



March 10, 2025

Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave, Bldg 66
Silver Spring, MD 20993
Docket No. FDA-2024-D-2707

Re: APHL comments in response to Docket No. FDA-2024-D-2707

On behalf of the Association of Public Health Laboratories (APHL), please accept the following comments on the draft guidance, "Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency", published to the *Federal Register* on January 7, 2025.

APHL works to strengthen laboratory systems in the US and globally and APHL member laboratories protect the public's health by monitoring, detecting, and responding to biological, chemical, and radiological agents and other diverse health threats. Many APHL member laboratories design, validate, and utilize laboratory developed tests (LDTs) to prevent the spread of disease, conduct surveillance, and respond to public health emergencies.

APHL supports the finalization of the draft guidance "Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency" and similarly detailed guidance documents that support successful adherence to Food and Drug Administration (FDA) policies. APHL is formally submitting the following comments, on behalf of its members, to improve comprehension of LDT regulations and support laboratories performing tests of public health significance.

- The generic validation template, "[General IVD Emergency Use Authorization \(EUA\) Request/Pre-EUA Template](#)" and acknowledgement that alternative approaches may be occasionally needed based on the stage of the outbreak and availability of validation materials, provides both the structure and flexibility necessary to efficiently and effectively respond to an emerging health threat.
- The guidance document shares an appropriate level of detail, outlining validation study recommendations and linking to additional resources.
- Additional validation templates and recommendations for specific outbreaks as has been provided for mpox would be helpful and appreciated.
- APHL encourages the FDA to work with data standardization experts to determine a structured format for the universal device identifier (UDI) and to request manufacturers electronically submit the UDI in the agreed-upon format. This will facilitate incorporation into the Laboratory Interoperability Data Registry, allowing for data exchange across regulatory and healthcare systems.

APHL appreciates the opportunity to provide recommendations to the FDA to help shape guidance documents related to the Medical Devices, Laboratory Developed Tests Final Rule. For more information, please contact Amanda Cosser, APHL Manager of Public Policy and Regulatory Affairs, at amanda.cosser@aphl.org. APHL looks forward to continued conversations with the FDA.

Sincerely,

Handwritten signature of Kara J. Levinson in black ink.

Kara Levinson, PhD, MPH, D(ABMM)
Chair, LDT Task Force
Association of Public Health Laboratories
615.262.6303 kara.levinson@tn.gov

Handwritten signature of Scott J. Becker in black ink.

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories
240.485.2747 scott.becker@aphl.org