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Submitted electronically to Charles.Strickland@hhs.gov

Re: Preservation and Expansion of Current Domestic Capacities for Laboratory-Based Testing and Manufacturing of Over-The-Counter (OTC) Rapid Antigen and Point-Of-Care (POC) Nucleic Acid Amplification Tests (NAATs)

Responding Entity: AdvaMedDx, the diagnostics division of The Advanced Medical Technology Association (AdvaMed)

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To Whom it May Concern,

Thank you for the opportunity to provide comments on the Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR) Request for Information (RFI) entitled, “*Preservation and Expansion of Current Domestic Capacities for Laboratory-Based Testing and Manufacturing of Over-The-Counter (OTC) Rapid Antigen and Point-Of-Care (POC) Nucleic Acid Amplification Tests (NAATs)*,” published February 16, 2022 on SAM.gov.

The RFI seeks to ascertain from the diagnostics industry and other stakeholders recommended policies, permitted under Title III of the Defense Production Act of 1950, that would address industrial base/technology issues to sustain and bolster the manufacturing capacity for diagnostic tests and technologies for SARS-CoV-2, which have been scaled to unprecedented heights during the pandemic.



The RFI emphasizes the essential nature of “a robust and resilient public health industrial base [to] ensuring the health and security of the United States.”

AdvaMedDx appreciates the opportunity to offer comments to this RFI. The association commends the Administration for the public-private partnerships that have supported the unprecedented reach of testing across the U.S. to date and for laying out a bold vision of expanded public-private partnerships beyond this RFI as indicated in the recently-issued “[Public Health Supply Chain and Industrial Base One-year Report](#)” in response to Executive Order 14017. This report provides a more holistic view of the Administration’s commitment to leveraging several public-private arrangements to sustain and strengthen diagnostic manufacturing and laboratory infrastructure for the health and security of all Americans. These stated plans hold tremendous promise, and many reflect priorities the association has pursued with the Administration and on Capitol Hill throughout the pandemic. AdvaMedDx is committed to working with the Administration and our private sector partners to support the thoughtful development of detailed plans and their ready execution.

These plans should include public private arrangements such as warm-base manufacturing; vendor managed inventory (VMI) of the Strategic National Stockpile (SNS); increased investment and broadening of authorities of HHS’s Biomedical Advanced Research and Development Authority (BARDA) and the National Institutes of Health Rapid Acceleration of Diagnostics (RADx Program), including its Independent Test Assessment Program (ITAP); among others highlighted in comments below.

Importantly, the opportunity before the U.S. Government (USG) today is not only to improve ongoing preparedness and strengthen readiness for future emergencies, but to also sustain diagnostics manufacturing and laboratory capacity beyond this pandemic to facilitate equitable access to routine and innovative testing for all diseases and conditions, and across all communities, to reduce disparities in patient care and outcomes. This is essential to the health and security of our country.

AdvaMedDx’s response to the RFI includes:

- About AdvaMed and AdvaMedDx
- IVD Industry Overview and Mobilization in Response to COVID-19
- The Importance of Public-Private Partnership to Diagnostics Industry Mobilization
 - Establish a Permanent Public-Private Diagnostic Testing Forum
- Improved Public Policy Necessary to Enhance Preparedness:
 - Strategic National Stockpile and Vendor Managed Inventory
 - Warm base manufacturing and industrial base expansion
 - BARDA
 - RADx
 - RADx ITAP: Model Expansion to Accelerate Bringing At-Home Tests to Market for Additional Infectious Diseases
 - Infrastructure to develop, manufacture, and deploy new diagnostics for CDC identified emerging pathogens of concern when no commercial test exists
- Modernizing Policies, Extending Infrastructure Improvements to Equitably Extend the Reach of Testing



About AdvaMed and AdvaMedDx

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical technology association, representing over 400 member companies. AdvaMedDx, a division of AdvaMed, represents over 75 manufacturers of *in vitro* diagnostic (IVDs) tests and technologies.

The ongoing experience of manufacturers of IVD tests during the COVID-19 pandemic provides critical insight into the capability of industry, when faced with a new pathogen, to rapidly develop and manufacture at scale quality tests that are essential front-line tools in the fight against the pathogen, while also augmenting the availability of instruments used in laboratories and at the point-of-care to run tests. As such, the association is well positioned to provide considered and constructive recommendations to the RFI.

