

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0664149	<b>(X3) Date Survey Completed</b> 11/10/2021
<b>Name of Provider or Supplier</b> Roxbury Laboratory Associates Llc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2021</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program and an interview with the laboratory personnel (LP) , it was determined that the laboratory failed to enroll in proficiency testing for Bacteriology for Cycle 2, 2021. The laboratory inspection occurred on 11 /10/21 between 11 a.m. and 1 p.m. Findings include: 1. The Casper 096 report for the 2019-2021 was reviewed, and there was a 0 score for Bacteriology for cycle 2, 2021. 2. The LP indicated the proficiency agency, College of American Pathology (CAP), was not notified of the planned discontinuation of Bacteriology testing. 3. At approximately 12:00 p.m. on 11/10/21, the LP affirmed that there was no proficiency report for Bacteriology for the timeframe indicated above.</p>
<b>D2087</b>	<p><b>ROUTINE CHEMISTRY</b> 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>

This STANDARD is not met as evidenced by:  
 Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from the CMS 96 Report, laboratory proficiency reporting from CAP, and an interview with the LP on 11/10/2021 between 11:00 a.m. and 1:00 p.m., it was determined that there were two unacceptable (below 80 %) proficiency testing (PT) results for Chemistry in the 2010 and 2020 submission date ranges. Findings include: 1. On 11/10/2021, an inspection was conducted between 11:00 a.m. and 1:00 p.m. 2. During a review of the laboratory documentation from CAP , it was noted at approximately 11:30 a.m. that there were two unacceptable PT results for general chemistry. The laboratory utilizes the Horiba ABX instrument for general chemistry testing. The LP recognized these atypical results. 3. The findings and acceptable ranges were as follows: Cycle 3 2019 Chemistry Analyte: Iron (2/5 unacceptable) Sample Actual Result Expected Result (range) 11 72 39-58 12 78 51-76 Cycle 2 2020 Chemistry Analyte: Testosterone (1/2 unacceptable) Sample Actual Result Expected Result (range) 7 1 668-1241 4. The LP affirmed the unacceptable results listed above.

**D2123**

**HEMATOLOGY**  
 CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:  
 Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program and an interview with the laboratory personnel (LP) , it was determined that the laboratory failed to enroll in proficiency testing for Hematology for Cycle 3, 2020. The laboratory inspection occurred on 11/10/21 between 11 a.m. and 1 p.m. Findings include: 1.The Casper 096 report for the 2019-2021 was reviewed, and there was a 0 score for Bacteriology for cycle 2, 2021. 2.The LP indicated the proficiency agency, College of American Pathology (CAP) did not receive the proficiency data. 3. At approximately 12:15 0 p.m. on 11/10/21, the LP affirmed that there was no proficiency report for Hematology for the timeframe indicated above.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved

proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program and an interview with the laboratory personnel (LP) , it was determined that the laboratory failed to enroll in proficiency testing for Hematology for Cycle 3, 2020 and Bacteriology for Cycle 2, 2021. The laboratory inspection occurred on 11/10/21 between 11 a.m. and 1 p.m. Findings include: 1. The laboratory director did not ensure that the laboratory was enrolled in an HHS approved proficiency program for each testing cycle. 2. See D 2021 and D 2123 for details.