

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1080513	(X3) Date Survey Completed 06/26/2024
Name of Provider or Supplier American Health Mw Llc	Street Address, City, State 600 Executive Park, Louisville, KY	
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
D0000	A recertification survey was conducted on 06/26/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologist (CAP) Proficiency testing (PT) 2023 Event 2 (Erythrocyte Sedimentation Rate ESR3-B) and 2024 Event 1 (Erythrocyte Sedimentation Rate ESR3-A and K-C 2024 Ligand General Survey Event 1), and confirmed in interview, the laboratory failed to review Proficiency testing (PT) events for three of four testing events. Findings include: 1. Review of the laboratory PT events revealed the following: a. 2023 Event B Erythrocyte Sedimentation Rate - No CAP Evaluation Result, No Laboratory Evaluation record b. 2024 Event A Erythrocyte Sedimentation Rate - No Attestation, No CAP Evaluation Result, No Laboratory Evaluation record c. 2024 K-C Event 1 - No Attestation, No CAP Evaluation Result, No Laboratory Evaluation record 2. In an interview on 6/26 /2024 at 4:30 PM in the conference room, the laboratory director (LD) was asked if a review was performed for the PT events. The LD confirmed the PT events were not reviewed for the three testing events. This confirmed the findings.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and</p>

test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observation, manufacturer's instructions, and confirmed in staff interview; the laboratory failed to monitor and document room temperature for 4 of 4 storage areas. Findings included: 1. Observed on 06/26/2023 at 11:15 a.m. were the following areas in the laboratory where controls and calibrators were located: Coulter 6C Cell Control, and Beckman Coulter IQ Control/Focus Set; reagents: Beckman Coulter (Albumin, Glucose, Iron, and Cholesterol), Siemens Healthineers Dode Actin FSL Activated PTT Reagent, Siemens Healthcare CaCl₂ Solution; collection tubes with and without patient specimens: purple Greiner Bio-One GmbH Vacuette tubes and blue Greiner Bio-One GmbH Vacuette tubes: a.) Black fridge next to exit: controls: 2 boxes of 4 of each level (1-3) Coulter 6C Cell Control Lot 4218820K; reagents: 3 boxes of 4 each Albumin Lot 2627, 4 boxes of 2 each (1 and 2 levels) Glucose Lot 2703, 6 boxes of 4 each (1 level) Cholesterol, and 5 boxes of 2 each (1 and 2 levels) Iron Lot 2597, 2 boxes of 10 each Calcium Chloride Solution Lot 563928, and 1 box of 10 each of Dode Actin FSL Activated PTT Reagent Lot 562757. b.) Metallic fridge next to exit: 5 racks of 91 patient specimens in purple Greiner Bio-One GmbH Vacuette tubes Lot B240433A and 6 racks of 60 blue Greiner Bio-One GmbH Vacuette tubes Lot B2403335. c.) Fridge in front of storage room B: 5 boxes of 1 each IQ Control/Focus Set Lot 040-24, 3 boxes of IQ Calibrator Pack of 4 each Lot 221-23. d.) Storage room located next to laboratory office: 1 box of 20 packages of 50 purple Greiner Bio-One GmbH Vacuette tubes Lot B240433A and 1 box of 24 packages of 50 blue Greiner Bio-One GmbH Vacuette tubes Lot B2403335. No temperature monitoring devices were observed in the 4 storage areas. 2. The manufacturer's instructions on the label of each package stated a storage requirement of: Coulter 6C Cell Control 2 to 8 degrees Celsius, and Beckman Coulter IQ Control /Focus Set 2 to 8 degrees Celsius; reagents: Beckman Coulter (Albumin 2 to 25 degrees Celsius, Glucose 2 to 8 degrees Celsius, Iron 2 to 8 degrees Celsius, and Cholesterol 2 to 8 degrees Celsius), Siemens Healthineers Dode Actin FSL Activated PTT Reagent 2 to 8 degrees Celsius, Siemens Healthcare CaCl₂ Solution 2 to 25 degrees Celsius; and collection tubes with and without patient specimens: purple Greiner Bio-One GmbH Vacuette tubes 4 to 25 degrees Celsius and blue Greiner Bio-One GmbH Vacuette tubes 4 to 25 degrees Celsius. 3. In an interview on 06/26/2023 at 11:15 am, testing personnel (TP) #1 stated that the temperature was not monitored as of 06/15/2024. This confirmed the findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on a review of patient test reports and confirmed in staff interview, the laboratory failed to verify 3 of 3 reference intervals for Complete Blood Cell counts (CBC) for their patient population. Findings include: 1. Review of 3 patient test reports of individuals with different ages and genders titled "American Health Associates" for years 2023 and 2024 revealed reference intervals for CBC results: "Age: 86 Gender: M ... WBC 4.5-10.8 K/cmm RBC 4.00-6.60 M/cmm HEMOGLOBIN 14.0-18.0 g/dL HEMATOCRIT 42.0-54.0 % MCV 80.0-100.0 fL ... Age: 77 Gender: F WBC 4.5-10.8 K/cmm RBC 3.90-5.40 M/cmm HEMOGLOBIN 12.0-16.0 g/dL HEMATOCRIT 36.0- 48.0 % MCV 80.0-100.0 fL ... Age: 30 Gender: M WBC 4.5-10.8 K/cmm RBC 4.00-6.60 M/cmm HEMOGLOBIN 14.0-18.0 g/dL HEMATOCRIT 42.0-54.0 % MCV 80.0-100 fL ..." 2. In an interview on 06/26/2024 at 3:15 p.m. in the conference room, the testing personnel (TP) #1 was asked to provide documentation of verification of the reference intervals in use for their patient population. No documentation was provided. This confirmed the findings. Word Key: % = Percentage K/cmm = Thousands Cells Per Cubic Millimeter M/cmm = Million Cells Per Cubic Millimeter dL = Deciliter F = Female M= Male fL = Femtoliters g = Gram MCV= Mean Corpuscular Volume RBC = Red Blood Cell WBC = White Blood Cell

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the laboratory failed to present the maintenance logs for instrumentation for nine (9) of seventeen (17) months reviewed in the year 2023 and 2024. Findings include: 1. During a tour of the laboratory on 06/26/2024 at 11:10 AM, a Beckman Coulter AU5822 (SN 2016032671), a Sysmex CA2500 (SN 24121), a Beckman Coulter UniCel DXH900 Hematology Analyzer, an ISED (SN 03202), and a Beckman Coulter DXi 600 (SN 83590723) were observed to be in use. 2. Upon review of the Maintenance for the year 2023 and 2024 for all instrumentation, the maintenance records for six months of year 2023 (July, August, September, October, November, December) and three months for year 2024 (January, February, March) were not present. 3. In an Interview on 6/26/2024 at 4:30 PM, the Testing Personnel was asked for maintenance records for 2023 and 2024. No documentation was provided. This confirmed the findings.