IVD Industry Overview and Mobilization in Response to COVID-19

IVD companies develop and manufacture, for the commercial market, advanced diagnostic tests and platforms/instruments on which tests are performed in laboratories, physician offices, and other sites. The Food and Drug Administration (FDA) regulates the validation, manufacturing, and distribution of IVDs as medical devices, while also regulating the manufacturing processes of IVDs, quality management systems, and the analytical and clinical validity of IVDs, along with certain requirements after tests are on the market. During a public health emergency, the FDA uses the Emergency Use Authorization (EUA) process to rapidly assess medical devices, including diagnostics.

Dozens of AdvaMedDx member companies rapidly developed and manufactured, at scale, one or more Food and Drug Administration Emergency Use Authorized (EUA) laboratory or point-of-care tests for SARS-CoV-2, while also significantly augmenting molecular testing platforms/instrumentation in the U.S.

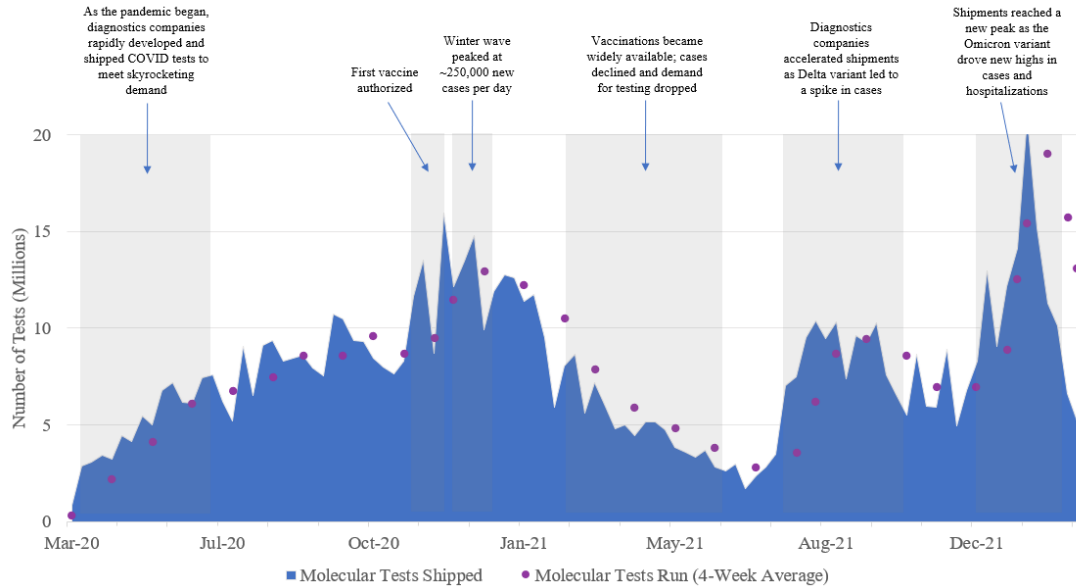
More specifically, AdvaMedDx has tracked domestic shipments of all laboratory-based and point-of-care molecular and serology/antibody tests for SARS-CoV-2 manufactured by 13 leading IVD companies, providing this aggregated information and associated analysis in weekly reports to policy makers to support our nation's collective response to the pandemic. ***The AdvaMed COVID-19 Test Supply Registry***¹ encompasses ~80% of the U.S. molecular market. To date:

- 800 million molecular tests have been manufactured and shipped to laboratories across the U.S. by Registry participant diagnostic companies, and
- 80 million serology/antibody tests have been manufactured and shipped across the country to date. AdvaMed members have also brought to market T-cell testing to aid in identifying individuals with an adaptive T cell immune response to SARS-CoV-2, indicating recent or previous SARS-CoV-2 infection
- More than 1 billion at-home, including over-the-counter (OTC) antigen tests have been brought to market in the U.S. by the IVD industry to date, based on assessment of publicly available information.
- Diagnostic testing is further leveraged each day to guide the care of hospitalized patients critically ill with COVID-19, including blood gas and hemostasis testing.

¹ ***AdvaMed COVID-19 Testing Supply Registry*** participating diagnostics manufacturers are Abbott, BD, Beckman Coulter, Bio-Rad, bioMérieux, Cepheid, Hologic, Ortho Clinical Diagnostics, QIAGEN, Roche Diagnostics, Sekisui Diagnostics, Siemens Healthineers, and Thermo Fisher Scientific. More information is available here: <https://www.advamed.org/industry-updates/hot-topics/covid-19/>



Figure 1 illustrates weekly shipments of molecular tests by AdvaMed Registry participant companies. 800 million tests have shipped since March 2020.



