

Inflexible Oversight of Laboratory Developed Tests Would Adversely Impact Public Health

APHL POSITION STATEMENT



Statement of Position

Regulatory or legislative approaches to expand federal oversight of laboratory developed tests (LDTs) must preserve the critical and unique work of governmental public health laboratories and not cause undue harm.

Recommended by: **APHL Environmental Health Committee**

Approved by Board of Directors: **December 2020**

Approved by Membership: **February 2021**

Sunset Date: **February 2026**

Contact: **Peter Kyriacopoulos**, Chief Policy Officer
(240.485.2766 or peter.kyriacopoulos@aphl.org)

Background

State and local governmental public health laboratories (PHLs) provide critical testing services not provided elsewhere by diagnostic manufacturers, or private and commercial clinical laboratories. Enforcement discretion by the US Food and Drug Administration (FDA) regarding LDTs has allowed public health laboratories to detect, characterize and surveil both existing and emerging health threats such as foodborne diseases, drug resistance, environmental contaminants, terrorist biological and chemical agents and genetic disorders in newborns. This flexibility of LDTs in the hands of experienced public health laboratory scientists provides vital data that enables informed public health actions by local, territorial, state and federal government and by the public.

Although FDA has not reported problems from LDTs developed at PHLs, due to growing concerns regarding lack of clinical validity for some clinical assays, draft guidance regarding oversight of LDTs was published in 2014.¹ Comments submitted ranged from full support of FDA's efforts to challenging their legal authority to regulate LDTs. In 2017 FDA announced that there should be "the opportunity to develop a legislative solution" and since then Congress has attempted to formulate broad revisions to diagnostic test regulation, including LDTs.²

The Association of Public Health Laboratories (APHL) expressed significant concerns during the drafting of the VALID Act of 2020,^{3, 4, 5} which would create a new FDA program to regulate all in vitro diagnostic tests, closely mirroring technical assistance the FDA provided Congress. The bill intends for most tests to be approved through a user fee funded technology precertification program to decrease the regulatory burden on diagnostic test manufacturers, however it includes only a very narrow public health exemption. The significant additional regulatory and financial burdens placed on public health laboratories would potentially force them to cut back on life saving programs as they redirect resources to comply with additional requirements. APHL is also concerned that the preemption clause could dismantle existing state programs for oversight of LDTs, the most developed of which is New York State's Clinical Laboratory Evaluation Program (NYS CLEP).⁶

At the other extreme, the Vital Act of 2020,⁷ would have removed LDTs from FDA authority and sought to regulate them through updates to the Clinical Laboratory Improvement Amendments (CLIA), an existing regulatory framework for quality laboratory operations in clinical and public health laboratories. APHL does not support any language that expunges FDA from oversight of LDTs.

APHL strongly believes that accurate and quality testing is critical; however, significant changes in oversight of LDTs that do not consider the unique role of public health laboratories may have unintended negative consequences on public health.

APHL's Recommendations

Congress and HHS should ensure any new oversight of LDTs:

- Provides equal opportunity to all laboratory community stakeholders for input on regulatory and legislative changes.
- Acknowledges that governmental public health laboratories are distinct from diagnostic manufacturers and commercial and private laboratories, and need to maintain flexibility for application of LDTs to ensure continued public health testing activities.

- Preserves public health through a clean exemption for public health surveillance using the HHS' Revised Common Rule definition of surveillance,⁸ without harmful exceptions regarding potential clinical use.
- Allows a risk based approach that understands the role of public health laboratories in the laboratory diagnostic test system.
- Avoids any unfunded administrative or financial mandates on government funded public health laboratories.
- Allows for a flexible and rapid response to emerging infectious diseases while maintaining needed oversight to assure quality by reviewing and reconsidering FDA's Emergency Use Authorization (EUA) process and procedures in the aftermath of the SARS-CoV-2 pandemic.
- Does not disrupt the use of shared protocols among members of laboratory networks, such as the Laboratory Response Network (LRN).
- Aligns with NYS CLEP or any other existing state LDT oversight programs.
- Ensures any regulations are not duplicative by consultation with laboratory accreditation organizations, including CLIA, the College of American Pathologists (CAP) and the International Organization for Standardization (ISO).
- Maintains a role for FDA, and provide the agency and laboratories with necessary resources to update agency and public health laboratory systems to help fulfill any reporting mandates.
- Provides CMS with the necessary resources to evaluate and implement updates to CLIA that will allow for improved oversight of the emerging technologies for LDTs.

References

1. US Food and Drug Administration (FDA) (2018, September 27). Laboratory Developed Tests. Retrieved from <https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests>
2. FDA (2017, January 13). Discussion paper on Laboratory Developed Tests (LDTs). Retrieved from <https://www.fda.gov/media/102367/download>
3. APHL (2020, June 29). Regulatory Response and Advocacy. Retrieved from <https://www.aphl.org/policy/Pages/regulatory.aspx>
4. Verifying Accurate Leading-edge IVCT Development Act of 2020, HR 6102, 116th Cong. (2020).
5. Verifying Accurate Leading-edge IVCT Development Act of 2020, S 3404, 116th Cong. (2020).
6. New York State Department of Health. (2020, June 29). Retrieved from <https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval>
7. Verified Innovative Testing in American Laboratories Act of 2020. S. 3512. 116th Cong. (2020).
8. 45 C.F.R. §46.102 (as revised in 2018).

Association of Public Health Laboratories

APHL works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.