

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0664149	<b>(X3) Date Survey Completed</b> 11/20/2019
<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>D2121</b>	<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> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records, random patient sampling and interview with testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Hematocrit (HCT) analyte. The findings included: a. American Association of Bioanalysts (AAB) proficiency program gave an unsatisfactory score 20 % for HCT, first quarter 2019. b. Based on the laboratory's annual testing declaration submitted for 2018-2019, the laboratory analyzed and reported 52,000 Complete Blood Count (CBC) which included the HCT analyte. c. The testing personnel confirmed (11/20 /2019, 14:30) that the laboratory received the above proficiency score of 20% for HCT.</p>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of second quarter (Q2-2019) of the American Association of</p>

Bioanalysts (AAB) proficiency testing reports, laboratory proficiency testing records and interview with the testing personnel, the laboratory failed to have a mechanism to review proficiency testing results that have an artificial score of 100% even though the laboratory's reported results were outside the grading range. The findings included: a. The laboratory received an artificial score of 100% for Folate for the (Q2-2019). The AAB proficiency test footnote reports revealed that for results with prefix codes indicated the following statement: # = "This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your results." The following proficiency sample was analyzed and reported by the laboratory: Folate Specimen: Value. Mean: Grading Score: Reported Range: Spec: 2 # 4.6 2.72 1.8-3.6 100% Note: True score should have 50%. b. The testing personnel confirmed (11/20/2019, 14:30) that the laboratory received the above artificial 100% passing score even though the reported results were outside the grading range for Folate analyte. c. Based on the laboratory's annual testing declaration submitted for 2018-2019, the laboratory analyzed and reported 1,500 for Folate analyte.

**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 review of PT program, interview with the testing personnel, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. See D 2121 and D 5215.