Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1016874	06/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Chris Burling Md, Pa	618 N Jefferson Suite 1, Mount Pleasant, TX	

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	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a recertification survey completed on June 11, 2025.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 laboratory policy, laboratory calibration verification documentation, and confirmed in interview, the laboratory failed to ensure calibration verification was performed every six months for two out of four calibration verifications performed on the Medonic M-Series Hematology Analyzer for records reviewed between March 2023 and January 2025. The findings included: 1. Review of the laboratory policy titled "Medonic M-Series hematology analyzer In House

	Procedure Manual", section "Calibration" included the following information: "Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months. Calibration must be performed more frequently than every 6 months if: - Major maintenance is performed that could affect calibration - Troubleshooting indicated a need for recalibration - The instrument is moved to another location" 2. Review of laboratory calibration verification for the Medonic M Series hematology analyzer, from 2023 to 2025, included the following two calibration verifications that elapsed a six-month period: September 2023: Calibration performed on: 9/18/2023. Next Calibration Due Date: 3/18/2024 May 2024: Calibration performed on 5/15/2024. Time elapsed since last calibration due date: 1 month and 27 days. Next Calibration Due Date: 11/15/2024 January 2025: Calibration performed on 1/8/2025. Time elapsed since calibration due date: 1 month and 24 days. 3. In an interview on 6/11/2025 at 12:20 hours, in the office, testing personnel (TP) 1 confirmed the laboratory had failed to ensure the calibration verification was performed every six months on the Medonic M Series hematology analyzer.