Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0673176	05/09/2019
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Through interview, review of the Roche Coaguchek manuafacturer's insert, review of laboratory charge reports, "Coaguchek finger stick PT log" , patient medication histories and lack of documentation it was determined that the laboratory failed to use the Roche Coaguchek coagulation analyzer as directed in the manufacturer's instructions when performing prothrombin time testing for ten of nineteen patients with prothrombin time testing from March 9, 2019 through May 7, 2019. Findings follow: A) In an interview on May 7, 2019 at approximately 01:15 PM the technical consultant, identified as number 2 on the CMS 209 form stated that the laboratory no longer performs moderately complex coagulation testing but only performs prothrombim time and INR testing on the (waived classified) Coaguchek instrument and refers all partial thromboplastin time testing to the referral laboratory. B) Review of the Roche Coaguchek manufacturer's insert revealed that "any failure to follow test system instructions, including those for limitations/intended use results in use that is considered high complexity and subject to all applicable CLIA requirements", and "the Coaguchek system is intended for use by professional healthcare providers for quantitative prothrombin time testing for monitoring warfarin therapy". C) Review of the Laboratory Charge Log revealed that prothrombin time testing was performed on nineteen different patients, identified on a separate patient identification list, beween March 9, 2019 and May 7, 2019. D) Review of the "Coaguchek finger-stick PT log" revealed that the prothrombin times for the nineteen patients identified above were performed on the Coaguchek instrument. D) Review of the patient's medication histories in the patient's medical records revealed that ten of patients with prothrombin

	time testing, identified on a separate patient identification list, had no history of warfarin therapy. E) Upon request, the laboratory could not produce test establishment documentation which would support using the Coaguchek as a highly complex methodology. F) In an interview on May 9, 2019 at approximately 11:00 AM the technical consultant, identified as number 2 on the CMS 209 form, and the testing personnel, identified as number 3 on the CMS 209 form, confirmed that prothrombin time tests were performed using the Coaguchek analyzer upon order with no regard of the patient's medication history or reason for the test order and that method establishment for using the Coaguchek as a highly complex method had not been accomplished.
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: . 1. Through a review of the policy and procedure manual, Osmetech Opti-Check Blood Gas Analyzer user manual, temperature records for 2018 and 2019, observations, lack of documentation, as well as interviews with staff, it was determined the Blood Gas laboratory failed to monitor temperatures and humidity that are essential for the proper storage of supplies and the operation of Blood Gas analyzer. As evidence by: A. A review of the Blood Gas policy and procedure manual revealed the laboratory failed to define ranges for room temperature and humidity. B. A review of the user manual for the Osmetech Opti-Check Blood Gas Analyzer appendix A revealed the technical specifications of the analyzer " Operating temperature 10-32 degrees Celsius (50-90 degrees Fahrenheit) and humidity 5% -95%." C. A review of temperature records for 2018 (12 of 12 months) revealed the Blood Gas laboratory failed to document daily room temperatures and humidity 20 of 31 days in January 2018; 15 of 28 days in February 2018; 13 of 31 days in March 2018; 16 of 30 days in April; 18 of 31 days in May 2018; 24 of 30 days in June 2018; 19 of 31 days in July 2018; 24 of 31 days in August 2018; 23 of 30 days in September 2018; 28 of 31 days in October 2018; 30 of 31 days in November 2018 and 28 of 31 days in December 2018. D. A review of temperature records for 2019 (4 of 4 months) revealed the Blood Gas laboratory failed to document daily room temperatures and humidity 29 of 31 days in January 2019; 24 of 28 days in February 2019; 30 of 31 days in March 2019 and 30 of 30 days in April 2019. E. During a tour of the Blood Gas laboratory on 5/8/2019 at 1500, the surveyor observed the following stored at room temperature: Osmetech Opti-Check Blood Gas Analyzer, one box of Opti-Check B Cassette (Lot # 903100 expires 9/2019 storage temperature 15-30 degrees Celsius) one box of Opti-Check Quality Controls (lot # 8223 expires 5/2020 storage temperature 15-30 degrees Celsius). F. In an interview on 5/8/2019 at 1500, Blood Gas laboratory personnel #1 (as listed on CMS form 209) confirmed the laboratory did not define ranges for room temperature and humidity and the laboratory failed to document daily room temperatures and humidity. 2. Through a review of the user manuals for Beckman Coulter Hematology Analyzer, Alere Triage Boisite Chemistry

