

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0668370	(X3) Date Survey Completed 06/07/2019
Name of Provider or Supplier Family Planning Associates	Street Address, City, State 8635 Firestone Blvd, Downey, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of patient testing records, laboratory testing reagents, and interview with the laboratory Director, the laboratory used expired KOH reagent to test 2 patients sample. The findings include: a. The laboratory used expired KOH reagents (lot# 1815611, expire date: 06/05/2019, provider: Healthlink) to test patients MRN# 391826 and 277269 on 06/07/2019. The laboratory reported the test result for the patient MRN# 391826 as negative and patient MRN# 277269 as positive. However, due to use of an expired reagent to test the sample, the validity of the patient's results can not be assured. b. On 06/07/2019 at 12:39 pm the laboratory Director affirmed that the laboratory testing personnel used an expired KOH reagent to do patient testing. c. The laboratory testing declaration form, signed by the laboratory Director indicates that the laboratory performs 250 KOH tests annually.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p>

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, patients test records, laboratory testing reagent and interview with the laboratory Director, it was determined that the laboratory Director failed to ensure that the testing personnel are performing the test methods as required for accurate and reliable results. The findings include: See D5417 and D6070.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, patients test records, laboratory testing reagent and interview with the laboratory Director, it was determined that the laboratory testing personnel did not follow the laboratory's policy and procedure for the patient testing. The findings include: a. The testing person #1, tested patients MRN# 391826 and 277269 samples on 06/07/2019 with a KOH reagent that expired on 06/05/2019 despite the laboratory's policy prohibits use of any expired reagents in patient testing. b. On 06/07/2019 at 12:39 pm the laboratory Director affirmed that the laboratory testing personnel used an expired KOH reagent to do patient testing. c. The laboratory testing declaration form, signed by the laboratory Director indicates that the laboratory performs 250 KOH tests annually.