Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472340	04/11/2025
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 04/8,9,10,11/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the administrative laboratory director, technical consultant and chief executive officer at the conclusion of the survey.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, records, and interview with the technical consultant, the laboratory failed to follow written policy for alarm system checks for the blood bank refrigerator during the review period of June 2023 through the current date. Findings include: (1) On 04/10/2025 at 10:45 am, the technical consultant stated units of packed red blood cells were routinely maintained in the blood bank refrigerator for patient transfusions; (2) Policy review revealed a policy for performing alarm checks quarterly for the blood bank refrigerator; (3) A review of records revealed there were no blood bank alarm checks documented from 06/01/2023 through 03/14/2024. (3) Interview with the technical consultant on 04/10/2025 at 10: 45 am confirmed the laboratory failed to follow the policy for performing alarm checks for blood product storage.
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 administrative laboratory director, the laboratory failed to follow their written policy to assess the competency of the technical consultant and general supervisor based on the position responsibilities as listed in Subpart M, for one of one person during the review period of May 2023 through the current date. Findings include: (1) On 04/08 /2025, a review of the laboratory policy titled "JCH Laboratory Competency Assessment Procedure" required competencies for the technical consultant and general supervisor based on job responsibilities be performed annually; (2) A review of the Form CMS-209 and personnel records for competency assessments performed during the review period of May 2023 through the current date identified competencies, based on job responsibilities, had not been performed as follows: (a) Technical consultant - not documented as performed prior to 03/27/2025 (b) General supervisor - not documented as performed prior to 03/27/2025 (3) The findings were reviewed with the administrative laboratory director who stated on 04/08/2025 at 03: 09 pm, the competencies had not been performed for the positions as shown above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation and interview with the administrative laboratory director, the laboratory failed to ensure five of five types of blood collection tubes were stored as required by the manufacturer in the central supply room. Findings include: (1) Observation of the central supply room and interview with the administrative laboratory director on 04/08/2025 at 2:00 pm, identified the following: (a) Four packages of BD Vacutainer PST Gel and Lithium Heparin tubes, lot # 4318900, storage temperature of 4-25 degrees (C) centigrade; (b) Four packages of BD Vacutainer K2 EDTA 7.2 mg tubes, lot # 4318853, storage temperature of 4-25 degrees C; (c) Four packages of BD Vacutainer Serum Collection tubes, lot # 4198181, storage temperature of 4-25 degrees C; (d) Nine bottles of BD BACTEC aerobic/F culture vials, lot # 4358877, storage temperature of 2-25 degrees C; (e) Nine bottles of BD BACTEC anaerobic/F culture vials, lot # 4241909, storage temperature of 2-25 degrees C. (2) Interview with the administrative laboratory director on 04/08 /2025 at 02:00 pm confirmed the laboratory was not monitoring the temperature of the Central Supply Room.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to label one of two containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 04/08/2025 at 11:35 am, the technical consultant stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation on 04/08/2025 at 11:37 am identified one unlabeled Coplin jar, appearing to contain material used to stain peripheral blood smears; (3) The findings were reviewed with the technical consultant who on 04/08/2025 at 11:38 am stated the Coplin jar contained staining material had not been labeled with the identity, expiration date, and lot numbers.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 04/08/2025 at 10:10 am, identified the following expired supplies were available for use: (a) One hundred BD Vacutainer Citrate Tubes with 3.2% buffered sodium citrate, lot #4102214, expired 01/31/2025 (2) Interview with the technical consultant on 04/08/2025 at 11:13 am confirmed the expired supplies were available for use.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 ensure the manufacturer's instructions were followed for performing maintenance procedures for two of two analyzers. Findings include: ACL ELITE (1) On 04/08/2025 at 11:35 am, the technical consultant stated the laboratory performed PT/INR, PTT, and D-Dimer testing using the ACL Elite coagulation analyzer; (2) A review of the "ACL Elite/Elite Pro System Maintenance Log" from the manufacturer showed the following required maintenances: (a) Weekly: (i) Clean instrument surface (ii) Clean rinse/waste reservoir (w/Clean A) (iii) Verify needles alignment (b) Biweekly: (i) Clean rotor

