Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1058440	12/12/2023
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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (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 (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (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 a review of the Medonic M Series Hematology analyzer calibration records, the Medonic User's Manual and an interview with the Laboratory Director, the laboratory failed to perform and document quality controls (QC) following calibration as per manufacturer's instructions. This was noted for two out of three calibrations performed from March 2022 to the date of the current survey, 12/12/2023. The findings include: 1. A review of the Medonic Hematology records revealed calibrations and QC as follows: A) Calibration 09/27/2022 at 13:35 PM. No evidence of QC following the calibration was available for review. B) Calibration 02/22/2023 at 13:42 PM. No evidence of QC following the calibration was available for review. 2. A review of the Medonic M Series User's Manual on page 62 in the Calibration Section revealed, "...17. It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. ...". 3. During an interview on 12/12/2023 at 12:00 PM, the above findings were reviewed and confirmed with the Laboratory Director.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of a final patient report and an intereview with the Laboratory Director, the laboratory failed to include all required information on test reports. This was noted for one out of one patient reports reviewed from the date of the last survey, 3/17/2022, to the date of the current survey, 12/12/2023. The findings include: 1. A review of a final patient test report for a Complete Blood Count (CBC) run on the Medonic M Series revealed only the address of the facility's sister site in Dothan, Alabama. No evidence of the physical address of the facility performing the CBC was available for review. 2. During an interview on 12/12/2023 at 12:00 PM, the Laboratory Director confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of Personnel records, a review of Proficiency Testing (PT) records, and an interview with the Laboratory Director, the Technical consultant failed to assess competency of non waived Testing Personnel for the Medonic M Series Hematology analyzer annually. This was noted for one out three Testing Personnel previously qualified since the date of the last survey, 3/17/2022. The findings include: 1. A review of Personnel records revealed Testing Personnel #1 to have competency assessments dated 6/28/2022 and 6/30/2023. The aforementioned documents only assessed competency for the BioFire respiratory panel. 2. A review of Proficiency Testing records revealed Testing Personnel #1 participated in three out of four Hematology PT events reviewed. 2. During an interview on 12/12/2023 at 12:00 PM, the Laboratory Director confirmed Testing Personnel #1 did perform patient testing on the Medonic. The Laboratory Director confirmed the absence of a competency assessment for the Medonic.