

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2310410	(X3) Date Survey Completed 06/12/2025
Name of Provider or Supplier Versiti Indiana, Inc	Street Address, City, State 349 South Main Street, Suites 201 And 205, Dayton, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A federal surveyor from the CMS CLIA Survey Branch conducted an announced CLIA validation survey at Versiti Indiana-Dayton from June 11, 2025, to June 12, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and found to comply with condition-level CLIA requirements. The following standard-level deficiencies were found during the CLIA validation survey completed on June 12, 2025.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records and an interview with the general supervisor (GS), the laboratory failed to ensure that all testing personnel signed the attestation form for one of one events of the Association for the Advancement of Blood & Biotherapies (AABB) Reference laboratory proficiency sample in 2025. Findings Included: 1. On June 11, 2025, at 12:00 p.m., review of the the AABB PT records for 2025, revealed that event one of the AABB Reference laboratory PT events signed by the laboratory director on April 16, 2025, was not signed by testing personnel. 2. In an interview on June 11, 2025, at 12:10 a.m., the GS confirmed the attestation was not signed by testing personnel who performed the PT.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the</p>

current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on a review of laboratory procedures, an interview with the general supervisor (GS) and the regulatory team, the laboratory failed to ensure that ten of ten (a sampling) procedures in use were approved, signed, and dated by the current laboratory director for the new laboratory certificate in November of 2024. Findings Included: 1. On June 12, 2025, at 9:00 a.m., the surveyor requested to see the laboratory director's current signature for procedures in use, as the laboratory was acquired on November 5, 2024, and issued a new certificate number. 2. The following sampling of ten procedures were not signed by the current LD under the new certificates: a. VER-REF-203-WI-01. b. VER-REF-301-WI-01. c. VER-REF-302-WI-01. d. VER-REF-304-WI-01. e. VER-REF-305-WI-01. f. VER-REF-309-WI-01. g. VER-REF-311-WI-01. h. VER-REF-314-WI-01. i. VER-REF-701-WI-01. j. VER-HEM-200-POL. 3. The laboratory provided a Quality Improvement plan called, The Dayton QMS Transition Plan, which addressed the laboratory procedure title changes, but the laboratory director had not sign the document to approve the changes. 4. In an interview on June 12, 2025, at 9:20 a.m., with the GS and regulatory team confirmed that the laboratory director had not signed all the current laboratory procedures.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, a lack of temperature records, and interview with the general supervisor (GS), the laboratory failed to monitor the room temperature for the molecular anti-room where one of one Qiagen QIAamp DNA Blood molecular kit was stored. 1. Observation while on a tour of the laboratory's molecular testing area on June 12, 2025, at 10:00 a.m., revealed one Qiagen QIAamp DNA Blood molecular kit was stored in the anti-room. 2. The Qiagen QIAamp DNA Blood Mini Kit (Lot #: 181014885, Ref #: 51106) manufacturer ' s storage requirement specified room temperature, between 15C and 25C. 3. In an interview on June 12, 2025, at 10:15 a.m., the GS confirmed that temperatures were not monitored in the molecular anti-room. Key: C = degrees celsius.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent

information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the general supervisor (GS), the laboratory failed to document the expiration date for one of one bottle of Sigma Aldrich DL- Dithiothreitol used for immunohematology testing. Findings Included: 1. Observation while on a tour of the laboratory on June 12, 2025, at 10:20 a. m., revealed one bottle of Sigma Aldrich DL- Dithiothreitol, Lot number 000Q349294, received 10-01-2024, did not include an expiration date. 2. In an interview on June 12, 2025, at 10:30 a.m., the GS confirmed that an expiration date was not provided by the Manufacturer, nor did the laboratory establish one.