Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2107019	03/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ourmed Llc	9188 Eastchase Parkway, Montgomery, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation during a tour of the laboratory and an interview with the Director of Operations, the laboratory failed to ensure specimen collection tubes stored in the laboratory were within the expiration date. Six packs of specimen collection tubes were found to be expired. The findings include: 1. During a tour of the laboratory, the following was noted: A. 1 pack of BD Vacutainer EDTA (Ethylenediaminetetraacetic acid) Blood Collection Tubes were found to have an expiration date of 1/31/2024 B. 4 bags of BD Microtainer EDTA Capillary Stick tubes were found to have an expiration date of 1/28/2021. C. 2 bags of BD Microtainer EDTA Capillary Stick tubes were found to have an expiration date of 3/31/2023. 2. During an interview on 3/27/2024 at 10:00 AM, the Director of Operations confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and

	precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of Beckman Coulter DxH 520 Hematology Quality Control (QC) records and an interview with the Director of Operations, the laboratory failed to implement a mechanism to monitor the accuracy and precision of test performance over time. This was noted from the date of implementation of the DxH 520, 4/19 /2022, to the date of the current survey, 3/27/2024. The findings include: 1. A review of Beckman Coulter DxH 520 QC records revealed only daily QC print outs from the instrument were retained. No evidence of Levy Jennings charts or peer group data was available for review at the time of survey. 2. During an interview on 3/27/2024 at 11: 30 AM, the Director of Operations confirmed that the laboratory had not printed and reviewed Levy Jennings charts for the DxH 520 and had not implemented any other method to monitor shifts and trends over time.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on a review of Validation records, a review of Personnel records, and an interview with the Director of Operations, the Technical Consultant failed to complete initial training on Testing Personnel for the Beckman Coulter DxH 520 hematology analyzer. This was noted for six out of seven Testing Personnel previously qualified since the date of implementation, 4/19/2022, to the date of the current survey, 3/27 /2024. The findings include: 1. A review of the Validation for the Beckman Coulter DxH 520 Hematology analyzer revealed an implementation date of 4/19/2022. 2. A review of the Personnel records revealed 2023 and 2024 annual competency assessments for Testing Personnel #2, #3, #4, #5, #6, and #7. However, no evidence of an initial training was noted for the DxH 520 analyzer. 3. During an interview of 3 /27/2024 at 12:00 PM, the Director of Operations confirmed patient testing for the DxH 520 began on 4/19/2022. The Director of Operations further confirmed the absence of documented training for the analyzer.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of Validation records, a review of Personnel records, and an interview with the Director of Operations, the Technical Consultant failed to complete

	six month competency assessments on Testing Personnel for the Beckman Coulter DxH 520 hematology analyzer. This was noted for seven out of seven Testing Personnel previously qualified since the date of implementation, 4/19/2022, to the date of the current survey, 3/27/2024. The findings include: 1. A review of the Validation for the Beckman Coulter DxH 520 Hematology analyzer revealed an implementation date of 4/19/2022. 2. A review of the Personnel records revealed 2023 and 2024 annual competency assessments for Testing Personnel #1, #2, #3, #4, #5, #6, and #7. However, no evidence of six month competency assessment was noted for the DxH 520 analyzer. 3. During an interview of 3/27/2024 at 12:00 PM, the Director of Operations confirmed patient testing for the DxH 520 began on 4/19/2022. The Director of Operations further confirmed the absence of training and competency assessments for the analyzer.