

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2076788	(X3) Date Survey Completed 12/21/2020
Name of Provider or Supplier Purohit Pediatric Clinic Moody	Street Address, City, State 2468 Moody Pkwy, Moody, 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 reviews of the 2018 - 2020 Medonic Hematology analyzer calibration records, the Medonic Operators Manual, and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to perform one out of six calibrations in the review period as frequently as required by the manufacturer. The findings include: 1. A review of the Medonic M Series Hematology Analyzer Operators Manual, Section 7: Calibration on page 59, revealed, "...Introduction...It is recommended to calibrate the instrument every six months. ...". 2. A review of the Medonic Hematology analyzer records revealed the last calibration of 2019 was performed on 11/25/2019; thereafter, the next calibration was eight and a half months later on 8/07/2020. 3. During an interview on 12/21/2020 at 12:20 PM, Testing Personnel #1 reviewed the above noted findings, and confirmed Medonic calibrations should be performed every six months. SURVEYOR ID #32558Licensure and Certification Surveyor</p>