Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1058440	11/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Prime Med	1970 Andrews Avenue, Ozark, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on reviews of the Medonic M-Series Hematology maintenance records, the Medonic M-Series User's manual, and an interview with the Laboratory Manager (LM), the laboratory failed to perform the six-month maintenance, as recommended by the manufacturer. There was no documentation the laboratory performed four out of four semi-annual cleaning procedures due in 2024-2025. The findings include: 1. A review of the Hematology maintenance records revealed the Medonic M-Series had no documentation for the six-month maintenance during the 22 months reviewed from 2024-2025. 2. A review of the Medonic M- Series User's manual revealed on page 66, "Section 8: Cleaning, Maintenance and Transport...Six Month Cleaning procedure". 3. The LM confirmed the above findings during the exit conference on 11-05-2025 at 1: 00 PM.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well

	as acceptable limits for and the frequency of calibration; and (a)(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 reviews of the Medonic M-Series User's manual, the Medonic M-Series Hematology calibration records and an interview with the Laboratory Manager (LM), the laboratory failed to perform calibration at least every six months, as required by the manufacturer. There was no record of one of two calibrations due in 2025. The findings include: 1. A review of the Medonic M- Series User's manual revealed on page 59, in Section 7: Calibration, the manufacturer's recommendation to perform calibration at least every six months. 2. A review of the Hematology calibration records revealed the Medonic M-Series had no evidence of calibration due September 2025. 3. The LM confirmed the above findings during the exit conference on 11-05-2025 at 1:00 PM.