 11.46 | 43.73 |
| December 2020 | 41.59 | 8.19 | 19.12 | 11.60 | 62.32 |
| January 2021 | 29.09 | 8.19 | 16.36 | 9.03 | 34.79 |
| February 2021 | 30.72 | 8.99 | 18.55 | 8.46 | 40.89 |
| March 2021 | 35.29 | 21.98 | 17.66 | 11.98 | 48.19 |

Note: See Figure 12B.