

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0664149	(X3) Date Survey Completed 05/02/2024
Name of Provider or Supplier Roxbury Laboratory Associates Llc	Street Address, City, State 435 N Roxbury Dr, Ste 300, Beverly Hills, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on Surveyors' review of laboratory's proficiency testing (PT) results from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), and interviews with the technical consultant (TC) and testing personnel (TP) on May 2, 2024, at approximately 11:00 a. m., the laboratory failed to attain at least 80% score in the proficiency testing program for the chemistry. The findings include: 1. The laboratory participated in the AAB-MLE PT testing program for the specialty of chemistry in the period of 2022 to 2024. However, it received an unsatisfactory score of 20% for third event of 2022 (Q3-2022), 60% score for first event of 2023 (Q1-2023), and 40% score for first event of 2024 (Q1-2024) for Chloride analyte resulting</p>

in an unsuccessful participation. Therefore, the accuracy of the patients' test results rendered by the laboratory during that time cannot be assured. 2. The TC and TP affirmed on May 2, 2024, at approximately 11:00 a.m. that the laboratory failed to achieve satisfactory performance for Chloride analyte for Q3-2022, Q1-2023, and Q1-2024. 3. Based on the laboratory's testing declaration form signed by the laboratory director on May 1, 2024, the laboratory performs approximately 68,000 tests in chemistry including Chloride annually.

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 the review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, interviews with the technical consultant (TC) and testing personnel (TP), it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent resulting to an unsatisfactory performance for the Nonchemistry first event in 2023 (Q1-2023) for the Platelet analyte. The findings included: 1. Based on the survey conducted on May 2, 2024, at approximately 11:00 a.m. and review of the proficiency testing results, it was determined that no corrective action was performed for Platelet for Q1-2023 when the laboratory obtained an overall score of 60%. The results were as follow: PT Q1-2023 Overall score 60% Specimen Reported Expected 1 259 206.0 - 343.0 2 *55 56.0 - 93.0 3 234 204.0 - 340.0 4 508 408.0 - 680.0 5 *52 55.0 - 92.0 2. The TC and TP affirmed on May 2, 2024 at approximately 11:00 a.m. that the laboratory obtained the PT scores in statement #1 but missed to conduct troubleshooting and develop a corrective action. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 50,000 samples annually for hematology that included Platelet in CBC panel. Thus, the reliability and quality of hematology patient results reported could not be assured at the time when the laboratory failed to attain an overall score of 80 percent.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on the surveyors' review of proficiency testing (PT) results from the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) from 2022 to 2024, review of documentation for quality control (QC) as well as ten (10) randomly selected patient records, and interviews with the technical consultant (TC) and testing personnel (TP); the laboratory director is herein cited for the repeated failure of Chloride analyte resulting to unsuccessful PT performance for consecutive testing events. See D2016.

D6010

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(2)

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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

Based on the surveyors' direct observation during the laboratory tour on May 2, 2024, at approximately 11:45 a.m., the laboratory director is herein cited for failing to ensure that since 2020, the fire extinguisher has not been checked since.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on the surveyors' review of the laboratory's proficiency testing records from the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) for 2022, 2023, and 2024, interviews with the technical consultant and laboratory assistant on May 2, 2024 at approximately 11:00 a. m., the laboratory director is herein cited for failing to ensure that the laboratory followed an approved corrective action plan when any proficiency testing result received a score less than 80 percent. See D2122.