Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0888169	06/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Southwest & Central	1425 Creech Rd, Naples, 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 from 06/25/2025 to 06/30/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have one out of four testing personnel (TP) rotate through the testing of Proficiency Testing (PT) for Chemistry specialty in 2 out of 2 years reviewed. Findings included: 1-Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 06/13/2025 revealed the laboratory had five TP listed (TP#1, TP#2, TP#3, TP#4 and TP#5), of these four TP participated in the Chemistry specialty testing (TP#1, TP#2, TP#3 and TP#4) for the i-stat Total Beta-Human Chorionic Gonadotropin (B-hCG) test. 2-Review of personnel records for TP#4, revealed that she had competencies evaluation on 2023, 2024 and 2025. 3-Review of American Proficiency Institute (API) PT records for 2023 (third event), 2024 (first, second and third event) and 2025 (1st and second event) in the specialty of Chemistry, revealed that TP#4 had no PT participation. During an interview on 06/25/2025 at 12:30 PM, with TP#4 she confirmed that she failed to participate in PT during this period.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	(b)(1) 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to sign attestation for Proficiency Testing (PT) for Chemistry for the 1st event of 2024. Findings included: 1-Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 06/13/2025, revealed that she was the LD, Clinical Consultant (CC) and Technical Consultant (TC). 2-Review of the Procedure Manual signed by the LD in February 2025, revealed that there was no designee to sign the PT attestations. 3-Review of American Proficiency Institute (API) Proficiency Testing (PT) records for first event of 2024, revealed that the LD failed to sign attestation for the Chemistry specialty for the i-stat Total Beta-Human Chorionic Gonadotropin (B-hCG). During an interview on 06/25/2025 at 12:00 PM, Testing Personnel #4 confirmed that the LD failed to sign attestation for the events of reference, she explained that the Chief Medical Officer signed at that time, no delegation of duties letter found for the Doctor of reference.