Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472340	02/07/2019
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	Recertification survey was performed on 02/04/19 through 02/06/19. The findings were reviewed with the technical consultant, testing person #1, testing person #2 and the chief executive officer during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1210; D5016: Routine Chemistry 493.1403; D6000: Laboratory Director, Moderate Complexity
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records. The following was identified for 5 of 61 testing events: (a) J-A 2017 Transfusion Medicine Event (i) The attestation was not signed by the laboratory director or designee. (b) J-B 2017 Transfusion Medicine Event (i) The attestation was not signed by the laboratory director or designee. (c) J-A 2018 Transfusion Medicine Event (i) The attestation was

	not signed by the laboratory director or designee. (d) J-B 2018 Transfusion Medicine Event (i) The attestation was not signed by the laboratory director or designee. (e) J-C 2018 Transfusion Medicine Event (i) The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with the technical consultant who stated the attestations had not been signed as indicated above.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry for Troponin I, CKMB, BNP (Brain Natriuretic Peptide), and ABG (G3+ cartridge: pH, pCO2, pO2) testing. Findings include: (1) The laboratory failed to perform two levels of quality control materials each day of patient Troponin I, CKMB (Creatine Kinase, Isoenzyme), BNP (Brain Natriuretic Peptide), and ABG (Arterial Blood Gas G3+ cartridge: pH, pCO2, pO2) testing. Refer to D5447; (2) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records. The following biases were identified (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Hematology Auto Differentials - FH9-C 2017 Event (i) Eosinophils Absolute- 4 of 5 results exhibited a negative bias (aa) FH9 - 12 SDI of -10.6 (bb) FH9 - 13 SDI of -11.3 (cc) FH9 - 14 SDI of -11.5 (dd) FH9 - 15 SDI of -11.2 (ii) Basophils Absolute - 4 of 5 results exhibited a negative bias (aa) FH9 - 12 SDI of -10.0 (bb) FH9 - 13 SDI of -6.5 (cc) FH9 - 14 SDI of -11.1 (dd) FH9 - 15 SDI of -10.8 (b) Hematology Auto Differentials - FH9-B 2018 Event (i) Lymphocytes % - 3 of 5 results exhibited a negative bias (aa) FH9 - 07 SDI of -2.1 (bb) FH9 - 08 SDI of -2.1 (cc) FH9 - 10 SDI of -2.2 (c) Critical Care Aqueous Blood Gas - AQI-A 2018 Event (i) pH - 3 of 5 results exhibited a negative bias (aa) AQI - 02 SDI of -2.0 (bb) AQI- 04 SDI of -2.0 (cc) AQI - 05 SDI of -2.1 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the technical consultant, and asked if the biases had been addressed. The technical consultant stated the biases had not been addressed.

D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology Auto Differentials (i) FH9-C 2017 Event (aa) 5 of 5 Blood Cell Identification, BCP-26, BCP-27, BCP-27, BCP-29, BCP-30 (b) Urine Drug Screening (i) UDS-C 2017 Event (aa) 1 of 1 Opiate Group, UDS-14 (c) Hematology Auto Differentials (i) FH9-B 2018 Event (aa) 5 of 5 Blood Cell Identification, BCP-16, BCP-17, BCP-18, BCP-19, BCP-20. (d) Plasma Cardiac Markers (i) PCARM-C 2018 Event (aa) 1 of 1 B-Type Natriuretic Pep PCAR-12 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded results; (3) The surveyor asked the technical consultant if the results had been documented as evaluated. The technical consultant reviewed the records and stated the non-graded results had not been documented as reviewed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for verifying morphology flags, precision determination of a new analzyer and changing lot numbers of quality control materials. Findings include: HEMATOLOGY (1) On the first day of the survey, the technical consultant stated that CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) On third day of the survey, the surveyor reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) Immature Grans? - "Perform manual differential" (b) Left Shift? - "Perform manual differential" (c) Neutrophilia - "Review manual smear" (d) PLT Clumps? - "Verify on slide. Recollect sample if present." (3) The surveyor randomly reviewed 9 patient records which contained morphology flags from CBC testing performed between 07/07/18 throught 02/06/19. For 3 of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the 3 records were: (a) Patient testing was

