

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0876462	(X3) Date Survey Completed 04/20/2022
Name of Provider or Supplier Family Planning Associates	Street Address, City, State 2322 Butano Dr Ste 205, Sacramento, 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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual and interview with the testing person (TP); it was determined that the laboratory failed to update protocols in place when changes in the practice occurred in the laboratory and the effective date and signature of approval by the laboratory director of such changes. The findings included: 1. On the day of the survey April 20, 2022, at approximately 10:45 a.m. the procedure manual in place had not been approved, signed, and dated by the laboratory director. 2. The TP affirmed on April 20, 2022, that the laboratory failed to update protocols for the current testing performed in the laboratory and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 1,100 patients test annually.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:
Based on observation on the lack of calibrated thermometers in the refrigerator and interview with the testing person (TP); it was determined that the laboratory failed to monitor the temperature of equipment essential for proper storage of reagents and specimens that adversely affect patient test results. The findings included: 1. On the day of the survey, April 20, 2022, based on observation and interview with the TP the laboratory failed to have calibrated thermometers on the refrigerator both conventional thermometers and digital thermometers (Expired January 22) that verify accurate temperature readings which affect reagents, proficiency and patients' samples testing. 2. The TP confirmed on 4/20/2022, at approximately 10:45 a.m. that the laboratory failed to calibrate the thermometers. 3. Based on the laboratory's submitted testing declaration volume, the laboratory tested and reported approximately 1,100 samples annually.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, three (3) randomly chosen patients, and interview with the testing person; it was determined that the laboratory director failed to be responsible for the overall operation and administration of the laboratory including assuring compliance with applicable regulations by delegating responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. See D5407 and D5413.