Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0468136	12/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pocahontas Medical Clinic P A	2901 Medical Center Drive, Suite 500, Pocahontas, AR	

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: Through a review of the Medonic M-Series operator's manual, 2020 and 2021 calibration documentation for the Medonic hematology analyzer, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform calibration on the Medonic analyzer every 6 months as required by the manufacturer. Survey findings include: A. In Section 7: Calibration section of the Medonic M-Series operator's manual states (Pg. 59), it states, "It is recommended to calibrate the instrument every 6 months." B. A review of Medonic calibration documentation for 2020 and 2021 revealed that calibrations were documented on 2/21/2020, 8/18/2020, 5/13/2021, and 11/12/2021. The time period between the calibration on 8/18/2020 and the calibration on 5/13/2021 was 9 months (3 months more than recommended by the manufacturer). C. In an interview, at 1:50 p.m. on 12/28/2021, the technical consultant (listed on the CMS-209 form as employee #9) confirmed the lack of calibration between 8/18/2020 and 5/13/2021.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Through a review of the laboratory policy and procedure manual, a review of hematology quality control documentation for February, August, November, and December 2021, a review of the technical consultants quality assessment reviews, and through interviews with laboratory staff, it was determined the laboratory failed to correct problems identified in the analytic systems quality assessments. Survey findings include: A. The surveyor reviewed the laboratory policies and procedures. The procedure titled "Quality Control Protocol" states, "Control results should be investigated when a shift or trend is noted" and further states, "The Quality Control results are reviewed periodically by the technical consultant to observe for biases, shifts, or trends...A report noting the acceptability of the Quality Control data is filed after each visit by the technical consultant and sent to the Laboratory Director." B. A review of Levey-Jennings graphs for quality control performed in February 2021 revealed two of three levels of quality control were shifted above the mean all month (18 of 18 points for each control). The normal control was documented above the mean by an average of 1.5 SD (standard deviations) and the high control was above the mean by an average of 1.7 SD through the month of February 2021. C. A review of Levey-Jennings graphs for quality control performed in August 2021 revealed two of three levels of quality control were shifted above the mean. The normal control was documented above the mean on 21 of 22 points during August 2021, by an average of 0.9 SD and the high control was above the mean 22 of 22 points during August 2021 by an average of 1.4 SD. D. A review of Levey-Jennings graphs for quality control performed November through December 2021 revealed two of three levels of quality control were continuously shifted above the mean through both months (33 of 33 points for each control). The normal control was documented above the mean by an average of 1.0 SD and the high control was above the mean by an average of 1.4 SD through the months of November and December 2021. E. The technical consultant performs quarterly quality reviews during visits to the laboratory. The surveyor requested copies of the technical consultants reports and was provided three reports dated 3/2/2021, 7/21/2021, and 12/7/2021. The report dated 3/2/2021 included a statement that "Quality control data review for the Medonic M series showed a slight positive bias on Hemoglobin. The bias was not great enough to warrant an adjustment at this time. Will continue to monitor." The report dated 7/21/2021 stated, "Quality control data review for the Medonic M series showed various biases on several analytes. The biases were calculated, and the calibration factor adjusted to correct. The controls were tested post adjustment with improvement." The report dated 12/7 /2021 included, "Quality control data review for the Medonic M series showed a slight positive bias on RBC and Hemoglobin. The instrument was successfully calibrated November 12, 2021. Post calibration the hemoglobin still has a slight positive bias." The technical consultant identified the shifts in quality control for hemoglobin in all of the reports for 2021 but the shifts were never corrected. F. During an interview, on 12/28/2021 at 2:30 p.m. the technical consultant confirmed

	the hemoglobin quality control was still shifted above the mean at the time of the survey and had remained shifted above the mean since February 2021 without being corrected.