Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2079944	02/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Epyc Diagnostics Llc	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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for multiple Chemistry analytes for the years 2019 and 2020. The finding included: 1. Based on review of PT records for 2019 and 2020, AAB reported the following unsatisfactory scores for the following analytes: Q3-2019 Iron = 40%, Q3-2019 Vitamin B12 = 50%, Q1-2020 Total Protein = 40%, Q2-2020 Glycohemoglobin = 0% and Q2-2020 Triiodothyronine = 60% 2. Based on the laboratory testing declaration submitted at the time of the survey on 02/11/2021 the laboratory analyzed and reported approximately 64,450 Routine and Special Chemistry tests for each year during the time the laboratory had unsatisfactory proficiency testing results. 3. The TP affirmed 02/11/2021 at approximately 2:00 p.m. that the laboratory received the above unsatisfactory proficiency testing scores
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) proficiency

	testing (PT) records and interview with the testing personnel (TP); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent in Coagulation for the first event of 2019 (Q1-2019) and Urinalysis in the third event of 2019 (Q3-2019) which is unsatisfactory performance. The findings included: 1. On the date of the survey 2/11/2021 at approximately 11:00 a.m. based on review of the PT scores, the laboratory obtained for Coagulation Activated Partial Thromboplastin (APTT) Q1-2019 and overall score of 40% and Urine Sediment Q3-2019 and a score of 50% as follow: Q1-2019 APTT Overall score 40%: Sample Reported Expected Score 1 39.9 32.2 - 43.5 A 2 43.1 26 - 35.1 U 3 48.3 35.6 - 48.1 U 4 51.8 38.5 - 52.1 A 5 33.2 23.8 - 32.2 U A = Acceptable U = Unacceptable Q3-2019 Urine Sediment overall score 50%: Sample 11 reported Blood /Hemoglobin cast; expected result mixed cellular cast and sample 12 reported Triple phosphate crystal which was the expected reported result. 2. The TP affirmed on 02/11/2021 at approximately 12:15 pm the laboratory obtained the PT scores in 1. 3. According to the laboratory testing declaration submitted on the day of the survey (02/11/2021) for the years 2019-2020, the laboratory performed approximately 11,333 Hematology samples (quarterly) during the time the laboratory received an unsatisfactory PT performance score.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of reagent manufacturer's product insert, ten (10) random review of patients reports from 08/02/2019 to 01/30/2021, and interview with the laboratory testing personnel; it was determined that for the year 2020, the laboratory failed to follow manufacturer's instructions for the periodic calculation for International Normalized Ratio (INR). The findings included: 1. The laboratory performed Prothrombin and Activated Thromboplastin Time on the Coagulation Instrumentation Laboratory equipment. The manufacturer's products insert states to "periodically verify for each thromboplastin lot number in use, the correct normal patient Prothrombin time mean and the International Sensitivity Index (ISI) value being used for calculating the INR value" 2. On the day of the survey 02/11/2021 at approximately 1:00 pm testing personnel confirmed that laboratory failed to periodically verify the accuracy of the INR calculation as mandated in the manufacturers package insert instructions. 3. Based on the laboratory's annual testing declaration submitted on 02/11/2021, the laboratory analyzed and reported approximately 34,400 hematology test results .
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient

	results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, random patient sampling, and interview with the general supervisor (GS) and testing personnel (TP); it was determined that the laboratory failed perform quality control on the Kirby-Bauer (KB) antimicrobial susceptibility testing method each day the test was performed. The findings included: 1. On the day of the survey, February 11, 2021, the laboratory lacked the documentation for KB antimicrobial susceptibility use of control organisms for each day the KB antimicrobial susceptibility test was performed. 2. The laboratory had not developed an Individualized Quality Control Program for KB susceptibility testing a procedure which may be used in the laboratory for the antimicrobial susceptibility testing method determination of QC frequency. 2. For two (2) out of ten (10) random patient sampling test results reviewed, covering period 8/16/2019 to 1/30/2021, the laboratory analyzed and reported patient test results for KB antimicrobial susceptibility during the time when the laboratory did not use control organisms for each day the KB antimicrobial susceptibility tests method was performed. 3. The GS and TP affirmed on 02/11/2021 at approximately 1:25 p.m. that the laboratory was not performing quality control organisms for each day the KB antimicrobial susceptibility test was performed.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of random patient testing records, quality control data, and interviews with the general supervisor and testing personnel; it was determined that the laboratory director failed to ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality control as they occur. See D5411 and D5507.