Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0906863	01/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dr V M Baich Pa	101 Baich Drive, Coleraine, MN	

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 observation, document review and interview with laboratory personnel, the laboratory failed to perform calibration verification on a hematology analyzer at least once every 6 months. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 01/08/20, at 1:05 p.m. 2. A Cell-Dyn Emerald hematology analyzer was observed as present and available for use during the tour. 3. The laboratory did not

	perform calibration verification activities during the time period reviewed, 2/8/18 through 1/8/20. 4. The laboratory was unable to provide calibration verification records for this time period upon request. 5. In an interview on 01/08/20, at 2:30 p.m., TP1 confirmed the above findings *This is a repeat finding from each of the 10/25 /2015 and 02/08/18 surveys* .