MEMORANDUM OF UNDERSTANDING

BETWEEN

American Clinical Laboratory Association, Association of Public Health Laboratories, Council of State and Territorial Epidemiologists

AND

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

This Memorandum of Understanding (MOU) sets forth the terms and understanding among the American Clinical Laboratory Association (ACLA), the Association of Public Health Laboratories (APHL), the Council of State and Territorial Epidemiologists (CSTE), 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 singularly as "Party" or collectively as "Parties") to collaborate to address laboratory testing surge capacity needs during emergency response.

BACKGROUND – An emerging pathogen that spreads quickly and/or has the potential to cause significant disease in humans could result in high volume laboratory testing demands that exceed the current U.S. public health infrastructure. The Laboratory Response Network (LRN) has expertise with characterizing infectious organisms and handling non-clinical samples, and many of its member public health laboratories have the ability to scale up routine operations to provide limited surge capacity during a response. This capability and capacity was utilized during Amerithrax 2001 and the response to the Middle East Respiratory Syndrome (MERS), Ebola, and Zika virus outbreaks. Commercial laboratories are an option to supplement the capacity of the public health laboratory system since they handle clinical samples every day, meet the requirements of the Clinical Laboratory Improvement Amendments (CLIA) program, and utilize a business model that emphasizes dispersed specimen collection facilities, throughput efficiency, and can increase staffing levels quickly.

ACLA is a not-for-profit association that represents the nation's leading commercial clinical and anatomic pathology laboratories, including national, regional, and specialty hospitals, End-Stage Renal Disease (ESRD), and nursing home laboratories. Created in 1971, ACLA offers members the benefits of representation, education, information, and research. Its primary purpose is to: advocate for laws and regulations that recognizes the essential role that laboratory services play in delivering cost-effective health care; encourage the highest standards of quality, service, and ethical conduct among its members; and promote public awareness about the value of laboratory services in preventing illness, diagnosing disease, and monitoring medical treatment. Commercial clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion to the nation's economy. ACLA will represent the commercial laboratory interests in preparedness discussions, surge capacity planning with APHL and CDC, and during emergency response.

APHL is a not-for-profit membership organization that represents governmental laboratories that perform specialized testing for the detection, characterization, and surveillance of diseases or conditions of public health significance. In collaboration with its members, APHL advances laboratory systems and practices, and promotes policies that support healthy communities. APHL serves as a liaison between laboratories and federal and international agencies, and ensures that the network of laboratories has current and consistent scientific information in order to be prepared for public health emergencies. Membership consists of over 800 local, territorial, county, and state public health laboratories; environmental, agricultural and veterinary laboratories; and corporations and individuals with an interest in public health and laboratory science.

CSTE is an organization of member states and territories that represents public health epidemiologists. CSTE works to establish effective relationships among state and other health agencies. It also provides technical assistance to partner organizations and to federal public health agencies, such as CDC. CSTE members have surveillance and epidemiology expertise in a broad range of areas, including occupational health, infectious diseases, environmental health, chronic diseases, injury, and maternal and child health. CSTE supports effective public health surveillance and sound epidemiologic practice through training, capacity development, and peer consultation. CSTE works to advance public health policy and epidemiologic capacity.

The Centers for Disease Control and Prevention/Center for Surveillance, Epidemiology and Laboratory Services/ Division of Laboratory Systems (DLS) works to strengthen the nation's clinical and public health laboratory system by continually improving quality and safety, informatics and data science, and workforce competency. In particular, DLS collaborates with the Centers for Medicare & Medicaid Services (CMS) on interpretation of CLIA regulations, works to enhance preparedness and provides cross-cutting laboratory training, advances interoperability of laboratory data and utilizes large datasets and best practices to make recommendations that improve patient outcomes. Because of its role in working with clinical laboratories and across CDC programs, DLS is well positioned to facilitate a relationship with commercial laboratories that may participate in emergency response.