	Analyzer, and Ortho Vitros 350 Chemistry Analyzer, temperature records for 2018 and 2019, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to monitor humidity conditions that are essential for the proper operations of the Hematology and Chemistry analyzers. As evidenced by: A. A review of the user manual section "Specifications" for the following analyzers revealed Beckman Coulter Hematology analyzer operating temperature 15-30 degrees Celsius and Humidity 10%-85%: Alere Triage Chemisty analyzer operating temperature 15-30 degrees Celsius and Humidity 10%-85%: Ortho Vitros 350 Chemistry analyzer operating temperature 15-30 degrees Celsius and Humidity 15%-75%. B. A review of the temperature records for 2018 (12 of 12 months) and 2019 (4 of 4 months) revealed the laboratory were not monitoring Humidity conditions. C. The surveyor requested Humidity for 2018 and 2019. None was provided. D. In an interview on 5/08/2019 at 1530 laboratory personnel #3 (as listed on CMS form 209) confirmed the laboratory were not monitoring humidity conditions. 35659 . 3. Through observation, lack of documentation and interview it was determined that room temperature was not documented in two of three rooms in which supply items with storage temperature requirement were stored. Findings follow: A) In a tour of the laboratory on May 8, 2019 at approximately 02:00 PM the following items with a storage temperature requirement of 4 degrees C. to 25 degrees C. were observed in a separate phlebotomy room ; 70 BD Na Citrate blood collection tubes lot# B19013 expiration date 2020-01-04, 270 BD EDTA blood collection tubes lot# 9004576 expiration date 2020-05-31, 50 BD Heparin blood collection tubes lot# B19013FS expiration date 2020-04-14, 3800 BD Serum blood collection tubes lot# 9059672 expiration date 2020-07-31, and 300 BD SST blood collection tubes lot# 9049992 expiration date 2020-02-29. B) Upon request, the laboratory was unable to provide room temperature records for the room identified above. C) In an interview on May 8, 2019 at approximately 03:00 PM, the testing personnel identified as number 3 on the CMS 209 form, confirmed that the room temperature of the room identified above was not documented.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Through a review of the Osmetech Opti-Check Blood Gas Analyzer user manual, 2018 and 2019 maintenance logs, lack of documentation, and interviews with Respiratory staff, it was determined the Respiratory laboratory failed to perform quarterly maintenance as specified by the manufacturer. As evidence by: A. A review of the user manual for Osmetech Opti-Check Blood Gas analyzer section 6.3 " "Quarterly Maintenance Performing the tHb Calibration" revealed: "the tHb chamber must be calibrated quarterly." B. A review of maintenance records for Osmetech Blood Gas analyzer for 2018 (4 of 4 quarters) revealed the quarterly maintenance was only performed in April of 2018 (1 of 4 quarters). C. The surveyor requested documentation of quarterly maintenance for the first quarter (January, February and March) third quarter (July, August and September) and four quarter (October, November and December) of 2018. None was provided. D. In an interview on 5/8 /2019 at 1430 Respiratory personnel #1 (as listed on CMS form 209) confirmed the laboratory failed to performed quarterly calibration of tHb chamber.

D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through review of the laboratory policy for "Emergency Issue of Blood", review of "Release for Uncrossmatched Blood" forms, lack of documentation, and interview it was determined that the laboratory failed to ensure and keep records of post release crossmatches on units released under emergency release protocol on four of four units released since January 1, 2019. Findings follow: A) In an interview on May 7, 2019 at approximately 01:30 PM, the technical consultant, identified as number 2 on the CMS 209 form, stated that the hospital laboratory has no blood bank crossmatching capabilities and patients seen in the emergency room that require transfusions are given O negative packed red blood cells (PRBC) on emergency release protocol and immediately transferred to a receiving hospital. B) Review of the laboratory policy for "Emergency Issue of Blood" revealed that the laboratory "will be 100% emergency of blood only" and "the facility will keep on hand O negative units only to be used for emergency release of blood" and "any requests for an out-patient transfusion will require that the patient be referred to another facility that has a full blood bank service". No mention of a method to follow-up with a post release crossmatch is addressed in the policy. C) Review of emergency release forms revealed that the laboratory released four units of packed RBC's under emergency release protoocol to three separate patients since January 1, 2019. The receiving patients and unit numbers are documented on a separate "Blood Bank Patient and Blood Unit" identification list. D) Upon request, the laboratory was unable to provide documentation of post-release crossmatch results for the patients and units cited above. E) In an interview on May 9, 2019 at approximately 10:45 AM, the testing personnel identified as number 3 on the CMS 209 form stated that no record was kept or sought from the hospital to which patients had been transferred. This was confirmed by the technical consultant, identified as number 2 on the CMS 209 form, during the exit conference on May 9, 2019 at approximately 11:45 AM.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Through review of the laboratory's policy and procedure for "Blood Bank Alarm", records of the blood bank refrigerator alarm checks, observation, lack of documentation and interview it was determined that the laboratory failed to perform blood storage refrigerator alarm checks for the period of May 8, 2017 through May 8, 2019 inclusive. Findings follow: A) Review of the laboratory's policy and procedure for "Blood Bank Alarm" revealed that the blood bank refrigerator has an alarm that sounds at the nursing station in the event of malfunction since the laboratory is not staffed on a 24 hour per day seven day per week basis. B) Review of the laboratory documentation for blood bank refrigerator alarm check revealed that the last documented alarm check was performed on May 8, 2017. C) Upon request, the laboratory was unable to provide documentation of blood bank refrigerator alarm checks performed since May 8, 2017. D) During a tour of the laboratory on May 8, 2019 at approximately 03:00PM, six units of packed red cells with the blood type of O negative, (unit numbers; W0451 19 402647, W0451 19 402168, W0451 19 402700, W0451 19 252682, W0451 10 204455, and W0451 19 204705) were observed in the blood bank refrigerator. E) In an interview on May 8, 2019 at approximately 03:00 PM, the testing personnel, identified as number three on the CMS 209 form, stated that the laboratory keeps six units of O negative packed red cells available at all times for emergency release and that no blood bank refrigerator alarm checks had been performed since May 8, 2017.