

Centers for Disease Control and Prevention
Center for Surveillance, Epidemiology and Laboratory Services
Division of Laboratory Systems

MEMORANDUM OF UNDERSTANDING

for

Diagnostic Surge Testing Capacity for Public Health Emergencies

This Memorandum of Understanding (MOU) sets forth the terms and understanding between the Advanced Medical Technology Association (AdvaMed), the American Clinical Laboratory Association (ACLA), the Association for Molecular Pathology (AMP), the Association of Public Health Laboratories (APHL), the College of American Pathologists (CAP), the Council of State and Territorial Epidemiologists (CSTE), the Food and Drug Administration (FDA), the National Independent Laboratory Association (NILA), and the Centers for Disease Control and Prevention/Center for Surveillance, Epidemiology and Laboratory Services/Division of Laboratory Systems (CDC/CSELS/DLS) (hereinafter referred to collectively as “Parties”). The Parties represented in this MOU agree to collaborate on enhancing laboratory testing surge capacity outside of CDC and public health laboratories before and during public health emergencies (PHEs).

BACKGROUND

An emerging pathogen that spreads quickly and/or has the potential to cause significant disease in humans, such as influenza, Zika, or SARS-CoV-2 virus, could result in demands for a high volume of laboratory diagnostic testing that exceeds the current testing capacity of the United States (U.S.) governmental public health laboratory system. Public health laboratories (PHLs) have expertise characterizing infectious organisms, handling clinical and non-clinical samples, and many have the ability to scale up routine operations to provide surge capacity during a response. The capability and capacity of PHLs was utilized during several outbreaks, including Anthrax 2001, the response to the Middle East Respiratory Syndrome, and Ebola outbreaks. However, public health laboratory systems are not currently designed to handle and execute diagnostic testing at a large scale and scope beyond the initial critical phases of public health emergencies. Furthermore, in the early phase of an emergency response, FDA-authorized tests and testing platforms may be inherently limited and may not be optimized for high throughput. The need to supplement public health laboratory diagnostic testing capacity has been demonstrated in previous virus outbreaks. At the advent of the H1N1 influenza virus outbreak, hospital-based clinical laboratories responded rapidly and effectively and the need for a coordinated and streamlined response from both public health and clinical diagnostic laboratories became apparent. The Zika virus outbreak resulted in the engagement of large independent laboratories with nationwide facilities. At the same time, hospital-based laboratories served the diagnostic needs of their patient populations. Most recently, the extensive demands for diagnostic testing during the coronavirus disease (COVID-19) pandemic quickly extended beyond public health laboratories and independent laboratories to other Clinical Laboratory Improvement Amendments (CLIA)¹ certified testing facility types.

¹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA>

Based on these experiences, partnerships and engagement between the public and private sector are crucial to supporting a significant increase in demand for diagnostic testing during a PHE and to respond to emerging public health threats before reaching the level of a pandemic. Furthermore, private sector and academia have resources that could be used for advanced surveillance methods, such as sequencing for variants of an infectious organism. The Parties of this MOU represent key stakeholders in the laboratory community, that in their respective roles, are collectively positioned to support laboratory diagnostic testing capacity. This MOU is intended to enable those partnerships through sharing of information and to further the mutual goal of engagement prior to and during an event that requires extensive capacity beyond CDC and public health laboratories. The outcome of these partnerships is referred to as external laboratory surge testing. This MOU is not intended to bind any of the Parties to specific future activities but is intended to set out a framework for undertaking those future activities, as may be consistent with applicable laws and subject to available appropriations. To that end, the Parties acknowledge that the unique needs of any such partnership and/or engagement may require either an amendment to this MOU or a newly drafted MOU.

CDC will collaborate with partners and use its existing relationships with other government agencies and stakeholders in the laboratory community to support external laboratory surge testing capacity for PHEs and emerging public health threats.

This MOU supersedes the 2018 MOU for Surge Testing Capacity signed by CDC, APHL, ACLA and CSTE², and is expanded to include appropriate partners positioned to support laboratory diagnostic testing community. This MOU can be updated on an annual basis to include other relevant partners that express interest and have the ability to support laboratory diagnostic testing capacity.

