



America's Blood Centers[®]
It's About *Life*.

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March 4, 2025

The Honorable Brad Finstad
2418 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Dan Crenshaw
248 Cannon House Office Building
Washington, D.C. 20515

Dear Representatives Finstad and Crenshaw:

America's Blood Centers (ABC) thank you for introducing the *Freedom for Laboratory Innovation and Testing Act*, to prevent federal funding from being used to implement the Food and Drug Administration's (FDA) Laboratory Developed Tests (LDT) final rule that adds regulatory burden without improving patient care.

ABC is the national organization bringing together community-based, independent blood centers. Our member organizations operate more than 600 blood collection sites providing close to 60 percent of the U.S. blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. All ABC U.S. members are licensed and regulated by the FDA.

Blood centers have developed and utilized LDTs that are lifelines in urgent, life-saving situations. The quality and validity of these tests are already ensured by a comprehensive regulatory framework including compliance with extensive FDA regulatory requirements, state specific requirements, and accreditation standards. Yet, despite these safeguards, in May 2024, the FDA issued a final rule subjecting in vitro diagnostic products to additional regulatory burden.

The current regulatory framework already includes a multi-layered approach providing rigorous oversight and regular inspections. The additional FDA regulations are redundant burdens on blood centers without providing any increase in patient safety. Indeed, these regulatory burdens will likely hinder patient care by introducing unnecessary delays and reduced availability of needed tests.

Thank you again for your focus on this matter and working to prevent federal funding from being used to implement this burdensome LDT rule. If you have any questions or we can be of any assistance, please reach out to Diane Calmus, Vice President of Government Affairs at dcalmus@americasblood.org.

Sincerely yours,

Kate Fry, MBA, CAE
Chief Executive Officer