800 million molecular tests have shipped by AdvaMed Registry companies to U.S. laboratories since March 2020

Further, the diagnostics industry has facilitated the robust expansion of laboratory capacity in the U.S. through the manufacturing and placement of instruments/platforms used to run tests. Prior to the pandemic, ~11,700 automated molecular testing instruments from AdvaMed Registry participants were available in labs across the country, accounting for 80-90% of all U.S. molecular instrument placements. By January 2022, the installed base increased by 110% to ~24,500 instruments.

Figure 2 illustrates the 110% increase in molecular laboratory instruments in the U.S. since March 2020.

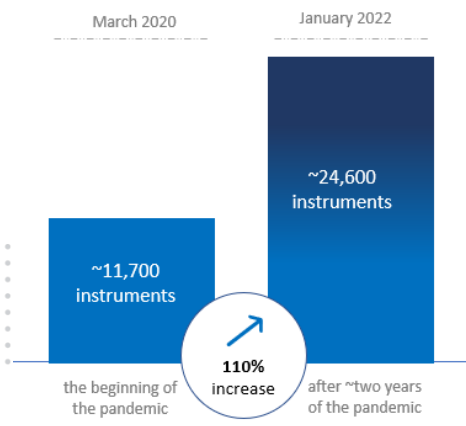
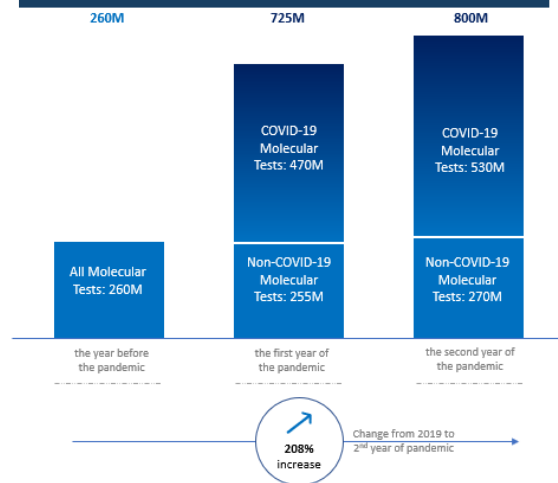


Figure 3 shows the dramatic increase in total molecular test shipments from 2019 (pre-pandemic) to the first two years of the pandemic.



The Importance of Public-Private Partnership to Industry Mobilization

Strong public-private engagement during the pandemic has supported the unprecedented diagnostic industry mobilization. The investment in diagnostics required to address the COVID-19 pandemic since January 2020 has exceeded that which the private sector could bear entirely on its own. Certainly, there has been tremendous private sector investment in developing tests and digital health tools; ramping efforts at existing manufacturing sites; adding new manufacturing, including for products previously outside of the scope of most diagnostics companies – such as precision plastics – to generate redundancies in supply chains; and more, yet the magnitude of diagnostics mobilization to date could not have been accomplished without public sector support and collaboration.

In particular, AdvaMedDx applauds the establishment during the pandemic of the the National Institutes of Health’s (NIH) Rapid Acceleration of Diagnostics (RADx) program and enhanced funding to reinforce the vital work of the Biomedical Advanced Research and Development Authority (BARDA) as examples of successful public-private engagement.

Throughout the pandemic, IVD companies and the association have engaged in close communication and collaboration with multiple entities in the USG, including the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), Department of Defense (DOD), Department of Health and Human Services (HHS), the Department of Homeland Security (DHS), Food and Drug Administration (FDA), Federal Emergency Management Agency (FEMA), the White House, and other entities. Though the character of these engagements has shifted during various phases of the pandemic, one constant has remained in the essential nature of strong public-private engagement to ensure as robust an ongoing response as possible.

✓ **Establish a Permanent Public-Private Diagnostic Testing Forum**

The experience of the COVID-19 pandemic demonstrates the imperative for a formal, permanent public-private advisory entity for clinical diagnostic testing. Such an advisory board or forum would improve short- and long-term preparedness and response to public health emergencies (PHEs) by ensuring regular and meaningful public-private coordination and collaboration among federal departments and agencies as well as between the USG and industry (diagnostics manufacturers, laboratories etc.). This heightened, regular, data-driven coordination would allow for improved alignment of supply and demand in times of emergency and for the informed development of long-term policy to sustain bolstered manufacturing capacity and lab capacity, as drops in demand occur, in between spikes of increased need for testing. It would also facilitate preparedness for any future emergency. Such long-term policies should include warm-base manufacturing agreements and VMI of the SNS, as explained below.

