

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2101598	(X3) Date Survey Completed 03/19/2026
Name of Provider or Supplier Total Healthcare	Street Address, City, State 3504 Hwy 280, Alexander City, 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>(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 calibration records and an interview with the Technical Consultant (TC), the Laboratory failed to perform calibration for the Sysmex XP-300 Hematology analyzer according to the manufacturer's specification. This was noted for one of the two possible calibrations in 2024. The findings include: 1. A review of the Hematology calibration records revealed the Sysmex XP-300 was calibrated on 02-20-2024 but no other calibration was performed and documented for 2024. The next calibration was performed with preventive maintenance on 01-23-2025. 2. An interview with TC on 03-19-2026 at 1:05 PM revealed an email from BIOMEDICAL ENGINEERING dated 12-05-2024 was sent to inform her that the Sysmex user manual procedure intervals did not include a 6- month or 12-month intervals. Surveyor also noted on the same email that effective 2025, a service vendor will be onsite at 12-month interval to address the necessary parts replacement of the Sysmex XP-300.</p>