

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0590252	(X3) Date Survey Completed 10/06/2020
Name of Provider or Supplier Salinas Pediatric Medical Group	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6067	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii)</p> <p>Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on staff interviews, review of 10 randomly selected patient test reports (medical records) from 01/11/2019 to 08/14/2020 and quality control data, and lack of training verification documentations on 10/06/2020 (survey date), it was determined that the laboratory failed to document training appropriate for the testing performed prior to analyzing patient specimens which must include: 1. The skills required for proper specimen collection, including patient preparation, if applicable; labeling, processing or preparation, transportation and storage of specimens. 2. The skills required for implementing all standard laboratory procedures; 3. The skills required for performing each test method and for proper instrument use; 4. The skills required for performing preventative maintenance, troubleshooting and calibration procedures; 5. A working knowledge of reagents stability and storage; 6. The skills required to implement the quality control policies and procedures of the laboratory; 7. An awareness of factors</p>

that influence test results; 8. The skills required to assess and verify the validity of patient test results through the evaluation of quality control (QC) samples values prior to reporting patient test results. 1. The laboratory had no documentation to show that an ongoing competency evaluation and training for the testing personnel performing moderate complexity testing. b. The laboratory testing personnel affirmed 10/06/2020 (survey date) at 11:30 a.m. that the laboratory had no documentation to show competency evaluation and training for the personnel performing moderate complexity testing for eight (8) testing staff noted on the CMS-209 Laboratory Personnel Report (CLIA) form. c. Based on the laboratory testing declaration submitted on 06/21/2016, the laboratory performed approximately 5,000 hematology tests annually.