

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0951370	<b>(X3) Date Survey Completed</b> 12/10/2018
<b>Name of Provider or Supplier</b> Pathology Associates Laboratory	<b>Street Address, City, State</b> 520 N Brookhurst St, Ste 119, Anaheim, 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>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> <p>This STANDARD is not met as evidenced by: Based on review of the third quarter (Q3-2017) American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event. The findings included: a. Q3-2017, AAB proficiency testing, the laboratory received a 0% scores for the following analytes. Analyte: Score: Event/Year: ALT 0 Q3-2017 Albumin 0 Q3-2017 Alk Phos 0 Q3-2017 AST 0 Q3-2017 Bili, Total 0 Q3-2017 Calcium 0 Q3-2017 HDL, Chol 0 Q3-2017 Chol, Total 0 Q3-2017 CPK, Total 0 Q3-2017 Glucose 0 Q3-2017 Iron 0 Q3-2017 Potassium 0 Q3-2017 Protein, total 0 Q3-2017 Sodium 0 Q3-2017 Trig 0 Q3-2017 BUN 0 Q3-2017 Uric Acid 0 Q3-2017 Abbreviations: Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Alkaline Phosphatase (Alk Phos) Bilirubin (Bili) High Density Lipoprotein (HDL) Cholesterol (Chol) Creatine Kinase (CK or CPK) Triglycerides (Trig) Urea Nitrogen (BUN) b. For five (5) out of seven (7) random patient test results reviewed covering period from 1/5 /2017 to 3/20/2018, five (5) patients have the above analytes analyzed and reported that cannot be assured. c. The testing personnel confirmed (12/10/2018, 1400) that the laboratory received the above unsatisfactory proficiency testing scores of zero.</p>
<b>D2098</b>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(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 review of the third quarter (Q3-2017) American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event. The findings included: a. Q3-2017, AAB proficiency testing, the laboratory received a 0% scores for the following analytes. Analyte: Score: Event/Year: FT4 0 Q3-2017 Pregnancy Serum 0 Q3-2017 TSH 0 Q3-2017 Abbreviations: Thyroxine, Free (FT4) Human Chorionic Gonadotropin (HCG, Pregnancy, Serum) Thyroid Stimulating Hormone (TSH) b. For four (4) out of four (4) random patient test results reviewed on 1/5/2017, four (4) patients have the above analytes analyzed and reported that cannot be assured. c. The testing personnel confirmed (12/10/2018, 1400) that the laboratory received the above unsatisfactory proficiency testing scores of zero. `

**D2121**

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

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.

This STANDARD is not met as evidenced by:  
 Based on review of the second quarter (Q2-2018) American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel, it was determined that the laboratory failed attain a score of at least 80 percent of acceptable responses for each analyte in each testing event. The findings included. a. Q2-2018, AAB reported the following unsatisfactory scores. Analyte: Score: Event/Year: Neutrophil% 40% Q2-2018 Monocyte% 60% Q2-2018 Basophil% 60% Q2-2018 b. For five (5) out of seven (7) random patient test results reviewed covering period from 1/5/2017 to 3/20/2018, five (5) patients have Complete Blood Count (CBC) test analyzed and reported in which the results cannot be assured. c. The testing personnel confirmed (12/10/2018, 1400) that the laboratory received the above unsatisfactory proficiency testing scores.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
 CFR(s): 493.1236(b)(2)

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).

This STANDARD is not met as evidenced by:  
 Based on review of the first quarter (Q1-2018) American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel, it was determined that the laboratory failed to verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance. The findings included: a. Q1-2018, AAB proficiency testing, the laboratory received a 100% score for Potassium analyte. Spec.: Reported Value:

Grading Range: Mean: #2 1.8 1.9-2.9 2.41 #4 3.5 3.6-4.6 4.05 Note: True score for Potassium should have been 50%. b. For five (5) out of seven (7) random patient test results reviewed covering period from 1/5/2017 to 3/20/2018, five (5) patients have Potassium test analyzed and reported that cannot be assured. c. The testing personnel confirmed (12/10/2018, 1400) that the laboratory received the above artificial 100% score for Potassium and that the laboratory did not have a corrective action for the failure in the proficiency testing.

**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 the American Association of Bioanalysts (AAB) proficiency testing records and 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 2087, D 5215, D 2098, and D 2121.