

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2044073	<b>(X3) Date Survey Completed</b>  03/12/2019
<b>Name of Provider or Supplier</b>  Sc Medical Inc	<b>Street Address, City, State</b>  19042 Soledad Canyon Rd, Santa Clarita, 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><b>HEMATOLOGY</b> 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 reviews of the third quarter (Q3-2016) and third quarter (Q3-2018) of the American Proficiency Institute (API) proficiency testing records, random patient test results, 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. API reported the following unsatisfactory proficiency testing scores. Analyte:Score: Event/Year: Gran 20% Q3-2016 Lymph 20% Q3-2016 Mono 20% Q3-2016 Neut/ Gran 0% Q3-2018 Abbreviations: Neut/Gran= Neutrophils/Granulocytes Mono= Monocyte Lymph= Lymphocytes b. For ten (10) out of ten (10) random patient test results reviewed covering period from 10/12/2016 to 12/5/2018, the laboratory analyzed and reported White Blood Cells (WBC) Differential which included the above analytes that failed the proficiency testing. c. The testing personnel confirmed (3/12/2019, 12:45) that the laboratory received the above unsatisfactory proficiency testing scores.</p>
<b>D6019</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iv)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on reviews of the third quarter (Q3-2016) and third quarter (Q3-2018) of the American Proficiency Institute (API) proficiency testing records, random patient test results, 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 2121.