



APHL Position Statement

Technology Transfer from Federal Agencies to Public Health Laboratories

A. Statement of Position

The nation's public health laboratories play an essential role in responding to emerging diseases, public health threats, and emergencies. Standardized methods for screening, testing and confirmation for agents of emergent public health significance require the rapid development and transfer of technology and expertise from federal agencies to public health laboratories that serve as the nation's first line of defense. This process of technology transfer must be sensitive to the needs of public health laboratories to comply with all existing regulations. Therefore, federal agencies must provide public health laboratories with a timely transfer of data and information relative to test performance as well as appropriate materials for quality assessment of assays. Federal agencies are urged to grant temporary exemptions to regulatory requirements for public health laboratories in situations where public health threats and emergencies exist.

B. Implementation

APHL will share this advocacy statement and seek opportunities to communicate these needs with key federal partners, and pursue opportunities to provide expert opinion and advice in order to facilitate the transfer of technology into public health laboratories as described in this document.

C. Background/Data Supporting Position

The urgency of public health threats necessitates that federal agencies work in partnership with state and local public health laboratories to both respond to a crisis and protect the public's health. In these situations, the transfer of federal laboratory resources to the state and local level is essential for the development, evaluation, and refinement of test methodologies ^(1,2).

The process of technology transfer must accommodate the need for public health laboratories to comply with federal regulations (e.g. FDA, CLIA), state requirements, and standards (e.g. CLSI, CAP, ISO, NELAC) that serve to assure the quality of diagnostic and environmental testing ^(3,4,5). Implementation of laboratory tests preceding approval through the appropriate federal regulatory mechanism requires that public health laboratories conduct well-defined verification of test parameters prior to implementation. Although not all federal agencies engaged in research and development are subject to these same regulatory authorities, they must endeavor to provide technologies and assays that can meet the regulatory requirements. Relevant information about test performance (e.g. sensitivity, specificity, interfering substances, special requirements for unusual specimen matrices) obtained during the development and inter-laboratory evaluation process must be made available to public health laboratories in a timely manner, as should any substantive changes that

may be later shown to improve test performance. Appropriate materials for verification, quality control and proficiency testing must also be provided.

Federal agencies are urged to write laboratory procedures in a manner consistent with standards and regulatory requirements (3,4,5,6). Protocols should be designed to use technologies that are readily available in state and local public health laboratories. In addition, these laboratories must have the opportunity to participate in the review and approval of written technical procedures. Feedback from public health laboratories on the assay performance, use of alternative reagents, and suggested modifications to the procedures must be considered by the developing agency, and appropriate changes must be shared with all laboratories using the methods. In turn, public health laboratories must participate in evaluation studies, perform in-house verification on new assays, routinely perform quality control, and participate in proficiency testing programs provided by the federal agencies or other approved sources, when available.

It is expected that unique public health emergencies will require rapid deployment of assays that do not satisfy regulatory requirements. Regulatory agencies must recognize the need for temporary exemptions to these requirements in such emergencies. There have been several recent examples of rapid technology deployment from the Centers for Disease Control and Prevention (CDC) to public health laboratories in response to infectious disease outbreaks and bioterrorism response. The most recent of which demonstrates how a successful partnership between the CDC and state and local public health laboratories can facilitate the transfer of technology into public health laboratories. The following examples demonstrate the different regulatory hurdles that impacted the rapid deployment of new tests.

- In 2009, shortly after the emergence of the 2009 Influenza A H1N1 pandemic virus, a new real-time RT-PCR molecular assay for the rapid detection of Influenza viruses was developed by CDC and released into state and local public health laboratories. Because this new assay was based on the previously FDA cleared RT-PCR molecular assay used for the rapid detection of seasonal influenza, FDA granted emergency use authorization (EUA) for this test. In addition, because many of the state public health laboratories were in the midst of upgrading their instrumentation to meet diagnostic requirements, EUA was granted to run the assay on detection instruments currently classified as research use only. Despite the overwhelming utility of this RT-PCR assay in the characterization and response to the pandemic, there would have been no FDA cleared diagnostic capacity for this novel virus without the EUA mechanism.
- In 2001, in response to the emergence of West Nile Virus in the United States, CDC developed tests for detecting the virus in birds and mosquitoes, as well as identifying infection in humans. However, the US Department of Agriculture (USDA) required that laboratories obtain import permits before CDC could provide materials necessary for public health laboratories to validate the test performance in their own laboratories. This resulted in a delay in the availability of West Nile tests in local jurisdictions.
- A molecular test (PCR) to rapidly screen for *Bacillus anthracis* spores in environmental samples was distributed to public health laboratories through the Laboratory Response Network (LRN) in response to the anthrax events of October 2001⁽⁷⁾. This test was needed for immediate use, but adequate materials to validate the performance of the

test in each laboratory were not available from CDC. Additional confirmatory testing was used to back-up the results obtained using the rapid PCR test. Numerous other tests have been developed for other potential agents of bioterrorism; however, the issue of verification and control materials still needs to be addressed.

- In 2003, CDC developed tests to help detect patients infected with the SARS virus. Institutional Review Board (IRB) approval was required as part of the FDA regulations for tests released under Investigational Device Exemption (IDE) provision. Deployment of these tests to public health laboratories was delayed pending approval by the CDC's IRB.

D. References

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6. ISO. 15189:2003, Medical laboratories-particular requirements for quality and competence. International Organization for Standardization
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8. Institute of Medicine. Biological Threats and Terrorism, Assessing the Science and Response Capabilities, The Progress, Priorities, and Concerns of Public Health Laboratories, Mary J.R. Gilchrist, PhD, Page 161, National Academy Press, 2002.

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