Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2006401	06/07/2023
Name of Provider or Supplier	**Street Address, City, State**	
Wetumpka Urgent Care	11 Cambridge Drive, Wetumpka, 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 Hematology analyzer calibration records, the Medonic User Manual and an interview with the Technical Consultant, the laboratory failed to perform and document calibrations with the frequency required by the manufacturer. The laboratory failed to perform two of two calibrations due in 2021. The findings include: 1. A review of the Medonic Hematology analyzer calibration records revealed a calibration performed on 12/11/2020 (reviewed during the previous survey). The next calibration was performed seventeen months later on 5/19/2022. 2. A review of the Medonic User's Manual on page 60 "Section "7: Calibration" revealed, "...Introduction ... It is recommended to calibration the instrument every six months". 3. During an interview on 6/7/2023 at 11:40 AM, the Technical Consultant confirmed the laboratory had no record of the two Medonic calibrations due in 2021. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on reviews of Quality Assurance records, Hematology records and the CDS (Clinical Diagnostic Solutions) eCQAP (Clinical Quality Assurance Program) reports, and an interview with the Technical Consultant, the laboratory failed to investigate biases noted in the CDS eCQAP reports for the Hematology Quality Controls (QC) and implement corrective actions. The surveyor noted biases in the Red Blood Cell (RBC) parameters in five of five reports reviewed from 9/1/2021 to 3/21/22. The findings include: 1. A review of Hematology records revealed no documentation of calibration for the Medonic M Series Hematology analyzer in 2021. The surveyor reviewed a calibration performed on 12/11/2020; there were no other calibration records until seventeen months later on 5/19/2022. (Refer to D5437.) 2. A review of the CDS eCQAP reports for Hematology QC revealed biases (greater or less than 2.0 SDI [Standard Deviation Index]) in comparisons with the peer group results, as follows: A) 9/1-9/30/2021 (Lot #22106): High QC for RBC, MCV (Mean Corpuscular Volume) and MCH (Mean Corpuscular Hemoglobin) B) 10/1-10/24/2021 (Lot #22106): same biases as above continued C) 10/24-11/30/2021 (Lot #22108): High QC for RBC; and Low, Normal and High QC for MCH D) 1/16-2/28/2022 (Lot #22111): Low QC for RBC and Hematocrit; High QC for Hemoglobin; Low and Normal QC for MCH E) 3/1-3/21/2022 (Lot #22111): same biases as above continued 3. A review of the Quality Assurance records revealed no notation of the biases evident in the CDS eCQAP reports or documentation of an investigation to determine the cause, or corrective actions implemented to alleviate the biases. 4. During the exit summation on 6/7/2023 at 2:35 PM the above noted concerns were reviewed and confirmed with the Technical Consultant. SURVEYOR ID# 32558 Licensure and Certification Surveyor