Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472340	05/19/2023
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 05/17,18,19/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
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, written policies and procedures, and interview with the technical consultant, the laboratory failed to have a written policy to assess the competency of the general supervisor, based on the position responsibilities as listed in Subpart M, for one of one person serving as general supervisor. Findings include: (1) On 05/18/2023 a review of the laboratory policy and procedure manual identified no evidence of a policy for assessing the competency of the general supervisor, including the frequency of the assessments; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of June 2021 through the current date identified competencies, based on job responsibilities, had not been performed for one of one person listed as general supervisor until 05/18/2023; (3) The findings were reviewed with the technical consultant who stated on 05/19/2023 at 09:00 am a policy had not been written and competencies had not been performed for the general supervisor until 05/18/2023.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant, the laboratory failed to follow their written policy for reporting a patient PT (Prothrombin Time) result beyond the reportable range for one of one report reviewed. Findings include: (1) On 05/17/2023 at at 10:55 am, the technical consultant stated the laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) testing using the ACL Elite analyzer; (2) On 05/18/2023 a review of a patient PT report performed on 09/14/2021, identified the PT result was reported as 178.0 seconds; (3) A review of the policy titled, "JCH PT Elite Policy" under "Reporting Results" stated "Report results that are above linearity as >115 sec"; (4) The findings were reviewed with the technical consultant who stated on 05/18/2023 at 01:45 pm, the policy had not been followed for reporting the result beyond the reportable range.
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 implementing two of two coagulation reagents. Findings include: (1) On 05/17/2023 at 11:43 am, the laboratory manager stated the laboratory performed PTT (Partial Thromboplastin Time) testing using the ACL Elite analyzer; (2) On 01/26/2023 at 09: 15 am, the laboratory manager stated the current PTT reagent, SynthaSIL lot #N1117768, was put into use on 01/28/2022; (3) A review of the manufacturer's instructions contained in the "Hemostasis Performance Manual" under "Establishing A Normal Reference Interval" under the heading "Specimen Collection and Preparation" stated the following for a 20 donor study: (a) "Donors should be healthy and have no known pathological conditions. Don't use samples from inpatients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-dose aspirin, etc"; (b) "Donors should span the adult age range"; (c) Donors should be equally divided between male/female". (4) A review of the implementation records for the PTT reagent identified that, although the laboratory had used 20 donors (identified as ten males and ten females), there was no documentation to show the health status and medication history of the donors to ensure they met the requirements for a normal donor; (5) The records were reviewed with the laboratory manager and testing person #2. Both stated on 01/27/2023 at 10:15 am, there was no documentation to prove the the health status and medication history of the donors.

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 the technical consultant, the laboratory failed to utilize the demonstrated reportable ranges for five of five analytes reviewed on the Ortho Vitros XT 7600 analyzer. Findings include: (1) On 05/17/2023 at 11:30 am, the technical consultant stated the laboratory began using the Ortho Vitros 7600 analyzer to perform routine chemistry testing, which included the analytes Alkaline Phosphatase, ALT (Alanine Aminotransferase), Amylase, Lipase, and Glucose using the Ortho Vitros XT 7600 analyzer in June 2022; (2) On 05/18/2023 a review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Alkaline Phosphatase - 14.9-1164.8 U/L (b) ALT - 7.9-717 U/L (c) Amylase - 43.7-892 U/L (d) Glucose - 33.6-600.8 mg/dl (e) Lipase - 21.6-1964 U/L (3) Interview with the laboratory manager on 05/18/2023 at 03:40 pm, confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) Alkaline Phosphatase - 20-1500 U/L (b) ALT - 4-750 U/L (c) Amylase - 30-1200 U/L (d) Glucose - 20-625 mg/dl (e) Lipase - 10-2000 U/L
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	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 calibration verification procedures at least once every 6 months for two of two analyte requiring calibration verification using the Ortho XT Vitros 7600 analyzer. Findings include: (1) On 05/17/2023 at 11:30 am, the technical consultant stated the laboratory began using the Ortho Vitros 7600 analyzer to perform routine Procalcitonin and DLDL (Direct Low Density Lipoprotein) testing using the Ortho Vitros XT 7600 analyzer in June 2022; (2) A review of calibration records for 2023 identified the calibration procedures for the above analytes were performed with less than three levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of records from 04 /05/2022 through the current date identified calibration verification had not been performed at least once every six months as follows: (a) Procalcitonin - Not performed since 04/05/2022 (performed during the implementation of the analyzer); (b) DLDL - Not performed since 04/05/2022 (performed during the implementation of the analyzer). (4) The records were reviewed with the technical consultant who stated on 05/18/2023 at 10:20 am, calibration verification procedures had not been performed every six months.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person #3, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for three of three months reviewed for testing performed using the the Ortho Vitros XT 7600 analyzer. Findings include: (1) On 05/17/2023 at 11:30 am, the technical consultant stated the following: (a) The laboratory began using the OrthoVitros XT 7600 analyzer to perform Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase, AST (Aspartate Aminotransferase), BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, Total Cholesterol, HDL (High Density Lipoprotein), Triglyceride, Troponin I, CKMB (Creatine Kinase Isoenzyme), Vancomycin, Alcohol, Ammonia, Lactic Acid, Procalcitonin, Lipase, and Amylase testing in June 2022; (b) Two levels of QC (quality control) materials were tested each day of patient testing. (2) On 05/19/2023 a review of records from February 2023 through April 2023 identified no evidence, such as Levey-Jennings graphs and cumulative statistical data, to prove that QC results had been monitored for variances (i.e.,biases, shifts, trends); (3) Interview with the technical consultant on 05/19/2023 at 10:15 am confirmed that QC data to include

