Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472340	05/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jefferson County Hospital	9170 Us Hwy 70, Waurika, OK	

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
D0000	The recertification survey was performed on 05/19,20,2021. The findings were reviewed with technical consultant #1 and technical consultant #2 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to have a written technical consultant and general supervisor competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On 05/19/2021, the surveyor reviewed personnel records for competency assessments performed during 2019, 2020, and to date in 2021. There was no evidence competencies had been performed for the technical consultant and general supervisor based on job responsibilities; (2) The surveyor asked technical consultant #1 if a written policy to evaluate the technical consultant and general supervisor, based on job responsibilities, was available and if competencies had been performed during the review period. Technical consultant #1 stated to the surveyor on 05/19 /2021 at 02:47 pm, a policy to evaluate the technical consultant and general supervisor based on job responsibilities had not been written; and competencies had not been performed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to ensure the demonstrated reportable range was utilized for a new analyzer for 2 of 2 test methods. Findings include: (1) On 05/19/2021 at 10:40 am, technical consultant #1 stated to the surveyor: (a) The laboratory performed Sodium, Potassium, Chloride, Blood Urea Nitrogen (BUN), Ionized Calcium, TCO2, Glucose, Creatinine and Hematocrit testing using two iSTAT analyzers (serial numbers: 393493 and 389725) and Chem 8+ cartridge beginning 07/14/2020; (b) The laboratory performed pH, TCO2, and Po testing using two iSTAT analyzers (serial numbers: 393493 and 389725) and the EEG+ cartridge beginning 02/10/2020. (2) On 05/20/2021, the surveyor requested the performance verification records to verify how the laboratory demonstrated performance verification on the Chem 8+ cartridge and EEG+ cartridge prior to reporting patient results on two iSTAT analyzers. The surveyor reviewed the records and identified the following: (a) Chem 8+ cartridge (i) TCO2 - The laboratory's reportable range was verified to report out patient values between 12 - 43 mmol/L. The manufacturer's reportable range was 5 - 50 mmol/L; (ii) Glucose - The laboratory's reportable range was verified to report out patient values between 25 - 583 mg/dL. The manufacturer's reportable range was 20 - 700 mg/dL. (b) EG6+ cartridge; (i) PCO2 - The laboratory's reportable range was verified to report out patient values between 18.7 - 91.9 mmHg. (3) The surveyor reviewed patient records between 12/05/2020 and 04/04/2021, and obtained the following examples of CO2, Glucose, and PCO2 patient testing that were reported outside the laboratory's verified reportable range as follows: (a) TCO2 patient testing (i) Patient resulted on 01/04/2021 at 03:21 am a value of >50 mmol/L; (ii) Patient resulted on 02/08/2021 at 06:42 pm a value of >50 mmol/L; (iii) Patient resulted on 04/04/2021 at 06:47 pm a value of >50 mmol/L. (b) Glucose patient testing (i) Patient resulted on 12/05/2020 at 06:09 pm a value of >700 mg/dL. (c) PCO2 patient testing (i) Patient resulted on 1/04/2021 at 03:48 pm a value of 126 mmHg; (ii) Patient resulted on 04/04/2021 at 06:46 pm a value of >130.0 mmHg; (iii) Patient resulted on 04/04/2021 at 07:30 pm a value of 115.5 mmHg. (4) The surveyor reviewed the findings with the technical consultant #1 who stated on 05/20/2021 at 02:05 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory.
