

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0590252	<b>(X3) Date Survey Completed</b> 02/27/2018
<b>Name of Provider or Supplier</b> Salinas Pediatric Medical Group	<b>Street Address, City, State</b> 505 E Romie Ln, Ste K, Salinas, 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 Surveyor review of proficiency testing (PT) records from American Association of Bioanalysts (AAB) and interview with the laboratory staff, the laboratory failed to attain at least 80% score for erythrocytes in the 3rd event of 2017, and is determined unsatisfactory analyte performance. The findings include: a. The PT records of the 3rd event of 2017 shows that the laboratory obtained "60%" score for the analyte erythrocytes. b. PT sample results review and an interview with the laboratory staff on 02/27/2018 at 11:10 am confirmed that the laboratory received the following scores: Sample Reported Expected ID Result Result 1 5.8 4.22 - 4.76 2 2.09 2.05 - 2.32 3 5.32 5.1 - 5.75 4 2.11 2.06 - 2.33 5 5.0 5.1 - 5.75 c. The laboratory's testing declaration form signed by the lab director on 2/27/2018 shows that the laboratory runs 50,000 samples annually in Hematology.</p>
<b>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p>

This STANDARD is not met as evidenced by:  
Based on Surveyor review of proficiency testing procedure, policy and records, and interview with the laboratory staff, the laboratory failed to take any action to correct problems associated with the proficiency testing failure, and any remedial action. The findings include: a. The laboratory did not provide any records to prove any action was taken after receiving the unsatisfactory proficiency test score for erythrocytes. b. The laboratory staff, on 2/27/2018 at 11:20 am, affirmed that no remedial action was taken.

**D5211**

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

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of PT records from American Association of Bioanalysts (AAB) and interview with the laboratory staff on 2/27/2018 at 11:25 am, the laboratory failed to review and evaluate the results obtained on proficiency testing performed. The findings include: a. The laboratory did not have any evidence of review and evaluation of the laboratory's proficiency testing (PT) results. b. The laboratory participates in AAB proficiency testing events however, it does not review and evaluate its performance by reviewing the PT results. c. The laboratory staff, on 2/27/2018 at 11:25 am, affirmed that no review of PT results were done.

**D6018**

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

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on Surveyor review of proficiency testing procedure, policy and records, and interview with the laboratory staff, the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include: See D5211 and D2128.