Had such a forum been in place during the pandemic, it may have positively influenced USG to maintain manufacturing capacity of OTC antigen tests, for example, in the summer of 2021, as vaccination rates increased and demand for testing dropped precipitously. In formal written and verbal comments, AdvaMedDx, on behalf of industry, encouraged warm-base manufacturing contracts at the time, flagging that manufacturing lines for such tests would be taken off-line without policy to generate demand signals. Industry made these recommendations informally and formally, including during the July 17, 2021, “*ASPR COVID-19 Testing Industry Day*” that was specifically focused on warm base manufacturing, flexible contracting, stockpiling, and industrial base expansion.



While a detailed prediction of the spikes of Delta and later Omicron could not have been made with precision, preparedness for the potential of future surges was encouraged by industry as a reasonable precaution, along with preparation for the start of the new school year and the beginning of influenza season. Long-term policy was not put in place and manufacturing capacity retreated in response to low demand.

Another area of focus of a public-private advisory body could be to oversee an update to the charter of the existing CDC-CMS-FDA Tri-Agency Task Force for Emergency Diagnostics, which was launched in 2019. The Task Force could refine its focus to ensure improved coordination to hasten access to government-held patient samples in order to facilitate the rapid development of tests. It also could ensure coordinated policy to make certain swift coding, coverage, and rational reimbursement for diagnostic, screening, serology/antibody, and T-cell testing is in place. This entity may also ensure that public policy, to provide clarity on the use cases for the tests, is strong. The Task Force should focus on collaboration with BARDA and RADx.

Improved Public Policy Necessary to Enhance Preparedness

The RFI requests industry feedback on policies that should be employed to sustain current domestic testing and manufacturing capacities established over the last 12 months to prevent capacity loss due to market volatility, and to expand domestic testing and manufacturing capacities with a specific focus on point-of-care molecular and over-the-counter (OTC) antigen testing. ASPR is also interested in recommendations for expansion activities that could support development and deployment of single and multiplex diagnostics for existing or emerging pathogens beyond SARS-CoV-2.

There is strong interest across AdvaMedDx member companies with one or more COVID-19 tests on the market in public-private mechanisms that could be used to sustain and extend manufacturing capacity. Broad comments on such mechanisms are included below. AdvaMedDx has encouraged diagnostic manufacturer member companies to individually provide detailed, company-specific feedback and recommendations to this RFI.

○ **Strategic National Stockpile and Vendor Manage Inventory Recommendations**

✓ **Increase and extend funding for the SNS**

The Strategic National Stockpile (SNS) is currently funded for five years, including \$1.657 billion for Fiscal Year 2022. Both the amount and the funding periods should be carefully examined. Given the relatively infrequent nature of a major health care crisis such as a pandemic, ten-year funding might be more appropriate. Funding levels should ensure the stockpile is maintained at pre-determined levels, and that products are rotated in accordance with industry-recommended shelf lives and updated to recognize innovative new technologies.

✓ **Reflect Innovation in SNS Inventory:**

As the USG reviews medical supplies and technologies for suitability in the SNS, it should account for advances in science and technology. Some technologies may become obsolete while others need to be added for consideration. AdvaMedDx recommends a formal mechanism for the government to consult with the private sector regularly to ensure the latest advances in medical technology are reflected in the SNS.



✓ **Leverage Vendor-Managed Inventory:**

A mechanism to support effective stockpiling and efficient distribution of items in the SNS would be through Vendor-Managed Inventory (VMI). VMI of the stockpile can ensure that critical and up-to-date medical technologies are readily available and rapidly deployed during any public health emergency.

Under the VMI system, the federal government would contract with a diagnostics manufacturer to hold the contracted stockpile supply in a domestic warehouse rather than in USG-owned and -operated warehouses. Under such an arrangement, the diagnostics manufacturer would be responsible for overseeing the storage and inventory management of the stockpiled diagnostic testing equipment and supplies, such as laboratory instrumentation, test kits, extraction reagents, sample collection and transport devices, plastic pipette tips, etc. To mitigate product expiration, the testing supplies would be continually rotated into commercial supply, as is currently done under the Shelf-Life Extension Program, which is managed by the DOD and FDA. When the stockpile is activated by HHS in response to an emergency, the diagnostics manufacturer would at once deploy the stockpiled items.

The advantages of VMI include mitigating risk to the federal government and ensuring up-to-date medical technologies are included in the SNS, as well as efficiently leveraging the storage and distribution expertise and infrastructure of private industry partners.

AdvaMedDx recommends VMI be employed by HHS to manage the SNS, with product-specific policies that account for the unique factors of various medical technologies.

