

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2084579	(X3) Date Survey Completed 05/10/2022
Name of Provider or Supplier Summit Pediatrics	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the calibration records, policy and procedures manual, and an interview with Testing Personnel #1, the laboratory failed to calibrate the Sysmex XP-300 Hematology analyzer every six months as per laboratory procedure. The laboratory failed to perform two of two calibrations due in 2021. The findings include: 1. A review of the calibration records revealed a calibration was performed on 10/8 /2020 and the next calibration was performed 05/4/2022, a year and seven months after the previous calibration. 2. A review of the policy and procedures manual revealed on page 4 "...Sysmex will come in to calibrate every 6 months...". 3. During an interview on May 10, 2022 at 11:45 AM, Testing Personnel #1 confirmed Sysmex did not perform calibrations in 2021 due to lapse in service contract.</p>