	performed on 04/07/18, with Left Shift? flags obtained; (b) Patient testing was performed on 07/07/18, with Immature Gran? flag obtained; (c) Patient testing was performed on 12/04/18, with Neutrophilia and PLT Clumps? flag obtained. (4) The surveyor reviewed the records with the technical consultant, who stated the flags obtained for the above 3 patients had not been verified. PRECISION DETERMINATION INSTALLATION OF A NEW ANALYZER (1) On the fourth day of the survey, the technical consultant stated to the surveyor the IL ACL Elite analyzer was put into use to perform PT/INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromblplastin Time) and D-Dimer testing on 06/09 /17; (2) The surveyor reviewed the manufacturer's Hemostasis Performance Verification Manual instructions for the Precision Determination of the IL ACL Elite, which were as follows: (a) Section 5-1 titled "PRECISION DETERMINATION," required 20 replicates using the following screening guidelines: (i) "TOTAL RUN PRECISION: Analyze the chosen materials over a number of runs and days so that there is a minimum total number of 20 replicates at each concentration (more days will give a better estimate of the day-to-day variability). Try to evenly balance the numbers of replicates per day in order to not bias the data to one or another." (3) The implementation records were reviewed by the surveyor with the following identified: (a) The minimum number of 20 replicates had not been documented as performed (i) 18 replicates had been documented as performed (4) The surveyor review the manufacturer's instructions with the technical consultant who stated the Total Run Precision had not been performed according to manufacturer instructions. CHANGING LOT NUMBER CONTROL (1) On the fourth day of the survey, the technical consultant stated to the surveyor the IL ACL Elite analyzer was put into use to perform PT/INR (Prothrombin Time/International Normalized Ratio) testing on 06 /09/17; (2) The surveyor reviewed the manufacturer's Hemostasis Performance Verification Manual instructions for the Changing Lot Number of Control of the IL ACL Elite, which were as follows: (a) Section 10-9 titled "CHANGING LOT NUMBER OF CONTROL," required 20 replicates using the following screening guidelines: (i) "2. Perform at least 20 runs (once per day for 20 days) of each test for each level of control. A greater number of runs may improve the statistics of the assay range." (3) The surveyor reviewed PT records and identifed the quality control lot numbers changed in June 2018.The laboratory failed to follow manufacturer instruction for changing the lot numbers as follows: (a) The minimum number of 20 replicates had not been documented as performed (i) 15 replicates had been documented as performed for PT normal lot# N0771137 quality control and PT abnormal lot# N0871604 quality control (4) The surveyor review the manufacturer's instructions with the technical consultant who stated the change in control lot numbers had not been performed according to manufacturer instructions.
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:

	Based on a review of records, observation, and interview with the technical consultant, the laboratory failed to ensure materials were being stored as required. Findings include: (1) On the first day of the survey, the surveyor observed the outpatient draw station. The following were examples of materials being stored in the area, along with the manufacturer's storage requirements: (a) Blood Collection tubes used for CBC (Complete Blood Count) testing performed on the Sysmex XS-1000i analyzer and collecting reference (send out) specimens: (i) BD Vacutainer PST Gel and Lithium Heparin tubes (8 tubes of lot# 8187744 with a storage requirement of 4-25 degrees Celsius) (ii) BD Vacutainer K2 EDTA tubes (25 tubes of lot#8249525 with a storage requirement of 4-25 degrees Celsius) (b) Blood Collection tubes used for Coagulation testing performed on the IL ACL Elite analyzer: (i) BD Vacutainer Buffer Sodium Citrate 3.2% tubes (9 tubes of lot#81565595 with a storage requirement of 4-25 degrees Celsius) (2) The surveyor reviewed temperature records for January 2018 through June 2018 and could not locate documented temperature records for the outpatient draw station; (3) The surveyor asked the technical consultant if the temperature of the draw station was being monitored. The technical consultant stated the laboratory was not monitoring the temperature of the outpatient draw station.
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: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, the technical consultant stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (b) Coagulation testing PT/INR (Prothrombin Time/International Normalized Ratio, PTT (Partial Thromboplastin Time) and D-Dimer was performed on the IL ACL Elite analyzer. (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs: (a) Sysmex 1000i Weekly Maintenance (i) Power Down IPU (b) IL ACL Elite Weekly Maintenance (i) Clean Instrument Surfaces (ii) Clean Rinse/Waste Reservoir (iii) Verify Needles alignment (3) The surveyor then reviewed maintenance records for 19 months (June 2017 through December 2018). There was no evidence the following maintenance had been performed: (a) Sysmex 1000i Weekly Maintenance (i) Between 10/22/18 and 11/05/18 (b) IL ACL Elite Weekly Maintenance (i) Between 07/10/17 and 07/21/17 (ii) Between 07/28/17 and 08/07/17 (iii) Between 04 /09/18 and 04/22/18 (4) The surveyor reviewed the records with the technical consultant, who stated the maintenance had not been documented as performed as required.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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--