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: Based on a review of records and interview with technical consultant #1, the laboratory failed to ensure data supported the QC frequency as defined in the QCP portion of the IQCP. Findings include: (1) On 05/19/2021 at 10:40 am, technical consultant #1 stated the following to the surveyor: (a) The laboratory performed Blood Gas (pH, pCO2, pO2) testing using two iSTAT analyzers (serial numbers: 393493 and 389725) and the EG6+ cartridge beginning 02/10/2020; (b) The laboratory performed Sodium, Potassium, Chloride, Blood Urea Nitrogen (BUN), Ionized Calcium, TCO2, Glucose, Creatinine, Hemoglobin and Hematocrit testing using two iSTAT analyzers (serial numbers: 393493 and 389725) and the Chem 8+ cartridge beginning 07/14/2020; (b) An IQCP had been developed for the test systems above. (2) The surveyor reviewed the IQCP (dated as effective on 01/15/2020 for the EG6+ cartridge; and 07/13/2020 for the Chem 8+ cartridge) and identified the QCP required two levels of external QC materials be performed once each month (i.e., approximately each 30 days); (3) The surveyor then reviewed the supporting documentation for the QCP and identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (b) Two levels of QC had been tested for 2 days (not at least 30 days). (4) The surveyor reviewed the records with technical consultant #1 and asked if additional documentation was available to support the reduced external QC frequency of monthly. Technical consultant #1 stated QC had not been tested for at least 30 days.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of written policies and interview with the director of nursing, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 2 of 12 units of packed red blood cells. Findings include: (1) On 05/19 /2021 at 10:55 am, technical consultant #1 stated to the surveyor the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) The surveyor reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood Product Transfusion Policy and Procedure" under the section titled, "DOCUMENTATION", stated: (a) "Vital Signs" (i) "Pre-transfusion vital signs should be taken within the 30 minutes preceding the transfusion." (ii) "Next set of vitals signs should be taken 15 minutes (+/- 5 minutes) after the beginning of the transfusion." (iii) "Subsequent vital signs should then be taken every 30 minutes (+/- 5 minutes) thereafter until the unit of blood product is

	completely infused." (iv) "All vital signs should be documented in the TAR system when possible. When TAR documentation is not able to be used, the paper Blood Transfusion Records should be used." (v) "If the patient is not in crisis, it is preferable to do the 30-minute post-transfusion vital signs prior to spiking the second unit of blood." (vi) "In emergencies only, vital signs may be recorded separately on anesthesia /surgery/emergency department records." (3) The surveyor then reviewed records for 12 units of PRBCs (Packed Red Blood Cells) that had been transfused between 01/14 /2019 through 07/28/2019 for 6 patients, and identified the following: (a) Vitals signs the first 15 minutes after the transfusion started (i) Patient # J00000618553 - Transfused with 1 unit PRBCs (unit # W091020455662) on 12/22/2020. The transfusion started at 09:05 pm and the first vital was documented at 10:50 pm (1 hour 45 minutes later). (b) Vitals signs every 30 minutes after the first 15 minutes of the transfusion (i) Patient #J00000623009 - Transfused with 1 unit PRBCs (unit #W09102114255) on 01/17/2021. The transfusion started at 07:04 pm and ended at 08: 17 pm. Vitals were document at 07:19 pm, 07:34 pm and 08:17 pm (43 minutes later). (4) The surveyor reviewed the findings with the director of nursing. The director of nursing stated on 05/19/2021 at 01:45 pm the written policy and procedure for blood administration had not been followed as indicated above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to make appropriate reference ranges available. Findings include: (1) On 05/19/2020 at 10:05 am, technical consultant #1 stated to the surveyor the ACL Elite analyzer was used to perform PT (ProthrombinTime) testing; (2) On 05/19/2020, the surveyor reviewed the implementation records for the current lot number of reagent and identified the following: (a) PT reagent - RecombiPlasTin 2G lot # N0100845 had been put into use on 05/04/2021; (b) The laboratory had established a PT normal reference interval of 10.3 - 12.6 seconds. (3) The surveyor then reviewed a patient PT report dated 05/08/2021 with a normal reference range of 9.9 -12.9 seconds; (4) The surveyor reviewed the findings with technical consultant #1. On 05 /19/2021 at 04:45 pm technical consultant #1 stated that although the laboratory had established a PT normal reference interval with a PT reagent lot change, the laboratory had not implemented the change into the laboratory's computer information system as indicated above.