Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0899197	10/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Southwest And Central	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was conducted on October 31, 2022. Planned Parenthood of Southwest and Central Florida clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide documentation of calibration for Total Beta-Human Chorionic Gonadotropin (B-hCG) testing on the Abbott i-Stat analyzer at least every six months from 11/21/2021 to 10/31/2022. Findings: Review of the i-Stat System Manual noted "In the United States, laboratory regulations (CLIA) requires that tests categorized as Non-Waived, a calibration verification procedure be performed and documented at least every six months." Review of the laboratory's procedure for i-Stat Testing under "Twice Yearly Quality Control Procedures" listed "Perform calibration verification using all three levels of calibration verification solution." Review of the calibration records revealed the last calibration documentation available for review on the i-Stat was dated 11/20/2021. On 10/31/2022 at 12:55 PM, Testing Personnel B stated he was unable to locate the

	calibration records for 2022. Word Key CLIA - Clinical Laboratory Improvement Amendments
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to include address of the laboratory on the laboratory test results reports given to six of six patients (#1, #2, #3, #4, #5, #6), and failed to include the units of measurement on the laboratory test results reports for three of three patients (#1, #2, #3) tested for Total Beta-Human Chorionic Gonadotropin (B-hCG) on the Abbott i-Stat analyzer. Findings: Review of patients' laboratory test results showed the address of the laboratory where the testing was performed was not listed on six of six patient reports reviewed, (#1, #2, #3, #4, #5, #6). Review of the instrument test printout showed the units of measurement for B-hCG performed on the i-Stat listed the units of measurement as "IU/L" (International Unit/Liter). Review of the laboratory test results reports showed the unit of measurement was not listed on three of three patients' reports (#1, #2, #3) tested for B-hCG. According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 10/28 /2022, the laboratory had an annual test volume of 2,984 tests, of that 298 tests were listed under the subspecialty of Endocrinology (B-hCG testing). On 10/31/2022 at 1: 20 PM, Testing Personnel B stated the address and units of measurement were not on the reports.