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COVID-19 Testing Supply Chain

Introduction

COVID-19 testing—including for diagnosis, screening, and surveillance—is a critical component of responding to the COVID-19 pandemic, and its implementation has posed numerous challenges. Issues have included those related to Food and Drug Administration (FDA) regulation of tests, reimbursement and coverage for testing, equitable access to testing, and infrastructure and supply chain stressors, among others. In particular, the diagnostic testing supply chain has shown evidence of significant and ongoing stress since early in the pandemic, and problems persist with ascertainment, production, and distribution of almost all testing supply chain components.

COVID-19 tests include molecular (e.g., polymerase chain reaction, PCR), antigen, and serology tests. Molecular and antigen tests are used for diagnosis, screening, and surveillance, while serology tests are currently used only for surveillance. Tests may be available in different settings based on their Emergency Use Authorization (EUA). Specifically, they may require a central laboratory for processing; may be available at the point-of-care in a Clinical Laboratory Improvement Amendments (CLIA)-regulated environment; or may be nonlaboratory tests, able to be carried out in any setting, including the home. Tests with EUA may be commercially manufactured test kits, which include all required test reagents in a single unit, or a laboratory-developed test (LDT), which are tests developed by and carried out in specific clinical laboratories. Although commercial test kits and the platforms to run them may be in short supply, LDTs rely on numerous reagents and components, most of which have been variably in shortage.

Private efforts, spearheaded by the American Society for Microbiology (ASM) and the Association for Supply Chain Management (ASCM), nationally monitor and publicly report on inventory and supply shortages experienced by clinical laboratories. Recent data from these efforts indicate that clinical laboratories are operating at 40% of their capacity, that key supply shortages continue (e.g., test kits, consumables), and that supplies for non-COVID-19 testing are being affected. The Biden Administration's "National Strategy for the COVID-19 Response and Pandemic Preparedness" notes that in an end-to-end manner the "federal government will identify, inventory, and monitor the need, availability, and manufacturing capacity of critical supplies," including for testing and Personal Protective Equipment (PPE).

Testing Supply Chain

To date, testing supply chain issues have largely arisen with molecular tests and specifically real-time RT (reverse transcriptase)-PCR tests that are carried out in central laboratories. These tests are highly complex, require specialized equipment and trained personnel, and involve numerous steps. Steps include sample collection, storage, and transport; sample preparation, including extraction of nucleic acid; and sample analysis and processing. These steps are described in further detail below.

Point-of-care and nonlaboratory tests are generally less complex. While they require fewer steps, they sometimes rely on specialized equipment for processing, but are often able to be read visually. These tests are simpler to manufacture and have a less intricate supply chain; however, this type of test was authorized for clinical use by the FDA later in the pandemic, and so supply chain issues have manifested more recently. Shortages have included foam swabs, nitrocellulose paper, and machinery needed to manufacture the tests.

In order to support the manufacturing and procurement of medical countermeasures to COVID-19, the Trump Administration developed Operation Warp Speed (OWS), an interagency effort involving the Department of Defense (DOD), the Department of Health and Human Services (HHS), and public-private partnerships between these agencies and the biomedical industry. Under the Biden Administration, OWS is being modified and renamed. Acting through OWS, DOD, and HHS invested to increase the manufacturing of COVID-19 diagnostics and procured diagnostics and ancillary supplies (e.g., pipette tips) for use in responding domestically to the pandemic. For example, DOD recently awarded $231.8 million to Ellume to increase production of its at-home over-the-counter test and procure 8.5 million tests.

Sample Collection

Individually wrapped, sterile, single-use swabs are the preferred tool to collect upper respiratory samples. Some tests may allow patients to swab themselves, while others require a health care professional to perform the sampling. Swabs used specifically for testing are FDA-regulated products constructed with a flexible stem and a bud made of synthetic materials that do not contaminate or interact with the patient sample. These are not substitutable with other cotton swabs or buds. Reports of swab shortages have been ongoing throughout the pandemic, representing a limiting factor in achieving adequate levels of testing nationwide.

Sample Storage and Transport

Swab samples must be placed in a preserving chemical solution while in transport to a lab for analysis. Point-of-care and nonlaboratory tests, in which evaluation of the sample is conducted almost immediately after it is taken, do not require sterile transport. The most common preserving transport solution is Viral Transport Medium (VTM), which

maintains the integrity of the respiratory sample and prevents contamination and degradation.

