Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0469373	05/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Waldron	1341 W 6th St, Waldron, AR	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based upon a review of policy and procedure, lack of documentation, and interview with laboratory staff it was determined that the laboratory failed to have corrective action for proficiency analyte with less than 80% and use of expired reagents. Findings follow: A) Review of the laboratory's policy and procedure titled WLDAR Lab Proficiency Testing states on page 6, "For each unacceptable result, the lab retains documentation of the results, the investigation, evidence of review, and remedial action taken." On page 10 states, "For each unacceptable results, there is a

	comprehensive investigation, a Corrective Action form will be completed, and sufficient remedial action taken to address and correct the issues identified in the investigation. Verification testing and remedial action is documents." No Corrective Action performed for 2024 Hematology / Coagulation - 2nd Event Glucose 50%. B) Upon request, the laboratory could not provide corrective action for 2024 Hematology / Coagulation - 2nd Event Glucose 50%. C) In an interview on May 1, 2025, at 08:43 a.m. the Technical Supervisor verified that policies and procedures defining acceptable /unacceptable quality control results and corrective actions to follow in the event of unacceptable proficiency analyte were not available. D) Review of the laboratory's policy and procedure titled WLDAR Lab Quality Control states on page 1, "Monitoring of Quality Control - General monitoring occurs daily, weekly, and monthly with departmental considerations for evaluation. Daily Quality Control - QC will be reviewed daily and initialed by two different lab techs. Corrective action will be documented on QC printouts. Any unresolved variance of control material will result in the immediate suspension of patient sample testing and reporting." No Corrective Action was documented for 9 out 31 days for CK level 1 and 3 being expired in July 2024. E) Upon request, the laboratory could not provide corrective action for July 2024 CK level 1 and 3 expired. F) In an interview on May 1, 2025, at 09:26 a.m. the Technical Supervisor verified that policies and procedures defining monitoring daily quality control and corrective actions the use of expired analyte were not available.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 reviewing individual Quality Control (QC) Chart laboratory staff had reagents available for use when they exceeded their expiration date. Findings following: A) Reviewing July 2024 Chemistry Individual QC Chart for Creatine Kinase (CK) Bio-Rad level 1 and level 3 expired for July 1 through July 9 indicated both levels expired. B) Reviewing package insert for Bio-Rad Liquid Unassayed Multiqual Level 1,2 and 3 states, "The stability claims given below are from the initial date of thaw. Make a note of when the date begins. Thawed opened CK is only stable for 7 days." No documents provided for when CK was initial thaw and opened. C) In an interview on May 1, 2025, at 09:26 a.m. the Technical Supervisor verified that CK levels 1 and 3 were used past expiration date.