

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0303442	(X3) Date Survey Completed 09/18/2023
Name of Provider or Supplier Northeast Al Peds	Street Address, City, State 829 Riverbend Drive, Gadsden, 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 calibration and quality control (QC) records, the Medonic user manual, and an interview with Testing Personnel #1, the Laboratory failed to ensure: a) Calibrations on the Medonic Hematology analyzer were documented every six months as per the manufacturers instructions; The laboratory failed to document two of two calibrations due in 2022. b) QC was performed after calibration and before patient testing on 7/13/2023. The findings include: 1. A review of the Hematology calibration records revealed the Medonic was calibrated 8/20/2021 and then seventeen months later on 1/30/2023. There was no documentation of a calibration the first half and second half of 2022. 2. A review of the Hematology QC records revealed the laboratory failed to perform and document QC after a calibration and before patient testing on 7/13/2023, 1 patient Complete Blood Count (CBC) performed. 3. A further review of the Medonic user manual revealed on page 59 "It is recommended to calibrate the instrument every 6 months." 4. During an interview on</p>

September 18, 2023, at 13:30 PM, Testing Personnel #1 confirmed the documentation for the calibrations performed in 2022 could not be located and no QC was performed prior to patient testing on 7/13/2023.