

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2016898	(X3) Date Survey Completed 07/19/2019
Name of Provider or Supplier Pathlab Services Inc	Street Address, City, State 7707 Garden Grove Blvd, Garden Grove, 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
D5215	<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 the American Association of Bioanalysts (AAB) proficiency testing records and interview with the Technical supervisor 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 reported an artificial 100% proficiency score for the following analytes. DHEA-S Spec.: Reported Grading Mean: Value: Range: 1? 63.4 69.1 81.34 Note: True score for DHEA-S should have been 50%. Lipoprotein Spec.: Reported Grading Mean: Value: Range: 1? 12.0 6-11 8.8 2? 21.0 10-19 14.9 3? 16.0 8.15 11.2 Note: True score for Lipoprotein should have been 40%. b. Q2-2018 AAB reported an artificial 100% proficiency score for the following analytes. DHEA-S Spec.: Reported Grading Mean: Value: Range: 1# 219.9 238.6-322.8 280.66 2? 138.8 154.9-209.5 182.21 Note: True score for DHEA-S should have been 0%. Insulin Spec.: Reported Grading Mean: Value: Range: 1? 22.3 39.1-65.1 52.08 2? 26.2 46.9-78.2 62.55 Note: True score for Insulin should have been 0%. Troponin I Spec.: Reported Grading Mean: Value: Range: 2? 1.85 2.18-3.98 3.75 Note: True score for Troponin I should have been 50%. c. Q1-2019 AAB reported an artificial 100% proficiency score for the following analytes. Insulin Spec.: Reported Grading Mean: Value: Range: 1# 36 79.2-132 105.6 2# 3.2 5.7-9.5 7.56 Note: True score for Insulin should have been 0%. d. Q2-2019 AAB reported an artificial 100% proficiency score for the following analytes. Insulin Spec.: Reported Grading Mean:</p>

Value: Range: 1# 22.8 40-66.6 53.3 2# 17 24.6-41 32.79 Note: True score for Insulin should have been 0%. e. The AAB has the following footnotes: ?= This score may not truly evaluate performance for these specimens which were not graded because of a lack of participants' consensus. #= this method was not grade due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed ranges should provide a reasonable guide to your performance, however exercise caution in evaluating your results. f. The laboratory's annual testing declaration submitted for 2018-2019 indicated that the laboratory analyzed and reported approximately 32,000 Routine Chemistry tests which included the above analytes. g. The technical supervisor confirmed (7/19/2019, 1630) that the laboratory received the above artificial 100% proficiency testing reports which the scores indicated failed or an unsatisfactory results.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

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 Technical supervisor it was determined that; the laboratory failed to at least twice annually, verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. The findings included: a. Q3-2018, AAB reported an unsatisfactory score 0% for Folate analyte. b. The laboratory's annual testing declaration submitted for 2018-2019 indicated that the laboratory analyzed and reported approximately 32,000 Routine Chemistry tests which included Folate analyte. c. The technical supervisor confirmed (7/19/2019, 1630) that the laboratory received the above unsatisfactory proficiency testing result.