



National Association of County & City Health Officials

The National Connection for Local Public Health

December 4, 2023

Robert M. Califf
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave, Bldg. 66
Silver Spring, MD 20993

RE: Medical Devices, Laboratory Developed Tests (LDT) Proposed Rule, Docket No. FDA-2023-N-2177

Dr. Califf,

The National Association of County and City Health Officials (NACCHO) appreciates the opportunity to submit comments on the Food and Drug Administration's (FDA) proposed rule phasing out its general enforcement discretion approach to laboratory developed tests (LDTs). NACCHO represents the over 3,000 local health departments across the United States, which run a substantial proportion of the country's sexually transmitted infection (STI) clinics and either house or are close partners with public health labs (PHL).

NACCHO understands the challenges in the current LDT market that FDA is trying to address. Accurate, quality, and timely testing is critically important, and FDA has a role in LDT oversight to assure the tests produce reliable results for patients and providers. At the same time, the proposed rule and any associated guidance must not result in unintended consequences that limit or eliminate access to testing or place undue burden on the public health system. Any final rule must ensure that the unique needs of public health are accounted for.

LDTs are utilized by PHLs and health departments to develop disease treatment and prevention guidelines, conduct surveillance, and respond to public health emergencies effectively and efficiently. PHLs and health departments use LDTs in many programs (infectious diseases, foodborne diseases, biological and chemical threat agents, biomonitoring, and newborn screening) and for many reasons. They are used:

1. When there is no FDA-approved test;
2. When the FDA-cleared tests do not meet all population, specimen type, or testing volume needs (examples include expanding to other ages/sources/matrices or automating a manual step in the assay to make it high-throughput);
3. When specimen collection is distant and the acceptable temperature range or turnaround time from collection to testing needs to be expanded; and
4. Where antimicrobial susceptibility and efficacy must be determined for drugs that may be FDA-cleared for a different indication.

These unique activities are traditionally not served by commercial test developers. Moreover, NACCHO is concerned that premarket review could impact emergency response given the lessons learned during the COVID19 pandemic. At the beginning of the pandemic, labs were unable to develop their own COVID tests because they needed to get emergency use authorization—in essence, pre-approval-to deploy their tests. This helped contribute to testing barriers and delays that impacted the effectiveness of public health activities in slowing the spread of the disease. While we acknowledge the critical importance of accurate and independent testing, the proposed rule should take into account these emergency or emerging situations where testing barriers can complicate public health activities and response.



NACCHO is also concerned about the impact of the proposed rule on the detection of STIs, which are currently impacting Americans at record numbers. Large numbers of STI clinics and health departments use LDTs for the detection of STIs. Many LDTs are used to broaden acceptable sample collection sites and methods to support STI testing in marginalized communities. This includes testing for gonorrhea and chlamydia in persons younger than 14, which is used to reduce the burden for supporting child sexual assault victims; allowing for multi-site collection for those who have receptive anal or oral intercourse to reduce disease burden in those communities; or use of a test for self-collection, which minimizes stigma.

These tests, which have long been used to address STI spread, are deeply important to address the emergency situation of rising rates of STIs. NACCHO is concerned that the proposed rule could make it more difficult to bring new tests to market or modify existing tests to meet emerging public health needs. To support the nation's efforts to address the rising rates of STIs, labs need continued enforcement discretion for tests of public health significance so access to this testing is not limited or eliminated.

NACCHO is also concerned that the proposed rule would place significant burdens on PHLs with limited staff capacity and limited operating budgets. PHLs do not profit from LDTs and perform them for the sole benefit of protecting public health, making the cost of potential user fees another burden. Similarly, the majority of PHLs have never submitted premarket approval (PMA) or 510(k) documentation, and they are not equipped to redirect staff for filing submissions. Each PHL performs dozens to hundreds of LDTs, and NACCHO recommends developing an alternative reporting approach for these specialized labs.

Local health departments have long relied on these labs and these related public health LDTs to fill unique gaps that impact the public health of their communities. While the proposed rule rightly excludes public health surveillance tests, which use systematically collected samples in connection with disease prevention and control where the results are not reported to the patient or provider, NACCHO is concerned that other LDTs of public health significance that are particularly important to achieving our nation's public health goals may be negatively impacted.

As FDA phases out its general enforcement discretion approach for laboratory developed tests and implements new rules, NACCHO requests that it considers providing legacy approval or continued enforcement discretion to LDTs of public health significance already in use, including those in the STI space or for potential emergencies, and to account for the potential unintended consequences of implementing this rule on PHLs. For any questions about these comments or to request further dialogue, please contact NACCHO's Chief of Government and Public Affairs, Adriane Casalotti, at acasalotti@naccho.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lori Tremmel Freeman'.

Lori Tremmel Freeman, MBA
Chief Executive Officer