At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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 the technical consultant, the laboratory failed to perform two levels of control materials each day of patient Troponin I, CKMB (Creatine Kinase, Isoenzyme), BNP (Brain Natriuretic Peptide), and ABG (Arterial Blood Gas G3+ cartridge: pH, pCO2, pO2) testing Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor the laboratory performed Troponin I, CKMB, BNP and ABG (G3+ cartridge: pH, pCO2, pO2) testing using the Abbott iSTAT analyzer; (2) On the third day of the survey, the surveyor asked the technical consultant if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The technical consultant stated an IQCP had been approved by the laboratory director on 01/16/19. Therefore, the surveyor determined two levels of QC (quality control) materials must be performed each day of patient testing before the IQCP was approved by the laboratory director on 01/16/19; (3) The surveyor reviewed QC and patient testing records for July 2017 through December 2018. The review indicated negative and positive QC materials had not been performed 47 of 47 days of patient testing reviewed; (4) The surveyor reviewed the records with the technical consultant who stated two levels of QC materials had not been performed each day of patient testing; (5) The following patient Troponin I, CKMB, BNP, and ABG testing had been performed when two levels of QC materials had not been tested: (a) Troponin I (i) Patient #2 - testing performed on 07/02/17 (ii) Patient #5 - testing performed on 08/01/17 (iii) Patient #9 - testing performed on 09/05/17 (iv) Patient #12 - testing performed on 10/13/17 (v) Patient #16 - testing performed on 11/12/17 (vi) Patient #18 - testing performed on 12/09/17 (vii) Patient #22 - testing performed on 01/04/18 (viii) Patient #25 - testing performed on 01/17/18 (ix) Patient #26 - testing performed on 02/05/18 (x) Patient #29 - testing performed on 03/04/18 (xi) Patient #33 - testing performed on 05/10/19 (xii) Patient #35 - testing performed on 06/04/18 (xiii) Patient #43 - testing performed on 10/01/18 (xiv) Patient #44 - testing performed on 11/03/18 (xv) Patient #46 - testing performed on 12/13/18 (b) CKMB (i) Patient #3 - testing performed on 07/02/17 (ii) Patient #7 - testing performed on 08/06/17 (iii) Patient #13 - testing performed on 10/13/17 (iv) Patient #20 - testing performed on 12/19/17 (v) Patient #24 - testing performed on 01/17/18 (vi) Patient #28 - testing performed on 02/19/18 (vii) Patient #30 - testing performed on 03/04/18 (viii) Patient #32 - testing performed on 04/10/18 (ix) Patient #34 - testing performed on 05/28/18 (x) Patient #36 - testing performed on 06/14/18 (xi) Patient #38 - testing performed on 07/10/18 (xii) Patient #47 - testing performed on 12/22/18 (c) BNP (i) Patient #4 - testing performed on 07/20/17 (ii) Patient #8 - testing performed on 08/20/17 (iii) Patient #11 - testing performed on 09/22/17 (iv) Patient #15 - testing performed on 10/23/17 (v) Patient #19 - testing performed on 12/12/17 (vi) Patient #27 - testing performed on 02/13/18 (d) ABG (i) Patient #1 - testing performed on 07/02/17 (ii) Patient #6 - testing performed on 08/06/17 (iii) Patient #10 - testing performed on 09/12/17 (iv) Patient #14 - testing performed on 10/23/17 (v) Patient #17 - testing performed on 11/26/17 (vi) Patient #21 - testing performed on 12/24/17 (vii) Patient #23 - testing performed on 01/09/18 (viii) Patient #31 - testing performed on 04/10/18 (ix) Patient #37 - testing performed on 06/22/18 (x) Patient #39 - testing performed on 07/15/18 (xi) Patient #40 - testing performed on 08/13/18 (xii) Patient #41 - testing performed on 09/02/18 (xiii) Patient #42 - testing performed on 10/01/18 (xiv) Patient #45 - testing performed on 11/07/18

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: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On the third day of the survey, the technical consultant stated to the surveyor Blood Bank alarms were checked quarterly for high/low activation; (3) The surveyor reviewed the refrigerator alarm check records from 06/01/17 through the 3rd day of the survey (02/05/19). The records indicated the alarm checks had not been performed quarterly. They had not been performed between 08/21/17 and 02/02/19; (4) The surveyor reviewed the records with the technical consultant who stated the alarm checks had not been performed quarterly as required.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the technical consultant, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for verifying morphology flags, precision determination of a new coagulation analyzer and changing lot number of quality control materials. Refer to D5411; (b) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (c) The laboratory failed to ensure materials were being stored as required. Refer to D5413; (d) The laboratory failed to perform two levels of control materials each day of patient Troponin I, CKMB, BNP (Brain Natriuretic Peptide), and ABG (G3+ cartridge: pH, pCO2, pO2, HCO3) testing. Refer to D5447.
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 the technical consultant, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex XS-1000i analyzer; (2) On the second day of the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 04/07/18 at 09:47 am; the second report was for an adult female patient with the testing performed on 12/07/18 at 11:35 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 4.2 - 6.1 10x6/L (b) Hemoglobin - 12.0 - 16.0 g/dL (c) Hematocrit - 37.0 - 47.0 % (3) The surveyor reviewed the findings with the technical consultant, who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (2) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services for Troponin I, CKMB, BNP (Brain Natriuretic Peptide), and ABG (G3+ cartridge: pH, pCO2, pO2) testing Findings

	include: (1) The laboratory director failed to ensure two levels of quality control materials were performed each day of patient testing. Refer to D5447;
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.