Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0869498	12/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Vasweb, Pa	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 announced CLIA recertification survey was conducted at VasWeb PA on 12/4/25 to 12/8/25. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200 493.1230 Condition: General Laboratory Systems D6000 493.1403 Condition: Moderate Complexity Laboratory Director
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to evaluate the overall quality of the general laboratory systems for four of four proficiency events from 6/05 /2024 to 12/04/2025. (See D5221 which is a repeat deficient citation)
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review and interview, appropriate laboratory staff failed to evaluate proficiency testing results for four of four proficiency events from 06/05/2024 to 12/04

	/2025. This is a repeat citation. Findings included: 1. The accepted Plan of Correction for the recertification survey dated 01/04/2024 signed by the Laboratory Director on 02/03/2024 indicated for D5221, the Laboratory Director would be responsible ensuring evaluations were evaluated with documentation with completion date of 06 /05/2024. 2. The American Association of Bioanalysts (AAB) proficiency evaluation results for third event 2024 (dated 9/09/2024), first event of 2025 (dated 2/03/2025), second event of 2025 (dated 5/12/2025), and third event of 2025 (9/09/2025) failed to include documentation of evaluation by the Laboratory Director. 3. On 12/08/2025 at 3:06 p.m. the Laboratory Director verified via email he had not documented evaluation of proficiency results as stated in the accepted Plan of Correction for the recertification survey dated 01/04/2024.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record reviews and interviews, the Laboratory Director failed to establish a policy to be onsite once every six months, failed to document any onsite visits from 1 /1/2025 to 12/04/2025. (See D6005), and failed to specify, in writing, the responsibilities and duties for three of three laboratory required positions (Laboratory Director,Clinical Consultant and Technical Consultant).(See D6032)
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to establish a policy to be onsite once every six months and failed to document any onsite visits from 01/01/2025 to 12/04/2025. Findings included: 1. The Laboratory policy and Procedure policy signed by the Laboratory Director on 10/30/2025, failed to contain a policy to be onsite once every six months and to document any onsite visits. 2. On 12 /08/2025 at 3:06 p.m. the Laboratory Director verified via email there failed to be an established policy to be onsite once every six months and failed to document any onsite visits from 01/01/2025 to 12/04/2025.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic

	phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review of the laboratory procedure manual and staff interview, the Laboratory Director failed to specify, in writing, the responsibilities and duties for three of three laboratory required positions (Laboratory Director,Clinical Consultant and Technical Consultant). Findings included: 1. Review of the laboratory's procedure manual, signed by the Laboratory Director on 10/30/2025, showed there was no written job descriptions for the Laboratory Director, Clinical Consultant and the Technical Consultant. 2. On 12/08/2025 at 3:06 p.m. the Laboratory Director verified via email there were no job descriptions for Laboratory Director, Clinical Consultant and the Technical Consultant.