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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D0668311 | (X3) Date Survey Completed 09/30/2021 |
| Name of Provider or Supplier Family Planning Associates | Street Address, City, State 601 S Westmoreland Ave, Los Angeles, 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 |
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| D6029 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on observation of Eldon test cards for Rh Typing, review of the laboratory document delegating responsibilities, the lack of laboratory documents, and interview with the Lab Manager, it was determined that the Laboratory Director was deficient in the practice of ensuring that all personnel received training and demonstrated the performance of Rh Typing for initial evaluation for competency. Findings included: 1. The laboratory performed Rh Typing using the EldonCard (TM) test system of applying whole blood onto a test card and the use of Ortho Clinical Diagnostics (TM) Surgiscreen Red Cell for quality control materials. 2. A laboratory document titled, "Delegation Form", effective 1/20/20, delegated responsibilities to Testing Person-2 (CMS209 Report) for review and approval of external proficiency tests, performance evaluation of all laboratory staff, and Daily QC review and approval. 3. Laboratory personnel affirmed (9/30/21 at 3pm) the aforementioned responsibilities included Rh Typing. 4. The laboratory failed to provide for review any record of Testing Person-2 training on the EldonCard test system and Surgiscreen quality controls; or any document of demonstrating performance of Rh Typing with QC and reporting of results. 5. Testing Person-2 affirmed (9/30/21 at 3pm) the responsibilities to assess the validity of QC performance daily, the performances on proficiency testing, and the</p> |

competency assessments of persons performing the test; without the provision of training and hands-on demonstrating Rh Typing using the EldonCard and Surgicreen QC.