✓ **Recognize Development of New In Vitro Diagnostic (IVD) Tools as Pathogens Emerge:**

AdvaMedDx recommends the SNS contain an adequate supply of diagnostic testing equipment, materials, and supplies, as it is critical to have the ability to rapidly test and diagnose patients who are sick or have been exposed to a pathogen. While it is not possible to stockpile diagnostic tests for an unknown pathogen, certain tests can be stockpiled that can help rule out other infections. For example, every year the stockpile could ensure it has certain tests for influenza, Respiratory syncytial virus (RSV), COVID-19 and other common respiratory illnesses. These tests could help rule out these particular pathogens and help identify if a new pathogen causes similar respiratory symptoms. Further, it is possible the stockpile should include agnostic raw materials and consumables that would support future infectious disease testing. Most laboratory based molecular instrumentation requires the same agnostic raw materials and consumables to perform any infectious disease test developed in a future public health emergency.

In addition, HHS could prioritize development of pathogen agnostic tests (e.g. host response-based) that can alert health care providers and public health officials when novel pathogens emerge. These tests could be informative for clinical decision-making (e.g. is the novel pathogen bacterial or viral) and to alert pathogen-specific test manufacturers to develop targeted tests soon after the outbreak.

AdvaMed recommends stockpiling the equipment necessary to process IVD tests – such as test instruments, analyzers, and other capital equipment – to rapidly scale up diagnostic testing infrastructure and help to ensure prompt testing of samples in communities that may not have an existing lab or testing infrastructure. In addition, medical supplies used in the collection, transport, and processing of IVD tests should be considered for the SNS. These include swabs, collection tubes, lancets, transport medium/tubes, and reagents such as DNA/RNA extraction kits, which are generally not specific to a particular test or pathogen.



As diagnostic tests to screen and diagnose for the new pathogen are rapidly developed, these tests should be added to the SNS as well.

○ **Warm Base Manufacturing and Industrial Base Expansion Recommendations**

Warm base manufacturing arrangements, widely sought by AdvaMedDx members with one or more COVID-19 tests on the market, are essential to a robust and resilient public health industrial base capable of ensuring the health and security of the US. The lack of adequate manufacturing capacity leading into—and at times during—the COVID-19 pandemic, contributed to testing shortages. To avoid this problem in the future, the federal government should contract with diagnostic manufacturers that have invested in expanded capacity during the COVID-19 pandemic to sustain these increased manufacturing levels. Warm base manufacturing contracts might also include provisions to support the development, manufacturing, and deployment of diagnostics not already available on the commercial market where public health officials, including at the CDC, determine an emerging pathogen is a threat to patient and public health.

✓ **Warm base manufacturing agreements**

Enabling sustained manufacturing (“warm base manufacturing”) of diagnostics would provide critical diagnostic testing supplies to ensure ongoing availability of testing, even as demand drops, and to be prepared for potential future spikes in cases necessitating increased testing. With a decrease in COVID-19 testing demand, manufacturers will adjust production capacities to a new level of reduced supply to match demand. This provides an opportunity for the federal government USG to partner with manufacturers to reserve some of this excess capacity to help ensure supply infrastructure preparedness for a future pandemic.

Again, take for example the steep drop in demand that followed effective vaccines becoming widely available in the summer of 2021. Demand for testing fell precipitously as cases declined and CDC revised its testing guidance. Without a strong market for testing, the diagnostics industry encouraged government policy to hold manufacturing capacity. Policy was not put in place and some companies were forced to scale back manufacturing capacity, capital expenditures, and workforce. This made it difficult for manufacturers to ramp their capacity to match skyrocketing demand when the Delta and Omicron variants spiked.

The USG should rapidly issue a Request for Proposals (RFP) to industry for the establishment of warm base manufacturing agreements. These contracts should be set up via bilateral agreements with companies, specific to their manufacturing capabilities and testing portfolios. Arrangements should be put in place for 12-24 months or longer. Agreements should recognize the potential for the arrangement to serve as a framework for long-term preparedness for the next public health emergency. Thus, agreements should contemplate extensions beyond 24 months. Warm base manufacturing would allow for stockpiling, including via vendor managed inventory, for public health emergencies.

Manufacturing capacity readiness should be established so that ramp-up time to pandemic peak supply demands can be reached within 60-90 days, instead of 12-18 months as occurred during the start of the COVID-19 pandemic. This clause would be triggered by the USG when the earliest evidence of need arises.

The costs of warm base manufacturing include those associated with maintaining diagnostic manufacturer and third-party manufacturing lines to support the production of raw materials, consumables, reagents, and other materials to meet anticipated testing needs. This includes costs to keep



manufacturing assets warm, reserve manufacturing space, and manage depreciation and maintenance for both vendor manufacturing lines and third-party supplier lines.

