Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0465446	11/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bradley County Medical Center	404 South Bradley Street, Warren, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Through a review of the proficiency test attestation records for nine events in 2022 and 2023, lack of documentation, and interviews with laboratory staff, it was determined that required signatures to attest to the routine integration of proficiency test samples in the patient workload were not present on 4 of the nine events reviewed. Survey findings follow: A) Review of the attestation forms for the following proficiency test events for arterial blood gas determinations revealed that they were not signed by the testing personnel: First Chemistry Core Event 2022; Third Chemistry Core Event 2022; and First Chemistry Core Event 2023. B) Review of the second Chemistry Core event of 2022 revealed that it lacked an attestation form signed by any testing personnel or the laboratory director. C) In an interview, at 01:23 p.m. on 11/7/23, the laboratory staff member (# 13 as listed on the form CMS-209) confirmed the attestation form was not available for Chemistry Core event # 2 in 2022 and required testing personnel signatures were not available for arterial blood gas events identified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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 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: Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature on each day of operation in one of six rooms in which supplies with storage temperature requirements were stored. . Findings follow: A) During a tour of the laboratory on 11/7 /23 at 10:45 a.m., six separate rooms (main lab, microbiology lab, blood bank, phlebotomy room, respiratory therapy and emergency room) containing laboratory items with a temperature storage requirement were observed. B) During a review of the laboratory's temperature records it was noted that no temperature records were presented for the microbiology lab area. C) During a tour of the laboratory on 11/9/23 at 11:00 a.m. 3 cartons of BacTAlert FA Plus blood culture bottles lot 00044181675, expiration date 2024-03-31 with a storage temperature requirement of 15 to 30 degrees C. were observed in the microbiology lab. D) Upon request, the laboratory could not present the temperature records for the microbiology lab in which the supplies identified above were stored. E) In an interview on 11/9/23 at 11:05 a.m. , the laboratory staff member (# 13 on form CMS 209) confirmed that temperature records for the micorbiology lab were not kept.
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 observations made during a tour of the laboratory, it was determined the laboratory had reagents available for use when they had exceeded their expiration date. Survey findings follow: A) During a tour of the laboratory at 11:00 a.m.on 11/9 /23, two bottles of stain (3 Step Solution A lot # 114823 and 3 Step Solution B lot # 114824) with expiration date of 1/2023 were observed available for use when they had exceeded their expiration date. B) In an interview on 11/9/23 at 11:05 a.m., the laboratory staff member (# 13 on the CMS 209 form) confirmed that the stains identified above had exceeded the expiration date and were available for use.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Through a review of the laboratory individualized quality control plan (IQCP) for arterial blood gas assays, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform control procedures using the frequency established by the laboratory. Survey findings follow: A) The IQCP for arterial blood gas assays states "the laboratory is following manufacturer's recommended quality control procedure by testing external quality control material for each shipment of a new kit lot number".. B) During a tour of the laboratory on 11/9 /23 at 11:10 a.m. the RAPIDPoint 1200 series arterial blood gas analyzer was observed in the emergency room with the analysis cartridge lot # 3320902717 loaded on the instrument. C) Upon request, the laboratory was unable to provide the external quality control results for cartridge lot # 3320902717. D) In an interview at 11:12 on 11/9/23, laboratory employee #19 (as listed on the form CMS-209) confirmed the lot number and instrument , identified above, did not have external quality control performed and stated "I do not recall running external quality control on this machine".