Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0673176	07/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Eureka Springs Hospital	24 Norris Street, Eureka Springs, 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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based upon review of laboratory policy and procedure, the manufacturer's user manual for the Beckman AU 480 chemistry analyzer and the Beckman Access chemistry analyzer, quality control (QC) results for complete blood cell count (CBC) analysis for May and June 2025, QC records for prothrombin time (PT) assays for May and June 2025, QC rescords for arterial blood gas (ABG) assays for May and June 2025, laboratory temperature/humidity records for May and June 2025, patient test results, lack of documentation, and interviews with laboratory staff, the laboratory failed to meet analytic system requirements as evidenced by: 5413: The laboratory failed to monitor humidity in rooms in which instruments with an operational humidity requirement were used. 5463: The laboratory failed to rotate the performance of QC among testing personnel. 5481: The laboratory reported ABG determination results when QC results were unacceptable and reported a CBS test result before QC was performed. 5537: The laboratory failed to perform QC for ABG analysis within eight hours of patient testing. 5545: The laboratory failed to perform QC for PT analysis within eight hours of patient testing. 5783: The laboratory failed to document corrective action when QC for ABG determinations failed to meet criteria for acceptability.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 upon observation, review of manufacturer's user manuals, laboratory temperature/humidity records, and interview with laboratory staff the laboratory failed to monitor humidity on 61 of 61 days in the room in which equipment with an operating humidity requirement was used. Findings follow: A) During a tour of the laboratory on 6/30/25 at 01:20 p.m. a Beckman AU 480 and Beckman Access chemistry analyzers were observed in the main laboratory room. B) Review of the manufacturer's user's manual for the Beckman AU 480 and Beckman Access chemistry analyzers revealed an operating non-condensing room humidity requirement of 20% to 80% for both analyzers. C) Review of the laboratory's room temperature/humidity records for May 2025 and June 2025 revealed that room humidity was not recorded for any day of the two months reviewed (61 of 61 days). D) In an interview on 7/1/25 at 11:15 a.m., the laboratory staff member (# 1 on the form CMS 209) stated that the hygrometer used to measure room humidity was not functional and has not been replaced.
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. This STANDARD is not met as evidenced by: Based upon the review of laboratory policies and procedures for quality control (QC), review of QC records for Hematology for the month of May 2025, patient results for complete blood cell testing (CBC), lack of documentation, and interview with laboratory staff, the laboratory failed to perform QC to identify possible immediate errors in the test system prior to reporting patient results. Findings follow: A) Review of the laboratory's QC policy and procedure for CBC assays revealed that QC was to be performed and acceptable prior to reporting patient results. B) Review of QC records for CBC assays in May 2025 revealed that on 5/7/25 QC was performed at 05: 46 p.m. C) Review of patient results revealed that on 5/7/24 at 09:41 a.m. a CBC was performed on patient 700335. D) Upon request, tha laboratory was unable to verify

	QC was performed and acceptable pior to 05:46 p.m. on 5/7/24. E) In an interview on 7/1/25 at 08:05 a.m., the laboratory staff member (# 1 on form CMS 209) stated stated "I believe we started at 08:35 a.m. on 5/7/25" and said that documentation of QC for CBC analysis performed prior to 05:46 p.m. on that day could not be found.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) (d)(7) Over time, rotate control material testing among all operators who perform the test. This STANDARD is not met as evidenced by: Based upon review of the form CMS 209, personnel records, quality control (QC) documentation for the I-Stat testing system, and interview, the laboratory failed to rotate QC among the testing personnel performing and reporting arterial blood gas (ABG) procedures. Findings follow: A) Review of the form CMS 209 revealed that laboratory staff members (#'s 2 through 15 on the form CMS 209) were listed as testing personnel for moderately complex testing. B) Review of personnel records for employees (3, 9, 12, and 14 on form CMS 209) revealed that they were found competent for ABG testing on the I-Stat testing system. C) Review of QC records for April, May, and June 2025 revealed that QC was only performed by testing personnel (#'s 5, 6 on the form CMS 209). D) In an interview on 7/1/25 at 10:20 a.m. the laboratory staff member (# 1 on the form CMS 209) stated that QC for the I-Stat system is only performed by testing personnel (#'s 5 and 6 on the form CMS 209) and testing personnel (3, 9,12,14) perform ABG testing on the I-Stat testing system. Staff member (# 1 on form CMS 209) further explained only laboratory personnel perform the QC testing but patient testing is performed by nursing and respiratory personnel as well.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon review of quality control (QC) records for Arterial Blood Gas (ABG) determinations, patient records for ABG testing, laboratory policies and procedures for quality control (QC), review of QC records for Hematology for the month of May 2025, patient results for complete blood cell testing (CBC), lack of documentation, and interview with laboratory staff, the laboratory reported ABG results when QC performance was unacceptable and reported complete blood cell (CBC) results prior to performing QC . Findings follow: 1) The laboratory reported ABG results when QC was unacceptable. A) Review of QC results for ABG analysis revealed that QC was performed and successful on 4/19/25, 5/30/25, and performed and unsuccessful on 6 /16/25, repeated and still unsuccessful on 6/17/25. No other QC records could be found. B) Review of patient records revealed that ABG analysis was performed and reported on a patient (identified as # 1 on a separate patient identification list) on 6/30 /25. C) In an interview on 7/1/25 at 10:20 a.m., the laboratory staff member (# 1 on form CMS 209) confirmed the QC performed on 6/16/25 and 6/17/25 was

