Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0668298	04/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Family Planning Associates Medical Group Ltd	659 W Washington St, Chicago, IL	

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
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (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. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with Testing Personnel (TP) #4, the laboratory failed to identify and document quality control materials in use and ensure they met the manufacturer's specimen acceptability requirements for Rhesus Factor D (Rh-D) quality control testing for 58 of 103 days reviewed affecting 1,809 patients. The findings include: 1. Review of quality control logs showed the laboratory failed to document Control Lot Numbers and Control Expiration Dates for: a. April 19, 2021 - April 30, 2021, 11 of 26 days in April b. May 1, 2021 - May 14, 2021, 12 of 25 days in May c. June 14, 2021 - June 30, 2021, 15 of 26 days in June d. July 1, 2021 - July 24, 2021, 20 of 26 days in July 2. TP #4 confirmed during an interview on 4/13/2022 at 11:15 a. m. that employee blood samples collected in EDTA (lavender top) tubes were utilized during this timeframe when quality control lot numbers and expiration dates were not documented. 3. TP#4 confirmed during an interview on 4-13-22 at 11:15 a.m. that the known employee Rh negative and positive controls were utilized for 28 days before redrawing new control samples. 4. Manufacturer's instructions for the anti-D reagent states, "clotted samples or those

	collected in EDTA should be tested within fourteen days from collection". 5. Review of patient testing records found 1,109 patients were tested for Rh-D from April 19, 2021 to May 14, 2021 and 700 patients were tested for Rh-D from June 14, 2021 to July 24, 2021 when the laboratory failed to document the QC materials in use and the stability of the known Rh positive and Rh negative controls could not be confirmed for the testing dates reviewed.