



APHL Position Statement

Regulation of Laboratory Developed Tests: Impact on Public Health Laboratories

A. Statement of Position

Regulatory or legislative approaches to the oversight of laboratory developed tests (LDTs) must preserve the critical and unique work of governmental public health laboratories.

B. Implementation

1. Provide continual feedback and constructive recommendations to preserve governmental public health laboratory practices to the Food and Drug Administration (FDA) on their oversight framework for LDTs
2. Communicate a consistent message of the importance to preserve governmental public health laboratory practices to outside stakeholders developing legislative proposals
3. Engage and educate key federal policy makers
4. Develop summaries, templates and briefing materials on the impact of LDT regulation for the Association of Public Health Laboratories' (APHL) membership to assist in engagement and education of local, state and federal officials

C. Background/Data Supporting Position

In July 2014, FDA notified Congress of their intent to release guidance on the oversight of LDTs. Prior to this announcement, FDA had long exercised enforcement discretion to regulate LDTs. Due to growing concerns about the lack of clinical validity for assays coming to market, FDA's proposed

guidance enforces premarket review requirements to establish these characteristics in LDTs and the establishment of a quality system to assure that the finished device will be safe and effective.

FDA opened a docket to accept public comment and hosted a public meeting January 8-9, 2015 to allow feedback from affected stakeholders. Comments from the public ranged from full support of FDA's efforts to challenging FDA's legal authority to exercise a right to regulate LDTs. Since this time, several groups and associations have proposed alternate frameworks to regulate LDTs, which are being introduced through legislation. One proposal would create a new FDA program to regulate all *in vitro* diagnostic tests while other proposals seek to regulate LDTs through updated language in the Clinical Laboratory Improvement Amendments (CLIA), the existing regulatory framework for clinical and public health laboratories. As FDA modifies its regulations and other entities propose their own frameworks, it is vital that public health laboratories are allowed the flexibility to continue to operate and provide critical testing services to protect the public's health.

Undue burden on the public health system will greatly reduce or eliminate testing that provides important public health benefits. Governmental public health laboratories form the backbone of a national laboratory network that monitors and

detects infectious and foodborne diseases, emerging drug resistance, environmental contaminants, terrorist agents, genetic disorders in newborns and other health threats. They provide critical testing services that are not replicated by diagnostic manufacturers, private, commercial or clinical laboratories. Public health laboratories develop and use LDTs to provide laboratory testing data—detection, characterization and surveillance—that inform broader public health actions.

Impact on Public Health Laboratories

APHL strongly believes that accurate and quality testing is critical; however, stringent regulatory or legislative oversight of LDTs will have unintended negative consequences on public health and the Nation's system of governmental public health laboratories at the federal, state and local level.

Inflexible regulatory oversight of LDTs that does not differentiate public health laboratories from commercial diagnostic manufactures or gives inadequate consideration to rare diseases has the potential to disrupt, delay or even eliminate critical testing conducted by government funded public health laboratories because they lack the administrative and financial resources to comply with proposed premarket review requirements. Critical public health testing services that are threatened include:

- A coordinated response to biological and chemical terrorism through national networks like the Laboratory Response Network
- Newborn screening for rare genetic disorders (SCID, sickle cell anemia, PKU)
- Surveillance for emerging antibiotic resistance
- Surveillance for emerging and re-emerging infectious diseases (measles, mumps, chikungunya)
- Effective response to public health emergencies

In February 2015, APHL submitted a [written comment](#) to FDA addressing their specific guidance.¹ The comment outlines concerns about its approach and provided constructive recommendations to ease the regulatory burden on public health laboratories such as 1) redefining rare diseases based on prevalence; 2) waiving the documentation requirements for established rare diseases as listed on the Office of Rare Diseases Research at the National Institutes of Health; 3) reframing the regulatory framework for governmental public health laboratories; 4) inclusion of public health laboratories in FDA's definition of a healthcare system.

APHL's Recommendations to Preserve Governmental Public Health Laboratory Activities

APHL encourages that any regulatory or legislative oversight of LDTs acknowledge that governmental public health laboratories provide fundamentally different services from private, commercial, and clinical laboratories and diagnostic manufacturers. APHL makes the following recommendations to preserve the integrity of public health laboratory testing under LDT regulation:

- Include language that acknowledges governmental public health laboratories are unique from diagnostic manufactures and clinical, commercial and private laboratories; therefore, public health laboratories need increased flexibility to ensure continued public health testing activities
- Preserve public health surveillance activities by including a definition of surveillance in regulatory frameworks.² Explicitly outline that assays with the intended use of surveillance will not be under the purview of the regulation
- Allow for flexible and rapid response to outbreaks and other public health emergencies through an expedited review process to permit

public health laboratories to use verified LDTs that are not covered under a secretarial declaration of a public health emergency or an emergency use authorization.

- Allow for eased regulatory oversight for off-label use of FDA cleared assays if the test is being used for public health purposes and does not significantly alter the assay's performance characteristics or intended use
- Maintain the explicit flexibility of newborn screening laboratories to provide uninterrupted and timely testing services as new disorders are added to the Recommended Uniform Screening Panel
- Ensure that all stakeholders in the laboratory community are given the opportunity to provide input and feedback on the regulatory and legislative oversight of LDTs, and that LDT regulation is not driven by a small subset of the community

D. References

1. APHL Comments to Docket: FDA-2011-D-0360-0001, Framework for Regulatory Oversight of Laboratory Developed Tests. Retrieved from http://www.aphl.org/policy/advocacy/Documents/APHL_Comments_on_LDT_Regulatory_Framework.pdf
2. Centers for Disease Control and Prevention (2014, May). Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories. Retrieved August 2, 2015 from http://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm?s_cid=su6401a1_w

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