	unsuccessful, and there was no subsequent QC performed before the ABG results were reported on the patient identified above. 2) The laboratory reported CBC results before QC was performed. A) Review of the laboratory's QC policy and procedure for CBC assays revealed that QC was to be performed and acceptable prior to reporting patient results. B) Review of QC records for CBC assays in May 2025 revealed that on 5/7/25 QC was performed at 05:46 p.m. C) Review of patient results revealed that on 5/7/24 at 09:41 a.m. a CBC was performed on patient 700335. D) Upon request, tha laboratory was unable to verify QC was performed and acceptable pior to 05:46 p. m. on 5/7/24. E) In an interview on 7/1/25 at 08:05 a.m., the laboratory staff member (# 1 on form CMS 209) stated stated "I believe we started at 08:35 a.m. on 5/7/25" and said that documentation of QC for CBC analysis performed prior to 05:46 p.m. on that day could not be found.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. This STANDARD is not met as evidenced by: Through review of quality control (QC) records for Arterial Blood Gas (ABG) assays, lack of documentation, review of patient ABG results, and interview with laboratory staff the laboratory failed to perform QC each eight hours of patient testing for ABG determinations the patient results reviewed. Findings follow: A) Review of QC records for ABG testing performed on the I-Stat analyzer revealed that QC was performed on 4/19//25, 5/30/25, 6/16/25 and 6/17/25 and no other QC records were provided. B) Review of patient results revealed that an ABG assay was performed and reported on patient (identified as # 3 on a separate patient identification list) on 6/30 /25. C) Upon request, the laboratory could not produce an Individualized Quality Control Plan (IQCP) for the I-Stat analyzer. D) In an interview on 7/1/25 at 09:10 a. m., the laboratory staff member (# 1 on the form CMS 209) stated the laboratory only performs QC for ABG assays on a once per month basis and that an IQCP for the I-Stat analyzer could not be found.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: Through review of quality control (QC) records for Prothrombin Time (PT) assays, lack of documentation, review of patient PT results, and interview with laboratory staff the laboratory failed to perform QC each eight hours of patient testing for PT determinations on two of three patient results reviewed. Findings follow: A) Review of QC records for PT testing performed on the Hemochron coagulation analyzer revealed that QC was performed on 5/10/25, 5/28/25, and 6/1/25 and no other QC records were provided. B) Review of patient results revealed that PT assays were performed and reported on patient (identified as # 2 on a separate patient identification list) on 5/7/25, and performed and reported on patient (identified as # 3 on a separate patient identification list) on 5/21/25. C) Upon request, the laboratory

	could not produce an Individualized Quality Control Plan (IQCP) for the Hemochron coagulation analyzer. D) In an interview on 7/1/25 at 09:10 a.m., the laboratory staff member (# 1 on the form CMS 209) stated the laboratory only performs QC for PT assays on a once per month basis and that an IQCP for the Hemochron coagulation analyzer could not be found.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based upon a review of laboratory policy and procedure, review of quality control (QC) results for arterial blood gas (ABG) determinations, lack of documentation and interview with laboratory staff, the laboratory failed to document corrective action taken when QC for ABG determinations failed to meet criteria for acceptability. Findings follow: A) Review of the laboratory's policy and procedure for QC revealed that the laboratory is to take and document corrective action when QC results fails to meet criteria for acceptability. B) Review of QC for ABG analysis revealed the results failed to meet acceptable results on 6/16/25 and 6/17/25 and there were no subsequent acceptable results or corrective action documented. C) An ABG analysis was performed on patient (identified as # 1 on a separate patient identification list) on 6/30 /25 D) Upon request, the laboratory could not provide acceptable QC results or documented corrective action for the instances of failed QC identified above, E) In an interview on 7/1/25 at 10:20 a.m., the laboratory staff member (# 1 on the form CMS 209) confirmed that the QC results for ABG analysis identified above were not acceptable and no corrective action was documented.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Based upon review of personnel files for six testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, the laboratory director failed to authorize six of six testing personnel to perform testing without direct supervision. Survey findings include: A) Review of personnel files for six testing personnel listed on form CMS-209 (Personnel #'s 3,5,6, 9, 12, 14) revealed written authorization from the laboratory director to perform moderately complex testing without direct supervision was not present. B) In an interview, at 02:30 p.m. on

	6/30/25, laboratory staff member #1 (as listed on the form CMS-209) confirmed the lack of written authorizations to test for employees (#'s 3,5,6,9,12,14 on form CMS 209).