Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475664	03/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Choctaw Memorial Hospital	1405 E Kirk, Hugo, 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 03/21/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer and laboratory manager during an exit conference performed at the conclusion of the survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the laboratory manager, the laboratory failed to have step by step procedures for one of four

	procedures reviewed. Findings include: (1) On 03/18/2025 at 12:20 pm, the laboratory manager stated qualitative serum pregnancy testing was performed using the Cardinal Health hCG Combo Rapid Test and serum samples; (2) A review of the test volume list completed for the survey identified the laboratory performed approximately 23 qualitative serum pregnancy tests annually; (3) On 03/19/2025, a review of the laboratory's policy and procedure manual identified the manufacturer's package insert for the test kit; and the laboratory manager confirmed on 03/19/2025 at 11:10 am that the package insert served as the procedure for the testing; (4) A review of the package insert identified it did not include the following: (a) Quality control procedures including identity, number and frequency of testing controls; (b) The laboratory's system for entering results in the patient record and reporting patient results. (5) The findings were reviewed with the laboratory manager who stated on 03/19/2025 at 12: 10 pm, the procedure did not include the information as stated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 laboratory manager, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test system introduced into the laboratory in March 2023. Findings include: (1) On 03/18 /2025 at 02:30 pm, the laboratory manager stated the laboratory began using the Siemens Rapid Response 500e analyzer to perform Blood Gas (pH, pCO2, pO2) testing on 03/27/2023; (2) On 03/19/2025, a review of the performance specification records for the analyzer identified the laboratory had demonstrated the following reportable ranges: (a) pH - 6.704-7.758 (b) pCO2 - 15.0-169.3 mm Hg (c) pO2 - 38.2-517.9 mm Hg (3) Interview with the laboratory manager on 03/19/2025 at 09:50 am confirmed the laboratory was using the following manufacturer's reportable ranges for the analyzer instead of the reportable ranges that had been demonstrated by the laboratory: (a) pH - 6.5-7.8 (b) pCO2 - 5-200 mm Hg (c) pO2 -10-700 mm Hg
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the

	laboratory manager, the laboratory failed to follow their written protocol for ensuring the Blood Bank pipettes were functioning properly for one of two pipettes during the review period of March 2023 through the current date. Finding include: (1) On 03/19 /2025 at 10:00 am, the laboratory manager stated the following: (a) Blood Bank testing, to include ABO/Rh, Antibody Screen, and Compatibility testing were performed using the Ortho ID-MTS gel system; (b) Two ID Tipmaster pipettes (Serial Number A17X03771 and Serial Number A23502591), which were multidelivery pipettes (delivering 12.5 microliters, 25 microliters, and 50 microliters), were used for the testing. (2) A review of the policy titled, "Blood Bank Pipetor Calibration Verification" stated, "The two pipetors used in blood bank should be routinely checked for its calibration to ensure quality in blood banking procedures. A calibration verification will be done on each Pipetor on an annual basis to check quality"; (3) A review of records from 2023 through the current date identified for one of two pipettes, each volume setting had not been checked as follows: (a) Serial Number A23502591 - For the pipette calibration check performed on 12/11/2024, the 25 microliter setting had not been checked for one of two pipette checks performed. (4) The findings were reviewed with the laboratory manager who stated on 03/20 /2025 at 12:45 pm the 25 microliter setting was used to dispense commercial A1 and B cells for reverse typing and dispense patient plasma for Antibody Screen and Compatibility testing; and had not been checked for accuracy at the 25 microliter setting as stated above.
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). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, 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 eight of eight emergency release forms reviewed. Findings include: (1) On 03/19/2025 at 10:00 am, the laboratory manager stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) A review of "Emergency Release of Uncrossmatched Blood/Blood Products" forms dated 03/05/2024 through 02/13/2025 identified eight of eight forms had not been signed by a physician for the following: (a) One unit of O negative packed red blood cells had been released to a patient on 03/05/2024; the form had been signed by an RN (Registered Nurse); (b) One unit of O negative packed red blood cells had been released to a patient on 03/07/2024; the form had been signed by an RN; (c) One unit of O negative packed red blood cells had been released to a patient on 05/07/2024; the form had been signed by an RN; (d) One unit of O negative packed red blood cells had been released to a patient on 07/09/2024; the form had been signed by a PA (Physician Assistant); (e) One unit of O negative packed red blood cells had been released to a patient on 08/15/2024; the form had been signed by an RN; (f) One unit of O negative packed red blood cells had been released to a patient on 08/16/2024; the form had been signed by an RN; (g) One unit of O negative packed red blood cells had been released to a patient on 12/08/2024; the form had been signed by an RN; (h) One unit of O negative packed red blood cells had been released to a patient on 02/13 /2025; the form had been signed by an RN. (3) The documentation was reviewed with

	the laboratory manager who stated on 03/20/2025 at 02:10 pm, the emergency releases as stated above, had not been signed by a physician.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Routine Chemistry, Endocrinology, and Toxicology testing performed using two test methods during the review period of March 2023 through September 2024. Findings include: (1) On 03/18/2025 at 02:35 pm, the laboratory manager stated the laboratory performed Acetaminophen, Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), BUN, Calcium, Carbamazepine, Chloride, Cholesterol, CK (Creatine Kinase), CKMB (Creatine Kinase Isoenzyme), Creatinine, CO2, Digoxin, Dilantin, Direct Bilirubin, Free T4 (Thyroxine), Gentamicin, GGT (Gamma-Glutamyl Transferase), Glucose, HCG (Human Chorionic Gonadotropin), HDL (High Density Lipoprotein), Hemoglobin A1c, Lactic Acid, LD (Lactate Dehydrogenase), LDL (Low Density Lipoprotein), Lipase, Magnesium, Phenobarbital, Potassium, Pro-BNP (Pro B-Type Natriuretic Peptide), Salicylate, Sodium, Theophylline, Total Bilirubin, Total Protein, Triglyceride, TSH (Thyroid Stimulating Hormone), Tobramycin, Troponin I (high sensitivity), Urine Creatinine, Urine Total Protein, and Vancomycin testing using two Siemens Dimension EXL 200 analyzers denoted by the laboratory as "EXL 1" and "EXL 2" which were used interchangeably; (2) On 03/20/2025, a review of records from March 2023 through September 2024 identified the relationship between the two test methods had not been evaluated between 03/23/2023 and 03/29/2024; (3) The records were reviewed with the laboratory manger who stated on 03/21/2025 at 09:30 am, the relationship between the above test methods had not been evaluated at least twice annually as stated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for four of six Immunohematology and Chemistry Miscellaneous proficiency testing events reviewed in 2024. Findings include: (1) A review of 2024 proficiency testing events identified attestation statements had been signed up to one month after the samples had been tested (after the graded evaluations were available

	from the proficiency testing program) for four of six events reviewed: (a) First Chemistry Core Event - The sample testing had been completed on 02/11/2024 and the attestation statement had not been signed by the laboratory director until 03/05 /2024; (b) First Immunohematology Event - The sample testing had been completed on 04/10/2024 and the attestation statement had not been signed by the laboratory director until 05/07/2024; (c) Second Chemistry Core Event - The sample testing had been completed on 06/06/2024 and the attestation statement had not been signed by the laboratory director until 07/08/2024; (d) Second Immunohematology Event - The sample testing had been completed on 08/13/2024 and the attestation statement had not been signed by the laboratory director until 09/09/2024. (2) The records were reviewed with the laboratory manager who stated on 03/19/2025 at 11:05 am the attestation statements had not been signed timely as stated above.