

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0668295	(X3) Date Survey Completed 08/16/2019
Name of Provider or Supplier Family Planning Associates	Street Address, City, State 2030 Coffee Rd, Ste A-1, Modesto, 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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the Laboratory Personnel Report (8/06/19) and 2018 laboratory test records, the lack of laboratory records, and interview with laboratory personnel, the laboratory failed to maintain an information system that included the identity of the person who performed the tests, including Rh Typing. Findings included: a. The Laboratory Personnel Report (8/06/19) included 11 testing persons. b. The laboratory had an electronic information system and failed to identify the testing person(s) for 9 out of 9 laboratory test records randomly selected from 10/22/18 to 12/26/18. c. Laboratory personnel affirmed (8/16/19 at 12:30 pm) the aforementioned test records' failure to identify the persons performing the tests. d. The reliability and quality of test results reported could not be assured when it was not known who performed the tests. Based on the stated annual test volumes, for each month of October, November, and December there were 583 waived tests, 33 provider-performed microscopy procedures, and 125 Rh Typings.</p>