

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0725975	(X3) Date Survey Completed 09/03/2024
Name of Provider or Supplier Women & Teens Healthcare Inc	Street Address, City, State 16876 Ne 19 Ave, North Miami Beach, 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 August 27, 2024 through September 3, 2024. Women & Teens Healthcare Inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to record Quality Control (QC) when the frequency for testing was reduced since July of 2022 until July of 2024 for the ABO Group & Rh Group Antibody Detection. Findings included: 1- The laboratory did not record daily quality control (QC) in 2023. The laboratory did not provide External QC files referenced in the QC log for 10/30/2022 and 02/05/2024 in the QC files provided. 2- Review of the Quality Control procedure section 3 states that "Data is collected for monitoring quality control including control material evaluation, tolerance limits, linearity and calibration. Data is reviewed and maintained in the department as well as Levy-Jennings and statistical analysis. A minimum of two levels of quality control samples will be run prior to and each day of patient testing. The laboratory will follow the Westgard multiple rule procedure for Quality Control acceptability as defined in the Quality Control." 3- The Blood Grouping Reagent instructions for use (PN e631200466 EN) Anti-D Anti-Rh BioClone is a qualitative</p>

test for recognition of the D(Rho) antigen on human red blood cells, states "Quality Control testing is required to confirm the reactivity of the product prior to use. Positive control-red blood cells known to possess the D antigen, preferably of phenotype R1. Negative control-red blood cells known to lack the D antigen." 4- Interview on 8/27/2024 at 1:50 PM with laboratory office manager stated that volume of testing had significantly decreased. Surveyor requested QC records. On 8/29/2024 the office manager sent incomplete QC logs and surveyor asked for follow-up documentation to be provided by 09/03/2024. 5-On 09/03/2024 the office manager emailed at 10:03 AM "We run a QC control and submit only failures to the laboratory for correction." The laboratory did not provide additional documentation.