

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0668308	(X3) Date Survey Completed 07/28/2021
Name of Provider or Supplier Family Planning Associates	Street Address, City, State 24241 Hawthorne Blvd, Ste 201, Torrance, CA	
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
D2153	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a)</p> <p>Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on observation of Eldon (TM) test cards and Ortho-Clinical Diagnostics (TM) Surgiscreen (TM) reagents for performing Rh Blood Typing, review of Event 3- 2018 proficiency testing reports from CMS (Report 155, Individual Laboratory Profile) and API (American Proficiency Institute) and patients test records, and interview with laboratory personnel, it was determined the laboratory failed to attain 100% for each analyte, constituting unsatisfactory testing for Rh Typing. Findings included: 1. CMS and API reported the unsatisfactory overall score of 80% based on the laboratory's incorrect/Unacceptable result (*) for 1 out of 5 samples for Rh Typing, as follows: Sample Lab Reported API ----- RH-15 Negative * Positive 2. The manually performed Rh Typing test required data entry of all results into electronic records. 3. Laboratory personnel affirmed (7/28/21 at 1PM) the aforementioned findings of the unacceptable result reported and that all patients' test results were (are) reported by manual entry into electronic medical records. 4. The unacceptable result demonstrated unsatisfactory Rh Typing. The reliability and quality of 305 patients results reported during the timeframe December 2018 to April 7, 2019 could not be assured. Some specific examples were as follows: Date ID Rh Typing reported ----- 12/17/18 1107936 Positive 12/18/18 TC Negative 12/19/18 1179536 Positive 12/20/18 1110705 Positive 1/10/19 376945 Negative 1/10/19 376979 Positive 1/31/19 379565 Negative .</p>