Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2006401	07/20/2021
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) Hematology proficiency testing (PT) records, personnel records, and an interview with Testing Personnel #5, the surveyor determined the laboratory failed to ensure proficiency testing samples were rotated between all personnel who performed moderate complexity Hematology testing on patients. This was noted on four of four 2020-2021 survey events reviewed. The findings include: 1. A review of API attestation statements revealed the Laboratory Supervisor had performed all the testing on all three 2020 surveys, and the first 2021 survey, performed from 3/17/2020 through 3/16 /2021, the most current survey. None of the PT testing had been performed by Testing Personnel #1, #2, #3, or #5. The surveyor also reviewed 2019 records, however the attestation statement for 2019 Event 1 was missing, and the 2019 Event 3 attestation statement was not signed by the Laboratory Director or the Testing Personnel 2. A review of the personnel files of testing personnel listed on the Form CMS-209 (Laboratory Personnel Report) revealed TP #2, #3 and #5 had been trained to perform moderate complexity Hematology testing on patients since the previous survey on 1/16 /2019. TP #1 was trained in October 2020, and TP #4 was a new employee trained in 2021. 3. During an interview on 7/20/2021 at 11:45 PM, Testing Personnel #5 reviewed the PT records and confirmed the Laboratory Supervisor had performed all the PT testing in 2020-2021. (The Supervisor was not listed on the Form CMS-209 because she is currently on leave, and the facility does not know if she will return to

	work again.) Testing Personnel #5 did not know who had performed survey Events 1 and 3 in 2019. The surveyor then explained all testing personnel listed on the CMS-Form 209 must periodically participate in the performance of proficiency testing. .
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 Testing Personnel #5, the laboratory failed to perform and document calibrations as per manufacturer's instructions. This was noted on one of seven calibrations performed in 2019-2021. The findings include: 1. A review of the Medonic Hematology analyzer calibration records revealed only the low control (run three times) was performed after the 3/14/2019 calibration. 2. A review of the Medonic User Manual, under "M-Series Calibration Instructions" revealed "...28. To verify calibration run three levels of control ...". 3. In an interview and review of the calibration records on 7/20/2021 at 1:50 PM, Testing Personnel #5 confirmed the above noted findings. .
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of API (American Proficiency Institute) Hematology proficiency testing (PT) records, and an interview during the exit summation, the laboratory failed to determine the cause of underlying problems evidenced by proficiency testing failures in the RBC (Red Blood Cell) parameters in CBC's (Complete Blood Counts) performed on the Medonic Hematology analyzer. The findings include: 1. A review of API Hematology proficiency testing records revealed the following: A) 2020 Event #2 (performed 7/24/2020): Hematocrit scored 80%; MCV (Mean Corpuscular Volume) and MCHC (Mean Corpuscular Hemoglobin Concentration) had failing scores of 60% each. The corrective actions documented the Technical Consultant determined the problem was due to "mixing problems", however a review of the instrument printouts for PT samples 8, 9, and 10 revealed an AF "Aspiration failed" error. There was no

	indication the error was noted or investigated. B) 2020 Event #3 (performed 11/10 /2020): Hematocrit and MCHC had failing scores of 60% each. The corrective action documented the results were "barely out of range" and the repeats were still out barely out of range. The laboratory attributed the failures were due to sample problems, however there was no indication the significant biases (+/- 2.0 SDI [Standard Deviation Index] in three or more of the PT sample results) in the RBC, Hematocrit, MCV, MCH, MCHC parameters were noted or investigated. 2. During the exit summation on 7/20/2021 at 5:00 PM, the surveyor reviewed and confirmed the above findings with Testing Personnel #5. .
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 files and an interview with Testing Personnel #5, the Technical Consultant failed to evaluate and document the 2019 competencies of two of five testing personnel listed on the Form CMS-209. The findings include: 1. A review of the poorly organized personnel records revealed Testing Personnel #2 and #5 had been performing CBC's (Complete Blood Counts) since the previous survey on 1/16/2019, however there was no documentation of the 2019 annual competency evaluations for these employees. 2. During an interview and review of the personnel files on 7/20/2021 at 11:55 AM, Testing Personnel #5 confirmed she was unable to locate the 2019 annual competency evaluations for Testing Personnel #2 or #5. SURVEYOR ID# 32558 Licensure and Certification Surveyor