	holder and optic path (ii) Reboot analyzer, (b) Monthly: (i) Clean air filter (3) A review of maintenance logs from August 2024 through March 2025 identified maintenance had not been documented as performed as follows: (a) Weekly: (i) Between 08/03/2024 and 08/17/2024 - Clean rinse/waste reservoir (w/CleanA) and verify needle alignment procedures were not performed (ii) Between 09/28/2024 and 10/13/2024 (iii) Between 01/25/2025and 02/08/2025 - Clean rinse/waste reservoir (w /CleanA) and verify needle alignment procedures were not performed (b) Biweekly: (i) Between 08/17/2024 and 09/07/2024 (ii) Between 09/21/2024 and 10/13/2024 (iii) Between 11/16/2024 and 12/15/2024 (iv) Between 12/15/2024 and 01/05/2025 (vi) Between 01/18/2025 and 02/15/2025 (vii) Between 02/15/2025 and 03/08/2025 (c) Monthly: (i) Between 08/16/2024 and 10/13/2024 (ii) Between 11/03/2024 and 01/05 /2025 (4) The records were reviewed with the technical consultant who stated on 04/11 /2025 at 09:15 am maintenance procedures had not been documented as performed as stated above. SYSMEX XN 550 (1) On 04/08/2025 at 11:30 am, the technical consultant stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN-550 analyzer; (2) A review of the manufacturer's instruction manual titled, "XN-L Series XN-550/XN-450/XN-350 - Troubleshooting", section 2.17 "Maintenance and Inspection Checklist" showed the following required maintenance procedure: (a) "Weekly - Routine Cleaning" (3) A review of maintenance logs from August 2024 through March 2025 identified maintenance had not been documented as performed as follows: (a) Weekly: (i) between 09/07/204 and 09/15/2024 (ii) between 10/19/2024 and 11/02/2024 (iii) between 11/23/2024 and 12 /01/2024 (iv) between 12/28/2024 and 01/06/2025 (4) The records were reviewed with the technical consultant who stated on 04/09/2025 at 04:52 pm, the weekly maintenance procedures had not been documented as performed as stated above. 48517 Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for the Ortho Vitros XT 7600 analyzer between June 2023 and December 2024. Findings include: (1) On 04/10 /2025 at 10:00 am, the technical consultant stated that chemistry and immunoassay testing was performed using the Ortho Vitros XT 7600 analyzer; (2) A review of the manufacturer's maintenance log showed the following required maintenance procedures: (a) Monthly; (i) Clean Cuvette Arm, Cuvette incubator, PM discard chute, Clean/Replace evaporation caps, PM incubator slot and insert blade channels, microsensor cover and ring areas, uIA reagent supply top cover, supply 3 pack opener, versa tip supply, reagent cooler filter; (ii) Perform system backup; (b) Bimonthly; (i) Change vapor adsorption cartridge; (ii) Clean master computer filter; (d) Six month; (i) Perform correction factors; (ii) Replace VITROS VersaTip Loader Compressor Filter; (iii) Replace system filter; (iv) Perform pad reflectance test. (3) A review of maintenance logs from June 2023 through December 2024 identified no documentation maintenance had been performed as follows: (a) Monthly - There was no documentation that monthly maintenance was performed for eight of 19 months; (b) Bimonthly - There was no documentation that bimonthly maintenance was performed for 14 of 19 months; (d) Six month - There was no documentation that six month maintenance was performed between 06/01/2023 and 11/01/2024. (4) The records were reviewed with the technical consultant who stated on 04/10/2025 at 10: 00 am, the analyzer maintenance had not been documented as performed as stated above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 administrative laboratory director, the laboratory failed to perform calibration verification procedures at least once every six months for the Ortho Vitros 7600 test system during the review period of 06/01/2023 through the current date. Findings include: (1) On 04/09/2025 at 10:45 am, the administrative laboratory director stated the laboratory performed direct low density lipoprotein (DLDL) testing using the Ortho Vitros 7600 chemistry and immunoassay analyzer; (2) A review of records from 06/01/2023 through the current date identified no evidence the calibration verification procedures had been performed for DLDL between 06/01//2023 and 10/24/2024. (3) The findings were reviewed with the administrative laboratory director, who stated on 04/09/2025 at 10:45 am, the calibration verification procedures had not been performed every six months as stated above.
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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP (Quality Control Plan) for five of five test systems. Findings include: (1) On 04/08 /2025 at 11:21 am, the technical consultant stated the laboratory performed the following testing and IQCP's (Individualized Quality Control Plans) had been developed for the test systems: (a) Blood Gas (pH, pCO2, pO2) testing using the iSTAT 1 analyzer and the EG6+ cartridge; (b) BNP testing using the iSTAT1 analyzer; (c) CK-MB testing using the iSTAT1 analyzer; (d) Troponin I testing using the iSTAT1 analyzer; (e) Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the iSTAT 1 analyzer and the Chem 8+ cartridge. (2) On 04/10/2025 a review of the IQCP's for the above test systems identified that QA (Quality Assessment) reviews of the QCP's were to be performed on an annual basis for each test system; (3) A review of records for the test systems

	from April 2023 through the current date identified no documentation that annual QA reviews had been performed prior to 03/10/2025; (4) The records were reviewed with the technical consultant who stated on 04/10/2025 at 09:15 am, annual QA reviews had not been documented as performed for the above test systems.