✓ **Industrial base expansion agreements**

During the pandemic, public-private arrangements have supported building out existing manufacturing lines and adding new lines or sites. In some cases, USG support has bolstered domestic manufacturing of raw materials or other supplies essential to diagnostics.

If a diagnostic manufacturing facility struggled to meet the testing demand in the COVID-19 pandemic, the USG could fund supply line(s) expansion to an existing facility to stand up additional supply capacity for future surge capacity. Within this investment, the USG would fund the cost of the additional line(s) expansion and allow the diagnostic manufacturer to utilize the additional line(s) supply capacity within non surge times but reserve the right to complete supply capacity of USG funded additional line(s) within surge capacity.

The USG should issue Requests for Proposals (RFPs) to diagnostics manufacturers capable of establishing or augmenting manufacturing for key raw materials and other supplies and components such as precision plastics and other polymers, extraction reagents, antibodies, specimen collection devices, and the like.

○ **Increased Investment and Broadening of Authorities of BARD and RADx Programs**

✓ **BARDA:**

The HHS Assistant Secretary for Preparedness and Response, through BARDA, has been providing significant support to IVD manufacturers to advance and accelerate the development of emergency diagnostic tests. Innovation should be fully embraced to ensure a broad range of testing, from those tests that enable advanced surveillance to facilitate triaging of patients based on their potential risk of deterioration, and beyond. AdvaMedDx is encouraged by the bolstering of this funding in the recently passed legislation to fund the federal government through September, and new flexibility to maximize innovation, including allowing funding provided by BARDA to be used to recoup costs already incurred for emergency test development prior to receipt of the funds.

Furthermore, federal contracting procedures and timelines can delay the transfer of R&D funding to manufacturers during an outbreak. This delays the pace of IVD development and is a significant disincentive to many manufacturers to develop tests at the risk of not being able to recoup initial development costs.

Additionally, more flexibility in how BARDA funds can be applied to reimburse development costs incurred during the earliest states of test development would be a significant incentive to manufacturers to accelerate the development of emergency diagnostic tests.

Finally, BARDA's authorities and funding should be expanded so that engagement on all pathogens of concern is achievable. For example, recently AdvaMedDx members were requested by CDC to develop a POC diagnostics for the mycotic (fungal) disease of *Candida auris*. There is no commercial market for such tests in the absence of coding, coverage, reimbursement, and clinical guidelines to recommend the tests, despite clear CDC evidence that such tests would have significant utility. In collaboration with member companies currently in possession of the technology to deliver a POC test for *C. auris*, AdvaMedDx approached BARDA, seeking to explore the potential for support from the agency to meet the public health needs set forth by CDC. AdvaMedDx was informed that BARDA authorities and budget precluded action on mycotic diseases.



✓ **RADx ITAP: Model Expansion to Accelerate Bringing At-Home Tests to Market for Additional Infectious Diseases**

AdvaMedDx and AdvaMedDx member companies view RADx as a tremendously successful initiative launched during the pandemic, aimed at speeding the innovation, development, and commercialization of COVID-19 testing technologies. The RADx program continues to invest in early innovative technologies to speed development of rapid and point-of-care COVID-19 testing.

At the end of 2021, RADx established the Independent Test Assessment Program (ITAP) that is providing critical acceleration to regulatory review by the FDA to increase the availability of high-quality OTC COVID-19 tests to the public. A range of diagnostic manufacturers report uniformly favorable experiences with this robust, efficient, and effective program.

AdvaMedDx strongly recommends the ASPR, FDA, BARDA, and RADx collaborate in using the ITAP program for other diseases and conditions for which self-collection and POC, including OTC testing, could provide significant benefit, beginning with common infectious diseases, including mycotic diseases. Presently, the only OTC tests approved or authorized by the FDA for infectious diseases are for HIV and COVID-19. As demonstrated keenly throughout the pandemic, all modalities of testing – lab-based and POC – are essential parts of our nation’s testing infrastructure.

○ **Infrastructure to develop, manufacture, and deploy new diagnostics for CDC-identified emerging pathogens of concern when no commercial test exists**

AdvaMedDx encourages the potential to add provisions to warm base manufacturing agreements to rapidly develop, manufacture, and deploy diagnostics that are not available on the commercial market in the laboratory or point-of-care modality sought by public health officials. It is often the case that CDC identifies a pathogen of concern causing a local or regional outbreak domestically or internationally, yet diagnostics for the pathogen in questions are not available on the commercial market. This public health problem can be addressed through thoughtful public-private arrangements.

