Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0469373	08/23/2023
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) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Through a lack of policy and procedure and interview it was determined that the laboratory failed to have control procedures and corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. Findings follow: A. Upon request, the laboratory could not produce policies and procedures that defined unacceptable quality control results and corrective actions to take in the event of control failures. B. In an interview on August 22, 2023, at 1:43

	PM the technical supervisor verified that policies and procedures defining acceptable /unacceptable quality control results and corrective actions to follow in the event of unacceptable quality control results were not available.
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: Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on August 23 at 3:46 PM. one (of one) Para-Pak EcoFix (Ref 901312, Lot 361020M, expiration date January 4, 2023) was observed in the laboratory. B) During a tour of the laboratory on August 23 at 3:48 PM one (of one) Cepheid Sample Collection Device (Ref 900-0370, Lot 21524600, expiration date June 30, 2023) was observed in the laboratory. B) In an interview on August 23 at 3:49 PM the technical supervisor confirmed that the items, identified above, had exceeded their expiration date and were available for use.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Through a lack of policy and procedure and interview it was determined that the laboratory did not include written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic systems. Findings follow: A. Upon request, the laboratory could not produce policies and procedures that defined the mechanism to monitor, assess and correct problems identified in the postanalytic systems. B. In an interview on August 22, 2023, at 1:45 PM the technical supervisor verified that policies and procedures defining postanalytic quality assessment were not available.