ROLES AND RESPONSIBILITIES

The CDC/CSELS Division of Laboratory Systems (DLS) is responsible for execution of activities listed. Other response related aspects such as development of situation-specific testing assays/diagnostics, distribution of specialized tests and test kits, and proficiency testing will likely be necessary but outside of DLS and the scope of this MOU.

CDC will:

1. Convene teleconferences and meetings with Parties to gather individual perspectives and viewpoints on solutions for implementing external laboratory surge testing capacity for and during public health emergencies. Take written minutes that capture individual responses provided by Parties without seeking consensus or recommendations.
2. Develop and implement tabletop and full-scale exercises to assess and evaluate partner roles and responsibilities for implementing external laboratory surge testing capacity.
3. In collaboration with Parties of this MOU, identify academic medical centers and/or private clinical and independent laboratories with national or regional presence with significant capacities that are determined by the testing needs of the PHE.
4. Establish a process for communication with critical partners and testing facilities before and during a response. Communication will include guidance for conducting risk assessments, safely handling specimens, performing laboratory testing and reporting results to public health.

² https://www.cdc.gov/csels/dls/documents/CDC-ACLA_APHL_CSTE_MOU_April_2018.pdf

5. Facilitate coordination with other relevant government agencies to appropriately plan and implement an external laboratory surge testing plan, including facilitating the communication of evolving regulatory requirements relative to laboratory test development and validation during a PHE.
6. Collaborate with relevant stakeholders to assist in standardizing and reducing the burden of electronic laboratory reporting of test results.

The Parties of this MOU will work cooperatively to:

1. Support CDC's effort to implement national external laboratory surge testing.
2. Collaborate with CDC to ensure timely responses to emerging pathogen outbreaks with pandemic potential, pandemics, and other public health emergencies.
3. Establish mechanisms and points of contacts for coordination and communication for their organization's members and among other partners.
4. Participate in teleconferences and meetings to discuss response plans and to address any issues that surface throughout the course of an emergency response to the extent consistent with the antitrust laws and other applicable laws.
5. Identify academic medical centers and/or private external surge testing laboratories with national or regional presence and specific testing capabilities and capacities to participate in responses.
6. Facilitate convening conference calls with external laboratories assisting in a response to a public health emergency.
7. Participate in training as well as tabletop and full-scale exercises to assess roles and readiness for implementing external laboratory surge capacity in response to a public health emergency.
8. Identify guidance, including biosafety expertise, and or training needs required for surge capacity testing.
9. Maintain awareness of compliance needs, regulatory requirements, and evolving regulatory directives granted by the Secretary of Health and Human Services.
10. Coordinate with member laboratories as appropriate to collect real world data assessing test performance and share this information with CDC and FDA and public health partners.
11. Identify electronic data exchange and public health data collection and reporting challenges from public health emergencies and make suggestions for addressing the challenges.

Party-specific Roles and Responsibilities

The Advanced Medical Technology Association (AdvaMed) will:

- Serve as a communications hub, facilitating linkages between its contact of private sector diagnostics manufacturers and the MOU Parties.
- Provide information regarding the aggregated, directional production of commercial tests by manufacturers, shipments of tests, and manufacturing capacity.
- Share perspective to bolster testing infrastructure, manufacturing, and policies concerning use cases for various diagnostic tests.

The American Clinical Laboratory Association (ACLA) will:

- Serve as a communications hub, facilitating linkages between its network of private sector clinical laboratories and the MOU Parties.
- Assist in identifying and engaging private sector laboratories to provide testing capacity for public health emergencies or an emerging pathogen outbreak with pandemic potential.
- Coordinate with private sector clinical laboratories and MOU Parties with respect to training, education, and preparedness activities.
- Collaborate with relevant stakeholders to assist in standardizing and reducing the burden of electronic laboratory reporting of test results.

The Association for Molecular Pathology (AMP) will:

- Serve as a communications hub, facilitating linkages between its subject matter experts, AMP leadership, and the MOU Parties.
- Leverage the members of its [Infectious Diseases Subdivision](#) and share clinical and technical molecular diagnostics expertise with the wider laboratory community. This subdivision is comprised of physicians, laboratory directors, and technologists.
- Leverage the members of its [Informatics Subdivision](#) to utilize Next Generation Sequencing bioinformatics capabilities and capacity.
- Recruit and help convene infectious disease and molecular diagnostics specialists to quickly implement surge testing in clinical laboratory settings especially in academic and community medical centers.
- Quickly ascertain, through surveys, the current capability for infectious agent testing, challenges, etc. among its members and recommend solutions.
- Rapidly develop and disseminate training on relevant topics using multiple modalities (e.g., online courses, webinars, etc.).