PURPOSE—This MOU will serve to increase national laboratory testing and strengthen future responses to public health emergencies by:

1. Creating processes for supplementing public health laboratory surge testing capacity during a response;
2. Establishing mechanisms for coordination and communication among CDC, APHL, CSTE and ACLA during a response;
3. Engaging commercial laboratories early in the response to maximize resources and decrease start-up time;
4. Ensuring that commercial laboratories have access to resources and information to effectively support a large scale response; and
5. Generating a common understanding of the performance requirements, testing algorithms, and result reporting requirements of diagnostics that may be deployed under appropriate emergency regulatory mechanisms (e.g. Emergency Use Instructions [EUI] or Emergency Use Authorization [EUA]).

RESPONSIBILITIES

1. ACLA will:
   - Identify large commercial clinical laboratories with nationwide presence and specific testing capabilities and capacities to participate in a response;
   - Collaborate with CDC to convene meetings or conference calls with commercial laboratories that participate in a response;
   - Participate in exercises to assess the roles of each Party as described in this MOU;

- Communicate with commercial laboratories that participate in a response, any concerns from public health regarding adherence to regulatory requirements (e.g., EUI or EUA) and maintaining compliance with CLIA regulations;

- Facilitate linkages, information, and technology transfer between the CDC and commercial laboratories; and

- Communicate with commercial laboratories the need to continually monitor test performance and provide data to CDC and Food and Drug Administration (FDA) to help identify performance issues.

2. APHL will:

   - Participate in exercises to assess the roles of each Party as described in this MOU;

   - Engage physician and epidemiologist organizations on behalf of public health laboratories to help provide education to clinicians with regards to emergency response testing guidance and the importance of adhering to regulatory requirements (e.g., EUI or EUA);

   - Coordinate with CSTE as much as possible early in a response to standardize state-specific public health laboratory reporting requirements of commercial laboratories; and

   - Develop strategies for electronic test order and result reporting between commercial and public health laboratories during a response in accordance with the Health Insurance Portability and Accountability Act, as amended (HIPAA), if applicable.

   - Participate in appropriate meetings and/or teleconferences to discuss preparedness for large-scale responses.

4. CSTE will:

   - Participate in exercises to assess the roles of each Party as described in this MOU;

   - Educate CSTE members and assist with education and outreach to clinicians with regards to emergency response testing guidance, the importance of adhering to regulatory assay instructions for use, and maintaining compliance to CLIA regulations;

   - Collaborate with APHL and CDC to facilitate the standardization of laboratory reporting requirements across states in accordance with HIPAA, if applicable; and

   - Participate in appropriate meetings and/or teleconferences to discuss preparedness for large-scale responses.

5. CDC/CSELS/DLS will:

   - Serve as the single a point of contact at CDC and liaison to the commercial laboratories.

   - Participate in exercises to assess the roles of each Party as described in this MOU;

   - Collaborate with the CDC Emergency Operations Center Laboratory Team, Office of the Associate Director for Laboratory Science and Safety (OADLSS), CDC agent specific Subject Matter Experts

(SME), FDA and CMS to specify the requirements for implementing diagnostics developed and deployed under appropriate emergency regulatory mechanisms;

- Collaborate with the CDC Emergency Operations Center Laboratory Team and CDC disease-specific SMEs to share testing guidance with laboratories in advance of publication, which will allow laboratories ample time to make operational changes;
- Serve as a liaison between CDC programs, the CDC EOC Laboratory Team, and the public health and commercial laboratories in the development or enhancement and evaluation of response assays.
- Serve as the coordinating contact within the agency to develop agreements for sharing materials (e.g. Biological Material License Agreements and or Material Transfer Agreement for transfers of assays and reagents to commercial laboratories);
- Engage with physician and epidemiologist organizations on behalf of public health laboratories to help provide education to clinicians with regards to emergency response testing guidance and the importance of adhering to regulatory requirements (e.g., EUI or EUA); and
- Work with CDC programs to coordinate electronic test order and result reporting to commercial laboratories and public health laboratories for newly developed and deployed emergency assays.

