

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0587839	<b>(X3) Date Survey Completed</b>  03/03/2021
<b>Name of Provider or Supplier</b>  Sierra Medical Group Inc	<b>Street Address, City, State</b>  38636 Medical Center Dr, Ste C, Palmdale, 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>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 reports and interview with the testing personnel (TP); 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: 1. The AAB reported an artificial 100% proficiency score for the Cardiac Markers/ Isoenzymes: Troponin I for the first event of 2019 (Q1-2019) and the third event of 2019 (Q3-2019) as follow: a. (Q1-2019) Specimen Reported Intended 1 # 8.81 3.18 - 5.3 2 0.33 0 - 0.35 3 ? 15.82 6.63 - 11.05 4 #43.33 13.04 - 21.74 5 #4.95 1.55 - 2.59 Note: True score for Troponin I should have been 20%. b. (Q3-2019) Specimen Reported Intended 1 0.24 0 - 0.32 2 #32.56 13.02 - 21.7 3 # 6.13 3.5 - 5.84 4 #13.88 7.95 - 13.25 5 #3.05 1.58 - 2.63 Note: True score for Troponin I should have been 20%. c. 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 participant's 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. 3. The testing personnel confirmed on 03/03/2021 that the laboratory received the above artificial 100% scores and that the laboratory did not have a corrective action for the failures in the proficiency testing. 4. According to the laboratory testing declaration submitted on</p>

the day of the survey (03/03/2021) for the years 2019-2020, the laboratory analyzed and reported approximately 100 Troponin I tests during the time the laboratory received artificial 100% PT performance scores.

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of the Policies and Procedures documents, interview with the testing personnel (TP), and quality assessment record review on March 3, 2021; it was determined that the laboratory failed to perform analytic systems quality assessment; a review that its quality assessment mechanisms and its effectiveness. Findings included: 1. Although the laboratory established a policy on Quality Assessment (Policies and Procedure No. 2 dated 7/1/2016) with a predetermined schedule of quality assurance activities consisting of QC Review, Personnel Training Evaluation, Test Tracking, Communication, Compliance Assessment, etc., no documentation of such activities was found. 2. The TP confirmed on 03/03/2021 at approximately 11:30 a.m. that the laboratory fail to perform and document quality assurance/assessment activities. 3. According to laboratory testing declaration, the laboratory performs and reports approximately 11, 050 patient tests annually.

**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 laboratory's Policies and Procedures, proficiency testing records, and interview with the testing personnel on March 3, 2021; it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when the laboratory receives artificial 100% proficiency testing scores. See D5215.