

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1066947	(X3) Date Survey Completed 08/31/2020
Name of Provider or Supplier Center Of Orlando For Women Llc	Street Address, City, State 1103 Lucerne Terrace, 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 August 31, 2020. Center of Orlando for Women clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5551	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)</p> <p>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the D (Rho) typing for two days when patients were tested in 2019. Findings: Review of the "Lab Log" showed that there were no results recorded for the positive and negative controls for the D (Rho) typing on 7/17/19 and 9/18/19. On 7/17/19, there were 14 patients tested, and on 9/18/19 there were 11 patients tested. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/01/20, the laboratory had an estimated annual test volume of 2000 D (Rho) typing per year. During an interview on 8/31/20 at 10:55 AM, the Administrator stated that it appeared that the lab log had been re-copied, and that the positive and negative control results were missing.</p>