

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2076188	(X3) Date Survey Completed 04/03/2024
Name of Provider or Supplier Planned Parenthood Of Southwest And Central Fl	Street Address, City, State 610 Oak Commons Blvd, Kissimmee, 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	Recertification survey was conducted on March 25, 2024 to April 3, 2024. Planned Parenthood of Southwest and Central Florida clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the i-Stat 1 System Manual, the procedure manual, the quality control (QC) logs and interview, the laboratory failed to provide documentation of calibration for Total Beta-Human Chorionic Gonadotropin (B-hCG) testing on the Abbott i-Stat 1 System analyzer at least every six months between 12/09/2021 and 05 /12/2023. Findings: Review of the i-Stat 1 System Manual noted "Coefficients used to maintain the accuracy of cartridge results over time are programmed into the analyzer via CLEW software updates every six months. Review of the laboratory's procedure for i-Stat Testing under "Twice Yearly Quality Control Procedures" listed "The software of the analyzer must be upgraded every 6 months per manufacturer recommendations." It also noted "Perform calibration verification using all three levels of calibration verification solution." Review of the laboratory's i-Stat QC Log:</p>

Calibration Verification noted, "This is the log we will use for calibration verification after every software update." Review of the calibrations logs showed the calibrations were performed on 12/09/2021 and on 05/12/2023 On 03/25/2024 at 12:12 PM, the Associate Director stated they were unable to locate the i-Stat calibrations for 2022.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of personnel records, and staff interview, the laboratory failed to document annual competency assessment on one (B) of eight (A - H) testing personnel in 2022. Findings: Review of competency records showed the laboratory failed to provide documentation of annual competency assessments for Testing Personnel B for 2022. On 03/25/2024 at 12:06 PM, the Associate Director stated they were unable to locate the competency assessments for Testing Personnel B for 2022.