

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2079944	(X3) Date Survey Completed 08/20/2018
Name of Provider or Supplier Epyc Diagnostics Llc	Street Address, City, State 21117 Osborne St, Canoga Park, 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 Surveyor review of laboratory's policy & procedure, quality control & patient testing records, and interview with the laboratory testing personnel, the laboratory failed to maintain an information or record system that includes the identity of the personnel who performed the test(s). The findings include: a. The laboratory's urinalysis test records shows the test was performed on March 21, 2018 for the patients, # 14016131 and 14016134. The testing person's identity was not documented. b. On August 20, 2018 at 2:55 pm laboratory testing personnel affirmed that the laboratory did not maintain any record to identify the testing person. c. The laboratory testing declaration form, signed by the laboratory Director on August 11, 2018, indicates that the laboratory performs about 785 urinalysis tests annually.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical</p>

consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions 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 Surveyor review of laboratory's policy & procedure, quality control & patient testing records, and interview with the laboratory testing personnel, the laboratory Director failed to assure compliance with the applicable regulations. The findings include: See D5787 and D6042.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory policy & procedure, patients sample and quality control test records, and interview with the laboratory testing personnel, the laboratory Technical Consultant failed to establish an appropriate quality control program for the creatinine test. The findings include: a. In the laboratory's LIS, the acceptable range for creatinine control level 1 was 1.96 - 3.01 for lot# 06537B. The testing personnel did not know where that range was from. The manufacturer's range was 1.96 - 2.94. The laboratory's quality control policy states it uses assayed control from manufacturer. The manufacturer's assayed control has its mean and assigned acceptable range. The lab might establish its own mean and acceptable range, instead. The laboratory did not have any records that shows the used range was established at the laboratory. b. On August 20, 2018 at 12:50 pm, laboratory testing personnel affirmed that the used quality control range for creatinine was not correct. c. The laboratory testing declaration form, signed by the laboratory Director on August 11, 2018, indicates that the laboratory performs about 26,658 tests in routine chemistry, annually.