Historically, even in the case of a declared public health emergency, when IVD manufacturers have developed emergency diagnostic tests typically there is great uncertainty as to the prospects for selling those tests. Tests, such as those for ZIKA or H1N1, often went unsold or were donated, as there was zero, or extremely limited, commercial market for these and other emergency IVDs. While a small market is clearly favorable from a public health perspective, this phenomenon serves as a significant disincentive for IVD manufacturers to invest in the development of emergency diagnostics.

Especially in cases when there is no declared public health emergency, commercialization of a new test to address an emerging pathogen is infeasible in the absence of coding, coverage, reimbursement, and clinical guideline foundation.

Take again the example of CDC’s interest in new commercial diagnostics for mycotic diseases as explained in the BARDA section above. Officials from the CDC Mycotic Disease branch encouraged AdvaMedDx members to develop new commercial POC tests to screen patients for *C. auris* and other fungal infections to address a worsening crisis of fungal infections in health care facilities and communities. The utility of a POC *C. auris* tests in hospital emergency rooms or in long-term care settings as patients are admitted is the rapid identification of patients colonized with *C. auris*, allowing swift infection control measures to be put in place to protect that patient and the entirety of the patient population, staff, and visitors from infection. While some AdvaMedDx member companies possess technology for such a test, the total lack of a commercial market is blocking these tests from reaching clinicians. This is a problem the USG can resolve.



AdvaMedDx recommends close alignment between CDC and BARDA to identify diagnostics unavailable on the commercial market to address emerging pathogens that threaten patient and public health. The guidance and collaboration of the RADx program could be leveraged to facilitate technology rapidly advancing through the FDA. Engagement with companies that have existing warm-base manufacturing agreements that have the capacity to readily switch over manufacturing lines could rapidly facilitate the development, manufacturing, and deployment of these needed diagnostics. The warm base agreements with guaranteed procurement provisions could eliminate the barrier of a lack of commercial market, putting tests quickly in the hand of clinicians. While the ease of switching a manufacturing line from one product to another will vary, in general, manufacturing lines dedicated to COVID-19 tests may be readily switched to a new test.

The benefit of such an initial diagnostic for an emerging pathogen program would be manufacturers and the USG would have a head start should any of these pathogens trigger a public health emergency.

Modernizing Policies, Extending Infrastructure Improvements to Equitably Extend the Reach of Testing

High levels of public and private sector investment to bolster and sustain our nation's testing infrastructure should be coupled with practical policy to ensure necessary clinical testing for all Americans, for all diseases and conditions, is supported with strong and modernized regulatory, coverage, reimbursement, and clinical guideline guidance and recommendation policies. In short, ensuring a modern policy landscape for testing would strengthen the supports upon which the nation's testing infrastructure, which is critical to public health and security, is rooted.

o Diagnostics Are Foundational to Health Care: Updating Guidelines, Regulation, and Reimbursement Policy

The U.S. has an opportunity to utilize the dramatic increase in lab and point-of-care instrumentation and the experience with at-home testing to extend the reach of testing, beyond the COVID-19 pandemic, for all diseases and conditions. Quality testing is foundational to the provision of informed clinical care, decision-making, monitoring of treatment, and screening for disease. Increasing access to screening and diagnostic testing is integral in efforts to eliminate disparities in overall health care access, treatment, and outcomes.

AdvaMedDx encourages the Administration to work swiftly, in collaboration with the private sector, to develop a roadmap to improve equity in access for all patients to quality diagnostic testing across all diseases and conditions. This roadmap should leverage bolstered manufacturing capacity and instrumentation augmentation and the recognized utility of point-of-care, including OTC, tests to extend the reach of testing by improving the cadence of updates to clinical guidelines to reflect diagnostics innovation, modernizing the regulatory framework for all diagnostics, and improving Medicare coverage and reimbursement policy. Careful consideration should be given to ensure this extended reach of testing is carried out for American Indians and Alaska Natives through HHS's Indian Health Service.

✓ Guidelines, Guidance and Recommendations

AdvaMedDx recommends the provision of increased support to public and private clinical guideline-setting entities to allow for guidelines to keep pace with technology. Guidelines often lag years behind innovations, resulting in restricted access to technology that can improve patient care and public health. CDC should explore the use of clinical guidance or recommendations as a swifter way to signal to clinicians and payers the utility of improved clinical workflows that include diagnostics in areas of



existing or emerging pathogens of concern, such as mycotic diseases and the increasing rise of antimicrobial resistance bacteria.

