

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0666419	(X3) Date Survey Completed 02/28/2024
Name of Provider or Supplier American Bio-Clinical Laboratories	Street Address, City, State 2730 N Main St, Los Angeles, 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 review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, interview with the technical supervisor (TS), and review of four (4) randomly chosen patients records; it was determined that the laboratory failed to attain at least 80% of the acceptable score in routine chemistry for DHEA, ferritin, TSH, and urine sediments tests. The findings included: 1. Based on review of PT records for the second event of 2023 (Q2-2023), AAB-MLE reported an unsatisfactory score report as follow: a. DHEA and ferritin 0%. b. urine sediment 50% 2. Upon further review of PT records, the surveyors also reviewed the TSH results from the third event of 2023 (Q3-2023) that resulted to a score 40%. 3. During the survey on 2/28/2024, the submitted laboratory testing declaration stated that the laboratory analyzed and reported approximately 4,962,309 routine chemistry tests including DHEA, ferritin, TSH and urine sediment during the time the laboratory had unsatisfactory proficiency testing results. 4. The TS affirmed on 2/28/2024 at approximately 12:00 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(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>

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's proficiency testing (PT) records from American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), and interview with the technical supervisor (TS); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for hematology on the second event of 2023 (Q2-2023). The findings included: 1. The AAB-MLE proficiency program gave an overall unsatisfactory score of 60% for coagulation for Q2-2023. 2. The TS confirmed on February 29, 2024, at approximately 12:00 p.m. that the laboratory received the above proficiency score of 60% for coagulation as described in statement #1. 3. Based on the laboratory's annual testing declaration submitted on the day of the survey February 29, 2024; the laboratory analyzed and reported approximately 1,403,217 hematology samples that include coagulation tests during the time the laboratory had unsatisfactory proficiency testing results.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on the surveyors' observation during the laboratory tour and interviews with the technical supervisors (TS) and testing personnel (TP) the laboratory failed to label reagents and solutions preparation and expiration dates in various sections of the laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory's tour on February 28, 2024, at approximately 4:00 p.m.; no opening, preparation, or expiration date labels were used or documented for the reagents and solutions (ex: immersion oil, bleach and distilled water). 2. The TS and TP affirmed in an interview conducted 2/29/2024, at approximately 4:00 p.m. that the reagents and solutions mentioned in statement 1 were not labeled with the opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 18,183,433 test samples.

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 records and interviews with the laboratory's technical supervisors (TS) and laboratory director (LD) on February 28,

2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic and analytic phases of the laboratory testing were monitored. See D5415.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on interviews with the technical supervisors (TS), review of proficiency test reports documents for chemistry and hematology on February 28, 2024; the laboratory director failed to ensure that laboratory personnel are properly trained and competent when performing the test methods as required for accurate and reliable results. See D2087 and D2121.