Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0970415	(X3) Date Survey Completed 03/06/2024
Name of Provider or Supplier Planned Parenthood Of Southwest &	**Street Address, City, State** 33 6th Street South Ste 110, Saint Petersburg, 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 onsite announced CLIA recertification survey was conducted at Planned Parenthood of Southwest & Central Florida Inc from 02/29/2024 to 03/06/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature and humidity records, review of the i-STAT1 System Manual, and interview with the Associate Director, the laboratory failed to document temperature and humidity percentage where the i-STAT1 Beta (B) Human Chorionic Gonadopin (HCG) testing was performed for 64 of 64 patients from 11/1/23 to 12/27/23. Findings included: Record review of the laboratory logs, revealed the room temperature and humidity percentage was not documented for the room where the i-STAT1 B HCG testing was performed from 11/01/2023 to 12/27/2023 for 64 patients. Record review of the i-STAT 1 System Manual, revision date 18-Oct-2021 revealed that the operating temperature should be 16-30C (61-86F) and the humidity percentage should be 10-90%. On 02/29/24 at 1:05 PM, the Associate Director confirmed the room temperature and humidity were not documented.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review of the Individualized Quality Control Plan (IQCP) and interview with the Associate Director, the laboratory failed to include the Risk Assessment when developing an IQCP for the Beta (B) Human Chorionic Gonadotropin (HCG) test performed on the i-STAT1 since testing began. A total of 64 patients were tested from 11/1/23 12/27/23. Findings Included: Review of IQCP, signed by the Laboratory Director on 11/8/22 and 2/2/23, for the i-STAT1 B HCG testing revealed that the risk assessment portion was not completed. On 02/29/2024 at 1:10 PM, the Associate Director confirmed that IQCP was missing the risk assessment section.