FUNDRAISING/SOLICITATION – Each of ACLA, APHL, and CSTE will make clear, in any solicitation for funds to cover the cost of its activities described in this MOU, that the organization is asking for the funds, not HHS or CDC. Neither ACLA, APHL, nor CSTE will imply that HHS or any component agency endorses any fundraising activities in connection with these activities. Each of ACLA, APHL, and CSTE will make clear to donors that any gift will go solely toward defraying the expenses of that organization, not HHS or CDC expenses. Each of ACLA, APHL, and CSTE will ensure that all of their constituents involved in activities described in this MOU will comply with the requirements of this paragraph.

PUBLICITY AND ENDORSEMENTS – Neither ACLA, APHL, nor CSTE will 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 or CDC serves as an endorsement of the general policies, activities, or products of ACLA, APHL, or CSTE; where confusion could result, publicity should be accompanied by a disclaimer to the effect that no endorsement is intended. Each of ACLA, APHL, and CSTE will clear all publicity materials for the event with HHS and CDC to ensure compliance with this paragraph. Each of ACLA, APHL, and CSTE will ensure that all of their constituents involved in activities described in this MOU shall comply with the requirements of this paragraph.

INTELLECTUAL PROPERTY – This MOU does not, and is not intended to, transfer to any Party any right in any intellectual property of one or more of the other Parties. All Parties agree that written material provided by CDC is not subject to copyright, and is therefore available for use in the public domain. HHS and CDC will 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. The Parties acknowledge that the transfer or other disposition of other types of intellectual property will be memorialized in a separate agreement.

Each of ACLA, APHL and CSTE, by signing this MOU, grant full permission and a royalty-free, non-exclusive, irrevocable license to HHS and CDC to use, reproduce, publish, distribute, and exhibit materials directly and exclusively resulting from that organization's provision of services pursuant to this MOU for use in education, training, and other purposes consistent with CDC's mission.

CONFIDENTIAL INFORMATION – If Party that shares confidential information with any other Party pursuant to activities described in this MOU will clearly mark all information, in any format, as confidential. Any recipient Party of confidential information will safeguard the information at least as restrictively as it safeguards its own confidential information.

PUBLIC AVAILABILITY – This MOU will be publicly available.

FUNDING – Nothing in this MOU intends to create a legally binding obligation among any one or more of 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 the activities contemplated by this MOU, but no Party will be compelled to incur any cost, expense or charge in connection with those activities. Nothing in this Agreement shall obligate HHS, or CDC 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 any other Party and the results thereof. Each Party agrees that it will assume all risk and liability to itself, its officers, directors, 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 officers, directors, agents or employees with respect to the activities described in this MOU, 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 own officers, directors agents or employees, while conducting activities under and pursuant to this MOU. The Government's liability shall be governed by the provisions of the Federal Tort Claims Act, as amended (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 and activities it describes, 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 first date that each Party has signed this MOU.

REVISIONS/AMENDMENTS – Each Party enters into this MOU voluntarily. The Parties may revise or modify this MOU by written amendment or other document, which will only take effect once signed by an authorized representative or official from each of the Parties.

TERMINATION AND TERM – This MOU may be terminated by one or more Parties with thirty (30) days' advance written notice to each of the other Parties. Unless terminated by a Party or unless the Parties enter into a new written agreement that continues or furthers this MOU's contemplated collaborative efforts while superseding or replacing the MOU itself, this MOU will automatically renew on each anniversary of the Effective Date for a successive one-year additional term.

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By signing below, each individual signing on behalf of a Party certifies that they are authorized to execute this MOU on behalf of that Party and that, once signed, the MOU will be binding and enforceable against that Party in accordance with the MOU's terms and conditions.

American Clinical Laboratory Association

By: _____ Date: 4/25/18

Name: Julie Khani
Title: Resident

Association of Public Health Laboratories

By: _____ Date: 4/10/2018

Name: Eric C. Blank, Dr. P.H.
Title: Senior Director, Public Health Systems and Programs

Council of State and Territorial Epidemiologists

By: _____ Date: 4/25/18

Name: Jeffrey Engel, MD
Title: Executive Director

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

By: _____ Date: 4/30/18

Name: Reynolds M. Salerno, PhD
Title: Division Director