

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0968759	(X3) Date Survey Completed 11/29/2022
Name of Provider or Supplier Southern Family Health	Street Address, City, State 201 Old Highway 25 East, Columbiana, 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 Hematology records, the Quality Assurance (QA) plan, and an interview with Testing Personnel #1, the Laboratory failed to perform calibrations on the AcT diff Hematology analyzer every six months as per the QA policy. The laboratory failed to perform one of two calibrations due in 2021. The findings include: 1. A review of the Hematology calibration records revealed the AcT Diff was calibrated 2/9/2021 and then thirteen months later on 3/25/2022. There was no documentation of a calibration the second half of 2021. 2. A further review of the QA plan revealed on page 2 B.5 "Calibrations are done according to manufacturer's recommendations and at least every six months." 3. During an interview on November 29, 2020, at 10:57 AM, Testing Personnel #1 confirmed the calibration due in August 2021 was not performed.</p>