	Levey-Jennings graphs and cumulative statistical data were reviewed each month on the analyzer (viewed on the analyzer's computer screen), however, there was no record of the reviews since the data had not been printed and maintained.
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 the technical consultant, the laboratory failed to perform QC (quality control) as stated in the IQCP's (Individualized Quality Control Plans) for two of six test systems. Findings include: (1) On 05/17/2023 at 11:15 am, the technical consultant stated the laboratory performed the following testing and IQCP's had been developed for the test systems: (a) Urine Drug Screen testing using the Jant Accutest test kit; (b) Troponin I testing using the cTnI cartridge and the iSTAT 1 analyzer. (2) On 05/18/2023 a review of the QCP's (Quality Control Plans) for the above IQCP's identified the following: (a) Urine Drug Screen - Two levels of QC materials were to be tested on a weekly basis and with new lot numbers of test kits; (b) Troponin I - Two levels of QC materials were to be tested on a monthly basis and with new lot numbers of cartridges. (3) A review of QC records for the test systems from June 2022 through April 2023 identified that QC testing had not been performed as stated in the QCP's as follows: (a) Urine Drug Screen - There was no documentation to prove QC had been performed between: (i) 12/24/2022 and 01/01/2023 (ii) 02/11/2023 and 02/19/2023 (iii) 03/29/2023 and 04/16/2023 (b) Troponin I - There was no documentation to prove QC had been performed between: (i) 01/05/2023 and 03/30/2023 (ii) 03/30/2023 and 05/04/2023 (c) Blood Gas - There was no documentation to prove QC had been performed between: (i) 02/25/2022 and 04/05/2022. (4) The records were reviewed with the technical consultant who stated on 05/18/2023 at 03:05 pm, QC had not been performed as stated above.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and testing person #3, the laboratory failed to follow the manufacturer's specifications for the Vitros Performance Verifier Controls for two of two lot numbers used from 02/19/2023 through the current date. Findings include: (1)

	On 05/17/2023 at 11:30 am, the technical consultant stated the following: (a) The laboratory began using the OrthoVitros XT 7600 analyzer to perform Amylase, Glucose, Chloride, and Lipase testing in June 2022; (b) Two levels of Vitros Performance Verifier QC (quality control) materials were tested each day of patient testing (level one lot #D8955 and level two lot #G9072 were in use during the review period). (2) On 05/19/2023 a review of the manufacturer's instructions (package insert) for the control materials identified the manufacturer provided a range of means for the laboratory to use when establishing their mean with new lot numbers of QC materials and provided a fixed SD (standard deviation) for the laboratory to utilize for each analyte; (3) Interview with testing person #3 on 05/19/2023 at 09:30 am and a review of records for the analytes Amylase, Glucose, Chloride, and Lipase confirmed the following: (a) Although the laboratory utilized the manufacturer's SD for each analyte, they did not establish their own means when new lot numbers of QC materials were put into use; (b) The laboratory calculated the means from the range of means instead of establishing laboratory specific means. (4) The records were reviewed with the technical consultant and testing person #3. Both stated on 05/19 /2023 at 09:40 am, the laboratory did not follow the manufacturer's instructions for the control materials.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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, written policy, and interview with the technical consultant, the laboratory failed to comply with 21 CFR 606.160(b)(3)(v). The laboratory failed to ensure that emergency release of blood forms had been signed by the physician for one of one emergency release reviewed. Findings include: (1) On 05 /17/2023 at 11:05 am, the technical consultant stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) On 05/18/2023 a review of the manual titled, "Laboratory Blood Bank Policy and Procedure" contained the policy titled, "Emergency Issue of Blood Products" and stated, "When the lab receives the call for the uncrossmatched blood, the patient information is entered on the BBK Emergency issue Forms (both copies). The O Negative units are delivered to the emergency department along with one copy of the BK Emergency Issue Form for the physician to sign..."; (3) Review of documentation for emergency issue of one unit of O Negative PRBC's to a patient on 09/14/2021 at 02:03 pm, identified the "BBK Emergency Issue Form" appeared to be signed by a nurse practitioner and not a physician. (4) The documentation was reviewed with the technical consultant who stated on 05/19/2023 at 01:05 pm, the ER release had not been signed by a physician.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. 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 patient test reports included the name and address of the laboratory location where the testing was performed for five of nine reports reviewed. Findings include: (1) On 05/18/2023, a review of patient reports identified the reports did not include the name and address of the laboratory location where testing was performed for the following: (a) Patient BNP testing performed on 11/20/2022 at 07: 23 am; (b) Patient Qualitative Serum HCG testing performed on 01/01/2023 at 10:55 pm; (c) Patient Troponin I testing performed on 02/19/2023 at 03:04 pm; (d) Patient Lactic Acid testing performed on 05/15/2023 at 07:31 pm; (e) Patient CMP (Comprehensive Metabolic Panel) and Lipid Panel testing performed on 05/17/2023 at 04:41 am. (2) The reports were reviewed with the technical consultant who stated on 05/18/2023 03:45 pm, the reports included the name and address of the main hospital location and not the name and address of the laboratory location where the testing was performed.