Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2085734	(X3) Date Survey Completed 02/06/2018
Name of Provider or Supplier Bethel Blood And Cancer Center Pa	**Street Address, City, State** 3256 S Pine Ave Ste 303, Ocala, FL	
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
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 record review and staff interview, the facility failed to perform and/or document the calibration verification at least once every 6 months for the Cell Dyn Emerald hematology analyzer. The findings include: The record review on 2/6/18 of the calibration documentation for the Cell Dyn Emerald hematology analyzer showed

	calibration was performed in April 2016 and August 2017. The interview with the laboratory manager on 2/6/18 at 11:00am confirmed calibration had not been performed every 6 months as manufacturer instructions require.