✓ **Modernizing Regulation**

AdvaMedDx encourages the Administration’s robust support for the passage of legislation to modernize oversight of all diagnostic tests – both *in vitro* diagnostics (IVDs) and laboratory developed tests (LDTs) – by creating a single, diagnostics-specific, FDA regulatory framework aimed at promoting innovation and improving public health outcomes. Specifically, the association is urging Congress to move the legislative process forward this year to improve and pass, as part of the Medicare Device User Fee Authorization, the Verifying Accurate Leading-Edge IVCT Development Act” (or “VALID” Act) to close existing gaps in regulation of diagnostic tests. The bipartisan, bicameral VALID Act was introduced by Senators Michael Bennet and Richard Burr and Representatives Diana DeGette and Larry Bucshon, M.D. This diagnostic regulatory reform legislation would modernize the regulatory framework applicable to all diagnostic tests, providing much-needed clarity while enhancing the availability of high-quality, innovative tests to improve patient care and public health. By closing gaps in regulation, the VALID Act would give confidence to patients and providers in the quality and performance of all tests, regardless of where the tests were developed. AdvaMedDx appreciates HHS’ and FDA’s support for modernized authorities.

✓ **Improving Coverage for Innovative New Technologies**

Modernizing Medicare coverage to allow for improved access to breakthrough technologies and to broaden access to screening tests to promote the early detection of disease to improve outcomes is essential to any effort to improve equity in patient and public health care and outcomes. AdvaMedDx is encouraged by recent CMS listening sessions on a potential Transitional Coverage for Emerging Technologies (TCET) concept.

✓ **Resolving Reimbursement Reductions Undermining Testing Infrastructure**

Robust laboratory infrastructure across the country is essential to the implementation of any national testing strategy to increase access to appropriate screening and diagnostic testing during non-emergent times and to prepare for future pandemics. Before the COVID-19 pandemic, the laboratory industry was struggling with the impacts of cuts under the Protecting Access to Medicare Act of 2014 (PAMA).

Current policy implementing the PAMA has led to rounds of dramatic Medicare reductions for most diagnostic tests, and the next reductions are set to begin January 1, 2023. Flawed implementation has led to projected reductions in Medicare reimbursement for laboratory services by \$10 billion, far eclipsing the \$2.5 billion in cuts originally presumed by the Congressional Budget Office. While this system was intended to result in Medicare Clinical Laboratory Fee Schedule (CLFS) rates reflecting private market rates, hospitals and physician office laboratories are largely excluded from reporting private payer rates and volumes, leaving a large portion of the laboratory market unrepresented in the CLFS rates paid by Medicare.

The long-term impact of PAMA is the unraveling of a strong testing infrastructure. The Administration should exert its authority to improve PAMA implementation to mitigate reductions. The Administration should also swiftly work with Congress to strengthen diagnostic reimbursement for the future, comprehensively reforming PAMA, to safeguard a robust national testing infrastructure.



○ **Maintain Access to Lab-Based and Point-of-Care Testing Expanded During the PHE**

During the Public Health Emergency (PHE), policy has been developed at the federal level to set up and support infrastructure to extend the reach of COVID-19 testing, including, importantly, in underserved communities. Policy makers should consider extending these policies beyond the PHE to bolster access to testing for all diseases and conditions beyond COVID-19 with a strong emphasis on the principle that all modalities of testing – laboratory-based and point-of-care (POC), including at-home testing – should be fully used.

✓ **Extend and Expand the Increasing Community Access to Testing (ICATT) program**

Consider, for example, the important opportunity before policy makers to extend and expand the CDC's Increasing Community Access to Testing (ICATT) program that supports free COVID-19 laboratory and point-of-care testing in pharmacies and other locations in U.S. communities that have been disproportionately affected by the pandemic. ICATT, which is based in over 11,000 pharmacies throughout the U.S., has facilitated well over 12 million tests performed thus far during federal fiscal year 2022. Currently focused only on COVID-19 testing, this new infrastructure could be extended and expanded to ensure underserved communities would have dramatically improved access to diagnostic testing for all diseases and conditions, as appropriate.

Further, during the PHE, pharmacies, clinics, physician offices and other sites in states that have not typically permitted point-of-care testing to be performed on site with results provided in under 30 minutes or less have extended the reach of POC testing effectively, with patients knowing in short order the result of their tests so that appropriate clinical steps could be taken per those results.

AdvaMedDx recommends policy makers continue efforts beyond the PHE to extend the reach of lab-based and POC, including at-home testing, for all diseases and conditions, as appropriate – particularly to individuals in underserved communities.

AdvaMedDx thanks the ASPR for the opportunity to provide these comments and would be pleased to confer on any recommendations included herein.

Sincerely,



Susan Van Meter
Executive Director
AdvaMedDx

