Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D1005790	**(X3) Date Survey Completed** 10/28/2020
Name of Provider or Supplier Huntsville Care Plus, Llc	**Street Address, City, State** 11100 South Memorial Parkway, Huntsville, 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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) 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. This STANDARD is not met as evidenced by: Based on reviews of the Medonic Hematology analyzer calibration records, the Medonic User's Manual, a patient report, and an interview with the Laboratory Supervisor, the surveyor determined the laboratory failed to perform and document one of three 2019-2020 calibrations with the frequency required by the manufacturer. The findings include: 1. A review of the Medonic M Series Hematology Analyzer User's Manual on page 59, revealed, Section 7 Calibration "...It is recommended to calibrate every six months.". 2. A review of the Medonic Hematology analyzer records revealed calibrations were performed as follows: A) 7/8/2019 at 11:52 AM using Boule Calibrator Lot # 21904-24 with 7/26/2019 expiration B) 1/31/2019 at 6:42 PM using Boule Calibrator Lot # 21912-24 with 2/28/2020 expiration C) 7/1/2020 at 9:56 AM using Boule Calibrator Lot # 22004-24 with 7/28/2020 expiration 3. During an interview on 10/28/2020 at 1:00 PM, the Laboratory Supervisor reviewed the instrument printouts for the "first calibration in 2020", and confirmed all the Medonic printouts were dated 1/31/2019. The surveyor asked if there was an explanation for the date discrepancy. The Supervisor stated the calibration was

	performed by the previous Supervisor, however there may have been a problem with the date on the Medonic. The surveyor then asked if the patient CBC's (Complete Blood Counts) performed after the calibration showed the same problem. The Supervisor reviewed patient records, and provided the surveyor with the first patient CBC performed the next morning; the CBC was dated 2/1/2020. The Laboratory Supervisor stated she had no explanation why the 2020 calibration was dated 1/31 /2019, and was unable to provide a Medonic calibration from early 2020. SURVEYOR ID #32558 Licensure and Certification Surveyor