Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0898826	08/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pricare Pa	44 Aliant Parkway, 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	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 a review of the Hematology calibration records, the policy and procedure manual, and an interview with the Technical Consultant, the laboratory failed to perform and document Emerald Cell Dyn Hematology calibrations with the required frequency specified by the laboratory policy. The laboratory failed to perform one of two calibrations due in 2021. The findings include: 1. A review of the Emerald Cell Dyn Hematology records revealed calibrations were performed on 3/5/2021 and ten months later on 1/28/2022. There was no documentation of a calibration performed the second half of 2021. 2. A review of the policy and procedure manual revealed the Quality Control/Calibration policy specified, "Hematology analyzers must be calibrated according to the following schedule: a. at least once every six months". 3. During the exit interview on August 8, 2022, at 1:40 PM, the Technical Consultant confirmed the above findings. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Alfa Wasserman Ace Axcel Chemistry analyzer records and an interview with the Technical Consultant, the laboratory failed to perform one of four calibration verifications (C-V) for Cholesterol (Chol), Triglyceride (Trig), High-density lipoprotein (HDL), and Low-density lipoprotein (LDL) (four out of eighteen analytes) due in 2021 - 2022. The findings include: 1. A review of the records for the Alfa Wasserman Ace Axcel Chemistry analyzer revealed analytes on the instrument were calibrated with one calibrator. Analytes calibrated with less than three calibrators must have a C-V every six months as per CLIA requirements. 2. A review of Chemistry records revealed a C-V was performed using Audit Microcontrol linearity kits, as follows: A) 3/05/2021: all 18 Chemistry analytes B) 9/13/2021: all Chemistry analytes except Chol, HDL, Trig and LDL C) 3/16/2022: all 18 Chemistry analytes, and D) 7/25/2022: all 18 Chemistry analytes 3. During the exit interview on August 3, 2022, at 1:40 PM , the surveyor reviewed the Chemistry records with the Technical Consultant, who confirmed the laboratory had missed verifying the calibration for four analytes during the 9/13/2021 Alfa Wasserman Ace Axcel C-V. SURVEYOR ID #'s 32558 and 46291 Licensure and Certification Surveyors