

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0716773	(X3) Date Survey Completed 05/06/2025
Name of Provider or Supplier All Womens Health Center Inc	Street Address, City, State 4131 Central Ave, Saint Petersburg, 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 All Women's Health Center Inc on 5/06/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director for a minimum of two years for five of six proficiency events from 2023 to 2025. Findings included; 1. Proficiency records failed to include testing records, signed attestation records, and submissions to proficiency program for 2023 second event and third event, and 2024 first event, second event, and third event. 3. Testing Person A confirmed at 10:53 a.m. on 5/6/25, the laboratory had not maintained proficiency records of testing records, signed attestation records, and submissions to proficiency program for 2023 second event and third event, and 2024 first event, second event, and third event.</p>

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on record review and interview, the Laboratory Director failed to ensure five of six proficiency testing events (2nd, and 3rd for 2023 and 1st, 2nd, and 3rd for 2024) were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action for one of six proficiency evaluation results (1st event of 2024). Findings include: 1. The laboratory manual was approved by the Lab Director 01/07/25. The manual included a Lab Director responsibility policy which stated the Lab Director would review and sign the returned proficiency testing results and must ensure that a corrective action plan was followed when proficiency results were unacceptable or unsatisfactory. 2. Review of the 2nd and 3rd events for 2023 and the 1st, 2nd, and 3rd events for 2024 proficiency evaluation reports failed to have any documentation of review by the Lab Director or any other staff. 3. The 1st event of 2024 evaluation results documented the laboratory received a score of 60% which is an unacceptable result. There was no documentation of corrective action for the unacceptable result. 4. Testing Person A confirmed at 10:53 a.m. on 5/6/25 the lack of documentation of review of proficiency evaluation results of the 2nd and 3rd events for 2023 and the 1st, 2nd, and 3rd events for 2024 and corrective action for the unacceptable score for the 1st event of 2024 evaluation results.