The Association of Public Health Laboratories (APHL) will:

- Serve as a communications hub, facilitating linkages between its network of local, state and territorial governmental laboratories performing tests of public health significance and the MOU Parties.
- Engage with its network of laboratories to collect key data on response gaps/laboratory needs and share information with decision makers.
- Represent the interests of local, state and territorial governmental laboratories in preparedness and response discussions.
- Provide technical assistance, training and education to address scientific, biosafety, biosecurity, regulatory, procurement and other needs of local, state and territorial governmental laboratories performing tests of public health significance.
- Collaborate with public and private sectors to address challenges and facilitate standardized approaches to electronic data exchange and laboratory reporting of test results.

The College of American Pathologists (CAP) will:

- Serve as a communications hub, facilitating linkages between CAP members experts, CAP committees, and the MOU Parties.
- Leverage CAP-accredited academic medical centers, community hospitals, and private clinical laboratories to assist CDC to establish external surge testing capacity.

- Collect capability data for each CAP-accredited laboratory so the CAP can identify laboratories with capacity to support a response nationally for community-based testing to vulnerable patient communities.
- Educate and provide guidance for CAP-accredited laboratories and its members on adherence to any federal standards and requirements ensuring availability of reliable testing for rapid detection of agents for emerging pathogens.

The Council of State and Territorial Epidemiologists (CSTE) will:

- Serve as a communications hub, facilitating linkages between its network of state, local, tribal, territorial (STLT) epidemiologists, laboratories and the MOU Parties.
- Represent the STLT epidemiologists' interests in preparedness discussions.
- Develop surveillance case definitions, including clinical, epidemiologic and laboratory criteria necessary for characterizing the response and conducting national surveillance.
- Convene the Council, representing all 50 states, territories, and Washington DC to assure national coordination and assessment of epidemiologic response challenges as well as characterize, define, or establish epidemiologically relevant policy and communicate with MOU Parties as it applies to laboratory testing.
- Provide epidemiologic expertise regarding the feasibility of specimen collection and identification of individuals at high risk or higher risk for infection.
- Work with laboratory partners and jurisdictions to identify challenges and develop solutions and standardized approaches to electronic data exchange and public health reporting challenges that impact the transmission of laboratory data to public health agencies and across the public health system.
- Rapidly coordinate and disseminate training on relevant topics using multiple modalities, (e.g., online course, webinars, etc.) on relevant aspects of laboratory testing needed to support the epidemiologists' response.

Food and Drug Administration (FDA) will:

- Provide expertise in regulatory review of in vitro diagnostics (IVDs) and Emergency Use Authorization (EUA) authorities.
- Provide clinical and technical diagnostics expertise to facilitate discussions about planning and implementing surge capacity for diagnostic testing using FDA cleared, approved or EUA IVD assays that are approved/cleared/authorized for use in laboratories within the US healthcare system during emergencies.

The National Independent Laboratory Association (NILA) will:

- Serve as a communications hub, facilitating linkages between its laboratory members and the MOU Parties.
- Identify, help develop, and disseminate guidance among its membership on biosafety and training necessities, utilizing experts within its membership.

- Participate in and help develop training for future public health emergencies, calling upon experts in its membership who have served in a variety of roles within clinical laboratories, public health laboratories, and academic health settings.
- Assist in identifying and engaging private sector laboratories to provide testing capacity for public health emergencies or an emerging pathogen outbreak with pandemic potential.

FUNDRAISING/SOLICITATION

The Parties will make clear, in any solicitation for funds to cover the cost of their activities, that the organization, not HHS, CDC, or FDA is asking for the funds. These organizations will not imply that HHS or any component agency endorses any fundraising activities in connection with these activities. The Parties will make clear to donors that any gift will go solely toward defraying the expenses of the Parties, not HHS, CDC, or FDA expenses.

