

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2079944	(X3) Date Survey Completed 09/12/2024
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the survey on September 12, 2024, at approximately 11:05 a.m., a review of the laboratory's policy and procedure, College of American Pathologists (CAP) proficiency testing (PT) records, and an interview with the technical supervisor (TS), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for Carbon Dioxide (CO2) analyte in 2024. The findings include: 1. Based on review of PT records for the second event of 2024 (Q2-2024), CAP reported an unsatisfactory score report as follows: C02 PT Q2-2024 Overall score: 60% Specimen Reported Expected CHM-06 23 23 - 34 CHM-07 *10 25 - 38 CHM-08 17 16 - 27 CHM-09 *13 14 - 24 CHM-10 27 27 - 43 2. The TS affirmed by interview on September 12, 2024, at approximately 11:05 a.m. that the laboratory obtained the PT scores mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 960 Routine Chemistry test samples, including CO2 analyte, during the time the laboratory had unsatisfactory proficiency testing results.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
 Based on the lack of documentation of the testing personnel competency assessment, review of patient records, and interview with the technical supervisor (TS) on September 12, 2024, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the testing personnel competency for the year 2024. Findings include: 1. Based on the lack of the laboratory's policies and procedures and competency evaluations' records, the laboratory failed to have established and follow written policies and procedures for competency assessment of the testing personnel (TP) for Microbiology, Diagnostic Immunology, Chemistry, and Hematology specialties. 2. Based on the review of patient records, the laboratory failed to provide documentation of training and an initial and six-month competency assessment for the TP performing tests for moderate and high complexity. These involved sample processing, testing, and reporting results at the laboratory for the year 2024. 3. This deficient practice was affirmed by an interview with the TS on September 12, 2024, at approximately 11:57 a.m. 4. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory reported and performed approximately 1,600 test samples for Microbiology, Diagnostic Immunology, Chemistry, and Hematology specialties for which competencies of the testing personnel were not performed.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of the laboratory's policies and procedures, proficiency testing records and interview with the technical supervisor on September 12, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the postanalytic phases of the laboratory testing were monitored. 1. Less than 80 percent score in proficiency testing. See D2087

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
 Based on the interview with the technical supervisor, lack of documentation of testing personnel competency, and review of the laboratory's competency policies and procedures on September 12, 2024, the laboratory director is herein cited for failure to ensure that policies and procedures were established for monitoring individuals who

conduct analytical and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens and perform test procedures promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D5209