

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0966025	(X3) Date Survey Completed 05/19/2023
Name of Provider or Supplier All Womens Health Center Of Orlando Inc	Street Address, City, State 431 Maitland Ave, Altamonte Springs, 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 May 19, 2023. All Womens Health Center of Orlando INC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to monitor the storage of two D (Rho) typing reagents: Anti-D and Ortho Bovine Albumin within manufacturer's guidelines for 12 (January -December) out of 12 months in 2022 and 4 (January -April) out of 4 months in 2023. Finding included: 1. During the tour of lab on 5/19/2023 at 9:51 AM, a small fridge was noted under the pregnancy testing station. The fridge contained 2 temperature gauges. One temperature gauge was on the top shelf and had no reading levels to identify if it was Fahrenheit or Celsius (C). The other temperature gauge was in the freezer part of the fridge, frozen in ice. It could not be moved and the temperature values were not visible. The fridge also stored the following reagents: Anti-D(lot number DB341A1), Ortho Bovine Albumin (lot number BA007A) and sterile water used for Rhesus(RH) factor testing. 2. Review of Blood Grouping Reagent Anti-D (Anti-Rh) (Murine Monoclonal-Polyclonal Blend Bioclone) for Rapid Tube, Slide and Microplate Tests manufacturer's instructions read, "Store at 2 to 8 Celsius." 3. Review of "RH Testing Log"revealed the following:</p>

a The fridge temperature was 2 C - 8 C. b. 12 (January -December) out of 12 months in 2022, the fridge temperature was documented above 8 degrees C. c. 4 (January - April) out of 4 months in 2023, the fridge temperature was noted above 8 degrees C. 4. During an interview on 5/19/2023 at 12:11 PM, the Administrator acknowledged the fridge temperatures were out of range for D (Rho) typing reagents storage requirements.