

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2084579	<b>(X3) Date Survey Completed</b>  04/03/2024
<b>Name of Provider or Supplier</b>  Summit Pediatrics	<b>Street Address, City, State</b>  134 Foothills Parkway, Chelsea, AL	
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>D5441</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Sysmex XP-300 Hematology Quality Control (QC) records and an interview with Testing Personnel #2, the laboratory failed to implement a mechanism to monitor the accuracy and precision of test performance over time. This was noted from 7/27/2022 to the date of the current survey, 4/3/2024. The findings include: 1. A review of Sysmex XP-300 QC records revealed only daily QC print outs from the instrument were retained. No evidence of Levy Jennings charts or peer group data was available for review at the time of survey. 2. During an interview on 4/3/2024 at 10:45 AM, Testing Personnel #2 confirmed that the laboratory had not printed and reviewed Levy Jennings charts for the Sysmex XP-300 and had not implemented any other method to monitor shifts and trends over time.</p>