

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0869498	(X3) Date Survey Completed 01/04/2024
Name of Provider or Supplier Vasweb, Pa	Street Address, City, State 288 Crystal Grove Blvd, Lutz, FL	
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	An on-site announced CLIA recertification survey was conducted at VasWeb, PA on 01/04/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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 American Association of Bioanalysts (AAB) proficiency testing and interview with the Office Manager, the laboratory failed to have attestation statements signed by the Analyst and the Laboratory Director for five out of five events for Clinical Microscopy Proficiency Testing (1st, 2nd and 3rd Events for 2022, and 2nd and 3rd Events for 2023). Findings included: Record review of AAB Clinical Microscopy proficiency testing events revealed the 2022 1st and 2nd Events and 2023 2nd and 3rd Events attestation statements had not been signed by the Analyst, and the 1st, 2nd and 3rd Events for 2022, and 2nd and 3rd Events for 2023 attestations statements had not been signed by the Laboratory Director. On 01/03/2024 at 11:00 AM, the Office Manager confirmed the unsigned attestation statements by the Analyst and Laboratory Director.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
Based on review of American Association of Bioanalysts (AAB) proficiency testing results and interview with the Office Manager, the laboratory failed to document evaluation of Clinical Microscopy proficiency test (PT) results for two (2023 2nd and 3rd Events) out of 5 (2022 1st, 2nd, and 3rd Events, and 2023 2nd and 3rd Events) testing events reviewed. Findings included: Record review of AAB Clinical Microscopy proficiency testing results revealed that proficiency testing evaluation had not been documented for the 2023 2nd and 3rd testing events reviewed. On 01/04/2024 at 11:05 AM, the Office Manager confirmed the two proficiency testing events had not been documented by the Laboratory Director.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and interview with the Laboratory Director, the Technical Consultant (who is also the Laboratory Director) failed to evaluate and document competency semi-annually on one out of one (#B) newly hired Testing Person. Findings Included: Record review of the Laboratory Personnel Report (CMS 209) that was signed by the Laboratory Director and dated 01/04/24 revealed that the Laboratory Director was also the Technical Consultant. Review of employee files revealed that the Technical Consultant had not evaluated and documented competency semi-annually for Testing Person #B with a hire date of 08/15/2022. On 01/04/2024 at 10:30 AM, the Laboratory Director confirmed competency testing had not been completed semi-annually for Testing Person #B.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Personnel Report (Form CMS-209), personnel records, and interview with the Laboratory Director, the Technical Consultant failed to document an annual competency assessment for one Testing Person out of one (#A) for 2 out of 2 years (2022-2023) reviewed. Findings Included: Record review of the Laboratory Personnel Report (CMS 209) that was signed by the Laboratory Director and dated 01/04/24 revealed that the Laboratory Director was also the Technical Consultant. Review of employee files revealed that the Technical Consultant had not evaluated and documented competency annually for Testing Person #A for 2022 and 2023. On 01/04/2024 at 10:30 AM, the Laboratory Director confirmed competency assessment had not been completed for Testing Person #A.