Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0888169	07/19/2023
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 and Central Florida Inc on 07/19/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification records and interview, the laboratory failed

	to perform calibration verification every 6 months on the Abbott iStat analyzer from 06/23/2021 to 07/19/2023. Findings Included: Review of calibration verification records for the Abbott iStat revealed the calibration verification for beta - human chorionic gonaodtropin hormone (bHCG) had been performed 01/ 05/2022 and 06/17 /22 since the last survey conducted on 06/23/2021 to the date of the current survey (07 /19/2023). Record review of the laboratory's Individualized Quality Control Plan signed and dated by the laboratory director on 3/30/23, revealed "I-Stat does not alert when calibration verification is due since it is factory calibrated, updated software is released every 6 months, all analyzers must be updoated or they will cease to function,. Following an update, it is recommended performing liquid calibration verfication, three levels". On 07/19/23 at 03:20 PM, the Senior Health Center Manager stated Testing Personnel #A confirmed that the every 6 months calibration verification procedure had not been performed on the analyzer in 2023.