

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2133980	(X3) Date Survey Completed 06/30/2025
Name of Provider or Supplier Planned Parenthood Of Southwest & Central Fl	Street Address, City, State 236 East Bearss Ave, Tampa, 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 Planned Parenthood of Southwest & Central FL, Inc on 6/26-6/30/25. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6063 493.1421 Condition: Laboratory Testing Personnel
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of Chemistry (serum-quant) HCG pregnancy evaluation for 2nd event of 2024, they were assigned a proficiency testing scores that did not reflect laboratory test performance. Findings included: 1. The American Proficiency Institute (API) proficiency performance evaluation for Chemistry (serum-quant) HCG pregnancy for 2nd event of 2024 documented for HCG-06, HCG-07, and HCG-10 performance as, "Not Graded" and "See Data Summary". The Performance Review and Corrective Action Documentation form for 2nd event of 2024 signed as reviewed by the Lab Director 6 /27/24, did not document any verification of accuracy or review of the Data Summary. 2. The Laboratory Policy and Procedure Manual revised 12/2024, implemented and approved by the Lab Director 02/06/25, included policy for proficiency testing however, there was no procedure for if the proficiency testing scores that did not reflect laboratory test performance. 3. Testing Personnel D (the Clinic Manager),</p>

confirmed on 06/30/25 at 11:10 a.m., there was no documentation of verification of the Chemistry (serum-quant) HCG pregnancy for 2nd event of 2024 that was assigned a proficiency testing scores that did not reflect laboratory test performance.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on record review and interview, it was determined the Laboratory failed to verify the educational qualifications for 1 Moderate Complexity Testing Personnel (TP -E) of 5 Moderate Complexity Testing Personnel (TP-A, TP-B, TP -C, TP-D, and TP-E). (See D6065)

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory failed to verify the educational qualifications for 1 Moderate Complexity Testing Personnel (TP -E) of 5 Moderate Complexity Testing Personnel (TP-A, TP-B, TP -C, TP-D, and TP-E). Findings included: 1. Review of the Laboratory Personnel Report, signed by the Lab Director on 06/20/25, revealed five Moderate Testing Personnel (TP-A, TP-B, TP -C, TP-D, and TP-E). 2. Review of TP -E's personnel record showed there was no education available for review or evaluation of the equivalence to a United States Diploma. 3. TP-D confirmed on 06/26/25 at 12:30 pm, the requested proof of education and evaluation of the equivalence to a United States Diploma for TP -E was not available for review. The Associate Director of CQRM verified via email on 6/30/25 at 10:14 a. m. that TP-E did not have evaluation of the equivalence to a United States Diploma.