IMPORTANT INFORMATION

For Versiti Laboratory and Clinical Trial Services Clients

Testing Services

UPDATE

Versiti Adherence to FDA Final Rule (89 FR 37286)

March 7, 2025

This notice serves to provide detail for Versiti's planned adherence to the final rule **"Medical Devices; Laboratory Developed Tests" (89 FR 37286)** issued by the FDA aimed at helping to ensure the safety and effectiveness of IVDs offered as laboratory developed tests (LDTs). Versiti is committed to adhering to Stage 1 requirements as outlined in this rule **by May 6, 2025**.

Our approach will ensure compliance by implementing policies and procedures for:

1. **Medical Device Reporting** of significant adverse events associated with LDTs to the FDA.
2. **Correction and Removal Reporting** for any corrections or removals of LDTs conducted to reduce health risks or address non-compliance issues.
3. **Development and Maintenance of Complaint Files** to establish and maintain procedures for receiving, reviewing and evaluating complaints related to LDTs.

To ensure we stay ahead of regulatory changes, we have established a review committee dedicated to evaluating laboratory modifications and assessing future impacts of the FDA's final rule. This committee regularly reviews our laboratory processes and improvements ensuring alignment with the evolving FDA expectations.

Versiti believes in transparency, safety and regulatory compliance. We will continue to implement proactive strategies to ensure seamless compliance with FDA's final rule and continued service excellence. Should you have any questions about this communication, please contact our Client Services group at 800.245.3117 ext.6250 or labinfo@versiti.org.

Respectfully,

Megan McShea
Regulatory Manager, Versiti