

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1040918	<b>(X3) Date Survey Completed</b>  01/18/2022
<b>Name of Provider or Supplier</b>  South County Kidney & Endocrine Center	<b>Street Address, City, State</b>  23141 Moulton Pkwy Ste 102, Laguna Hills, 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 review of the laboratory's daily records and the proficiency testing (PT) result reports and the PT provider's information, and interview with the laboratory testing personnel (TP) and the technical consultant (TC), 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 was unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory used Medonic, a hematology analyzer, to perform Complete Blood Cell Counts (CBC), including but not limited to the following parameters, Red Blood Cell (RBC), Hemoglobin (Hgb) and Hematocrit (HCT). b. The laboratory enrolled CBC testing with American Association of Bioanalyst (AAB) PT provider. c. The laboratory attained scores of 20 % for each of RBC, Hgb, and HCT parameter in the Q2 2021 PT event, which was unsatisfactory analyte performance for the testing event. d. The laboratory performed in approximately 83 patient samples monthly. e. The laboratory affirmed (01/18/2022 @ 10:10 AM) that the laboratory failed to attain at least score 80% for RBC, Hgb, and HCT in the Q2 2021 PT event, which was unsatisfactory analyte performance for</p>
<b>D6016</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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</p>

director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's daily records and the proficiency testing (PT) result reports and the PT provider's information, and interview with the laboratory testing personnel (TP) and the technical consultant (TC), it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required. The findings included: a. The laboratory used Medonic, a hematology analyzer, to perform Complete Blood Cell Counts (CBC), including but not limited to the following parameters, Red Blood Cell (RBC), Hemoglobin (Hgb) and Hematocrit (HCT). b. The laboratory enrolled CBC testing with American Association of Bioanalysts (AAB) PT provider. c. The laboratory attained scores of 20 % for each of RBC, Hgb, and HCT parameter in the Q2 2021 PT event, which was unsatisfactory analyte performance for the testing event, see D-2121 the testing events.