

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0899197	<b>(X3) Date Survey Completed</b>  05/15/2025
<b>Name of Provider or Supplier</b>  Planned Parenthood Of Southwest And Central	<b>Street Address, City, State</b>  11500 University Blvd Ste B, Orlando, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Planned Parenthood of Southwest and Central Florida Inc on May 15, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6033 - 493.1409 Condition: Technical Consultant
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to create a competency assessment policy and perform initial competency assessments for 1 out of 1 Technical Consultant (A) in 2025. Findings Included: 1. On 5/15/2025 at 1:15 PM, the Center Manager stated Technical Consultant A was hired on 4/1/2025. Review of 2025 Competency assessments revealed Technical Consultant A had no documentation of initial competency assessments done in 2025. 2. Review of competency assessment policy revealed there was no policy for competency assessment. 3. On 5/15/2025 at 1:08 PM, the Center Manager stated initial competency assessments in 2025 were not documented for Technical Consultant A.</p>
<b>D6033</b>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPLEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p>

This CONDITION is not met as evidenced by:  
Based on record review and interview, the Laboratory failed to have qualified Technical Consultants for 1 out of 1 Technical Consultant (A) sampled for testing for Human Chorionic Gonadotropin (HCG). (D6035)

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**  
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:  
Based on record review and interview, the Laboratory failed to have qualified Technical Consultants for 1 out of 1 Technical Consultant (A) sampled for testing of Human Chorionic Gonadotropin (HCG). Findings included: 1. Review of Laboratory

Personnel Report CMS 209 signed by the Laboratory Director revealed Technical Consultant A was listed as Technical Consultant. 2. Review of Technical Consultant A's resume form revealed no documentation for a year of laboratory experience listed. 3. Review of Laboratory Director's delegation form revealed the Laboratory Director signed a delegation without a date to delegate Laboratory Director's duties to the Technical Consultant. 4. Review of laboratory training /competency verification assessments revealed Testing Personnel A had an annual competency assessment done on 04/08/2025 and was signed by the Technical Consultant on 4/8/2025 for HCG testing. 5. On 04/07/2025 at 6:43 PM, the Office Manager confirmed Technical Consultant A was not qualified for moderate complexity testing due to lack of experience.