PUBLICITY AND ENDORSEMENTS

The Parties will not use the name of HHS, or any component agencies, except in factual publicity. Factual publicity includes dates, times, locations, purposes, agendas, and fees involved with Party activities. Such factual publicity shall not imply that the involvement of HHS, CDC, or FDA serves as an endorsement of the general policies, activities, or products of the Parties; where confusion could result, publicity should be accompanied by a disclaimer to the effect that no endorsement is intended. The Parties agree that they shall not use the names of HHS, CDC, FDA, or the United States Government or their employees in any commercial advertising, promotional, or sales literature without the prior written consent of the respective federal agency. In addition, the Parties acknowledge that no Party logo or mark may be used without express written permission from the respective Party; such permission will not be unreasonably withheld, but may require additional written agreements.

INTELLECTUAL PROPERTY

This MOU does not, and is not intended to, transfer to either party any rights in any intellectual property of the other party. All Parties agree that the material provided by CDC and FDA is public domain material. HHS and CDC shall maintain full rights to re-use the content and material that it provides for any and all CDC purposes, and/or to share with other collaborators or requestors. FDA shall maintain full rights to re-use the content and material that FDA provides for any and all FDA purposes and/or to share with other collaborators or requestors.

Per mutual agreement between the Parties and CDC, each Party grants full permission and a royalty-free, non-exclusive, irrevocable license to HHS, CDC, and FDA to use, reproduce, publish, distribute, and exhibit materials arising from this agreement for use in education, training, and other purposes consistent with CDC's mission.

TRADE SECRET OR COMMERCIAL INFORMATION

CDC and FDA shall comply with 18 U.S.C. Section 1905, the Trade Secrets Act, and safeguard any Party proprietary and confidential information obtained pursuant to activities set forth in this MOU. A Party shall

clearly mark all information, in any format, of a proprietary and confidential nature provided to CDC or FDA, as such.

PUBLIC AVAILABILITY

This partnership agreement shall be publicly available.

LEGAL AUTHORITY

This MOU is authorized by Sections 301, 317, and 319D of the Public Health Service Act (42 U.S.C. 241, 247b, and 247d-4, as amended)

FUNDING

Nothing in this MOU intends to create a legally binding obligation between the Parties or the obligation of appropriated funds. Any activities under this MOU that contemplate future funding by the Parties will be carried out under a separate agreement under which the obligation of funds is appropriate. In general, each party is expected to bear the costs of its participation in their project. Nothing in this Agreement shall obligate HHS, CDC, or FDA to any current or future expenditure of resources in advance of the availability of appropriations from Congress.

LIABILITY

Each party will be responsible for its own acts and the results thereof and shall not be responsible for the acts of the other party and the results thereof. Each party therefore agrees that it will assume all risk and liability to itself, its agents, or employees, for any injury to persons or property resulting in any manner from the conduct of its own operations and the operations of its agents or employees under this agreement, and for any loss, cost, damage, or expense resulting at any time from any and all causes due to any act or acts, negligence, or the failure to exercise proper precautions, of or by itself or its agents or its own employees, while conducting activities under and pursuant to this agreement. The government's liability shall be governed by the provisions of the Federal Tort Claims Act, [28 U.S.C. 2671-80 (1976)].

GOVERNING LAW

This MOU shall be governed by applicable federal law.

ENTIRETY

This MOU represents the entire agreement of the Parties with respect to the subject matter hereof and supersedes all prior and/or contemporaneous agreements or understandings, written or oral, with respect to the subject matter of this MOU.

EFFECTIVE DATE

This MOU will become effective on the date of the last signatory to the agreement and will remain effective until an updated version is created.

REVISIONS/AMENDMENTS

It is understood and agreed that the Parties may revise or modify this MOU by written amendment hereto, provided such revisions or modifications are mutually agreed upon.

TERMINATION

This MOU is entered into voluntarily by all Parties and may be modified by mutual consent of authorized officials from the Parties and CDC. This MOU may be terminated by CDC with thirty (30) days advance written notice. A Partner may withdraw from this MOU with thirty (30) days advance notice, but such action will not automatically terminate the MOU with respect to the remaining Parties.

SIGNATURES

_____ [Date]
Christopher White
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