Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0673176	09/09/2021
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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of quality control (QC) reports for January 2021, review of the manufacturer's package insert instructions for Biorad Multiqual and Biorad Liquicheck QC material and interview it was determined that the laboratory failed to establish its own QC target and acceptable range values for 31 of 31 days reviewed. Findings follow: A) Review of the QC reports for January 2021 and the manufacturer's package inserts for Biorad Multiqual levels 1 & 3 lot# 45830 and Biorad Liquicheck levels 1 & 3 lot# 8522 revealed that the target and acceptable range used by the laboratory to evaluate QC results were identical to the range of means provided in the manufacturer's package inserts. B) Review of the manufacturer's package insert instructions for both the Biorad Multiqual and Biorad Liquicheck QC materials revealed that "it is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides". C) In an interview on 9/8 /21 at 10:47 AM the laboratory staff member, identified as number 3 on the CMS 209

	form, confirmed that the laboratory utilized the target and ranges published in the manufacturer's package insert to evaluate QC acceptability and did not establish their own.
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. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through observation, review of tests classifications on the FDA.gov website, review of Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) quality control records for April 2021 through July 2021, lack of documentation, patient result reports and interview it was determined that the laboratory failed to perform external quality control (QC) within eight hours of patient testing for 48 of 48 PT analyses performed. Finding follow: A) In an initial tour of the laboratory at 11:15 AM on 9/7/21 an Accriva Hemochron instrument was observed in the laboratory and the laboratory staff member, identified as number 3 on the CMS 209 form, stated that the Accriva Hemochron instrument was recently put into use to perform PT and PTT testing. B) Review of tests classifications on the FDA website revealed that PT and PTT tests performed on the Accriva Hemochron instrument were classified as moderate complexity. C) Review of QC records for April 2021 through July 2021 revealed that external QC was performed only one time each month. D) Review of patient test results revealed that 48 PT tests were performed from 4/27/21 to the date of the survey and none of the assays were performed within eight hours of external QC performance. E) In an interview on 9/8/21 at 10:00 AM the laboratory staff member, identified as number 3 on the CMS 209 form stated that it was thought that the Accriva Hemochron performed waived category testing and that they followed manufacturer's instruction by performing external QC for evey lot and shipment of test cartridges and once per month. F) Upon request the laboratory was unable to provide an IQCP for PT assays performed on the Accriva Hemochron analyzer and on 9/8/21 at 10:00 AM the laboratory staff member, identified as number 3 on the CMS 209 form, said that they had not established an IQCP for the Accriva Hemochron analyzer.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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: Through review of the laboratory policy and procedure "Reporting Quality Control

	Results", the Quality Control (QC) Log for January 2021, notes of corrective action, patient result reports, lack of documentation and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on one of one occasions in one of 31 days of operation when QC failed criteria for acceptability for sodium (NA), potassium, (K), and chloride (CL) analyses and corrective action required changes to the analytic systems. Finding follow: A) Review of the laboratory policy and procedure " Reporting Quality Control Results" revealed that action to be taken when QC fails criteria for acceptability incuded"with-hold patient results until the problem is solved and both controls are in acceptable limits" and "then you must rerun patients from the previous day" B) Review of the QC log for January 2021 revealed that level 1 and level 3 Biorad Mutliqual chemistry controls, Lot #' 45830 were flagged as unacceptable on 1 /30/21 with a corrective action of "repeated ISE controls" and were flagged as unacceptable on 1/31/21 with a corrective action of " OK after maint. tech support recommended manual enhanced cleaning". The latter corrective action represented a change in the analytic system. C) Review of patient result reports revealed that NA, K, Cl, tests were performed and reported on two patients, identified as numbers one and two on a separate patient identification list, on 1/30/21. D) Upon request, the laboratory was unable to provide documentation that the patient results reported back to the last successful QC on 1/30/21 had been evaluated. E) In an interview on 9/8/21 at 12:00 PM the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the Na, K, and CL results reported on 1/30/21 had not been evaluated and they should have been.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (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: Through a review of personnel records for three laboratory testing personnel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory director did not give written authorization for testing personnel to perform testing without direct supervision for two of three personnel reviewed. Survey findings include: A) Through a review of personnel records for the three laboratory testing personnel who have begun working since the last CLIA survey it was determined that the written authorization to test was not present for testing personnel, identified as numbers 3 and 8 on the CMS 209 form. There were no other written authorizations in the personnel records. B) Upon request, the laboratory was unable to provide written authorization to test from the laboratory director for the testing personnel, identified as numbers 3 and 8 on the CMS 209 form. C) In an interview, at 02:15 PM on 9/7/21, laboratory personnel #3 (as listed on the form CMS-209) confirmed the laboratory director had not signed written authorizations stating the tests each employee was

	approved to perform or whether direct supervision was required for the testing personel identified above.