There are a number of consumables (single-use products) associated with sample storage and transport, as well as with the subsequent steps of extraction and analysis. These include, for example, the plastic vials (with caps) used to receive and contain samples while in route to a laboratory for analysis. Delay in production of these consumables or general shortages place an additional constraint on nationwide testing capabilities.

Sample Preparation (Nucleic Acid Extraction)

A precursor to sample analysis is sample extraction, in which the organic or genetic material is isolated and prepared for examination and identification. This process involves the use of complex and highly specific reagents that maintain sample integrity through the isolation process. Extraction reagents are available prepackaged and premeasured in commercial kits. The speed at which these kits can be produced and used represents a rate-limiting step in testing. A shortage in a particular reagent may also delay the production of kits in general, regardless of the supply of other co-packaged materials. In addition, clinical laboratories carrying out LDTs often make their own extraction solutions using the component reagents; this ability is affected by the availability of the raw chemicals. Extraction may be performed on individual samples or on multiple samples at once using high-throughput extraction instrumentation. This machinery increases the speed at which multiple tests can be processed, but a shortage of these complex instruments has meant that such time-saving extraction is not always available.

Sample Processing

Sample analysis varies based on which type of test is used. In general, however, reagents used to test for the presence of virus or antibodies are highly specific and not substitutable with other test reagents. Any shortage in reagent thus acts as a limiting factor in the number of tests that can be performed. Materials of note include DNA primers and probes used in real-time RT-PCR tests. Commercial kits also exist to test patient samples. These prepackaged, premeasured kits are generally separate from extraction kits, and instead contain all the reagents necessary to perform sample analysis. The speed at which these kits can be produced, and potential shortages of reagents, represent limiting steps in test kit manufacturing.

The machinery used to perform sample analysis may also be highly complex, and can be very costly to procure and operate. Acquisition of these instruments may thus represent a limiting factor in the number of tests a laboratory can analyze at once. In addition, the speed at which the analytic machinery operates is relatively inflexible, representing a fixed delay in providing test results. Further, testing platforms are not always interoperable; that is, specific platforms are able only to run specific tests, and the FDA EUA process, which designates the components that must be used with a particular EUA authorized test, further restricts interchangeability. Increasing the number of machines may not always speed up the testing process, as skilled personnel to operate the equipment are also required and may be unavailable.

Ancillary Supplies and Resources

PPE is a critical component of testing. A lack of PPE—items such as gowns, masks, gloves, face shields, and goggles—and limited visibility into the PPE supply chain have been persistent concerns throughout the pandemic. This has been the result of both materials shortage and lack of specialized production equipment. OWS has invested in increasing manufacturing capabilities in an attempt to resolve these issues.

In addition to material shortages, there have been reports of personnel shortages. Conducting complex tests requires trained personnel capable of operating test machinery. This particular supply chain issue is not only the result of a lack of trained individuals with the necessary skill set, but also a consequence of the nature of the pandemic, which affects test kit manufacturers as well as laboratory specialists. A shortage in trained personnel represents another bottleneck in the return of test results.

Another consideration is that testing for other purposes (e.g., sexually transmitted diseases) cannot be put on hold to devote all resources to COVID-19 testing. Laboratories and testing facilities continue to carry out COVID-19 test analysis simultaneously with other testing.

Recent Federal Activity

The Biden Administration's COVID-19 national strategy highlights efforts to increase testing capacity in both the long and short term. The strategy identifies several actions to alleviate infrastructure and supply issues: (1) make a commitment toward investment in onshore manufacturing of tests and test supplies; (2) invest in laboratory capacity; (3) exercise legal authorities (e.g., the Defense Production Act (DPA)) to expand manufacturing capacity of tests and test supplies; and (4) promote predictable and robust federal purchasing of test supplies. Executive Order "A Sustainable Public Health Supply Chain" directs agencies to fill supply shortfalls "using all available legal authorities," including shortfalls for supplies such as test reagents, pipette tips, high absorbency foam swabs, nitrocellulose material for rapid antigen tests, and rapid test kits. Certain DPA-based action has been announced with respect to rapid at-home and point-of-care COVID-19 tests. In addition, the Biden Administration announced it will invest $815 million in the domestic manufacturing of test supplies, including pipette tips and nitrocellulose paper for rapid antigen tests.

Congress may consider retrospectively evaluating testing supply chain issues that have occurred during the COVID-19 pandemic to help identify key issues, challenges, and possible best practices moving forward. Congress may additionally consider actions aimed at further improving supply chain visibility so any potential shortage may be addressed at the earliest junction possible.

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