Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0948779	03/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Byron Family Health Care	200 Hwy 49 South, Byron, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 12, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiency was cited:
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 review of the Medonic Operator's Manual, calibration records for the

	Medonic Hematology Analyzer, and staff interview, the laboratory failed to perform calibrations every 6 months as required for the specialty of Hematology. The findings include: 1. Review of the Medonic Hematology Analyzer Operator's Manual states that "The Instrument has been calibrated by Boule prior to shipment. Good Laboratory practice, however, requires regular checks and calibration of the measured parameters." 2. Review of the Medonic Hematology Analyzer calibration records showed that the laboratory calibrated the Medonic Hematology Analyzer in May 2018 when the analyzer was installed. The Medonic Hematology Analyzer has not been calibrated since being installed. 3. Interview with staff # 2 (CMS 209 form) on Tuesday, March 12, 2019 at approximately 11am, in the break room, confirmed that the Medonic Hematology Analyzer has not been calibrated since May 2018 when it was installed.