Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472384	08/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Roger Mills Memorial Hospital	501 South L L Males Avenue, Cheyenne, 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 08/27,28/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer and general supervisor at the conclusion of the survey.
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on observation, and interview with the general supervisor, the laboratory failed to ensure three of three bottles of Fisher Brand Sun-Dex 50 glucose tolerance beverages were stored to minimize contamination. Findings include: (1) On 08/28 /2024 at 2:00 pm observation of the contents of the laboratory refrigerator identified the following materials: (a) Patient blood and urine specimens for storage; (b) Blood and urine quality control specimens; (c) Three bottles of Fisher Sun-Dex 50 glucose tolerance beverages for patient consumption. (2) Interview with the general supervisor 08/28/2024 at 2:00 pm confirmed the laboratory failed to minimize contamination by storing patient beverages for consumption with biohazard materials.
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by:

	Based on a review of records, written policy, and interview with the general supervisor, the laboratory failed to follow policies to ensure positive identification of a blood or blood product recipient. Findings include: (1) On 08/28/2024 at 11:00 am, the general supervisor stated that the laboratory collected specimens for blood transfusion testing performed by the Oklahoma Blood Institute (OBI); (2) A review of the OBI policy titled, "Pre and Post Transfusion guidelines for transfusion service clients" stated in section 6.2.4, "Attach the bracelet to the patient, tearing off the remaining strip of numbers. The bracelet must remain on the patient until completion of the transfusion."; (3) A review of the hospital policy titled, "Oklahoma Blood Institute: packaging" stated, "Patient armband to be placed on patient and armband tail with remaining stickers go with the specimen."; (4) Observation of the blood bank on 08/28/2024 at 11:00 am revealed a patient blood bank armband, that was paper clipped to a laboratory blood component issuance form along with the remaining stickers; (5) On 08/28/2024 at 11:00 am, the general supervisor confirmed that the armband was not placed on the patient according to their policy to ensure positive identification of a blood product recipient.
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 one of one box of Triage total 5 calibration verification materials were stored as required by the manufacturer. Findings include: (1) On 08/28/2024 at 11:00 am observation of the contents of the laboratory freezer identified the following: (a) One box of Triage Total 5 calibration verification materials, lot# 492350N (2) The storage requirement, as stated on the box was -20 degrees C (Celsius) or colder. (3) Observation of the freezer temperature logs from July 2023 to December 2023 identified the following: (a) The temperatures were warmer than -20 degrees C for 16 of 180 days reviewed. (3) The findings were reviewed with the technical consultant who stated on 08/28/2024 at 11:00 am, the freezer temperatures were not within the manufacturer's storage requirements.
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 general supervisor, 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 two of five emergency releases reviewed. Findings include: (1) On 08/28/2024 at 9:00 am, the general supervisor stated the laboratory maintained units of (PRBC's) packed red blood cells. The units were to be used for patient transfusions; (2) On 08/28/2024 a review of the policy titled, "Emergency Blood Transfusion Request" required an Emergency Release form be completed which stated, "I believe the life of (last, first, date of birth, patient identification #) will be in jeopardy without an emergency blood transfusion". The form included a space for the medical provider's signature; (3) A review of documentation of emergency issue identified the following for two of five patient records: (a) One unit of O positive packed red blood cells had been released to a patient on 10/25/2023. The "Emergency Blood Transfusion Request" form appeared to be signed by a mid-level provider and not a physician; (b) One unit of O negative packed red blood cells had been released to a patient on 06/24/2024. The "Emergency Blood Transfusion Request" form appeared to be signed by a mid-level provider and not a physician. (4) The documentation was reviewed with the general supervisor who stated on 08/28/2024 at 9:00 am, the emergency releases had not been signed by a physician.
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 general supervisor, the laboratory failed to make therapeutic reference ranges available for INR (International normalized ratio) testing for one of one patient report and failed to make appropriate reference ranges available for one of one patient venous blood gas report. Findings include: INR TESTING (1) On 08/28/2024 at 11:30 am, the general supervisor stated INR testing was performed using the Hemochron Signature Elite analyzer; (2) A review of one patient report with INR results reported on 02/04/2024 at 1:06 pm, identified the report did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (3) The report was reviewed with the general supervisor who stated on 08/28/2024 at 11:30 am, the patient report did not include a therapeutic range for INR. VENOUS BLOOD GAS TESTING (1) On 08/28/2024 at 11:30 am, the general supervisor stated venous and arterial Blood Gas (pH, pO2, pCO2, BE, HCO3, TCO2, and SO2) testing were performed using CG4+ cartridge and the i-Stat analyzer ; (2) On 08/28 /2024, a review of two patient reports identified identical reference ranges for venous and arterial blood gas testing as follows: (a) A patient venous blood gas tested on 12 /19/2023 with the following reference intervals: (i) pH - 7.35-7.45 (ii) pO2 - 80-105.0 mmHg (iii) pCO2 - 32.0-45.0 mmHg (iv) BE - 2.0-3.0 mmol/L (v) HCO3 - 22-26 mmol/L (vi) TCO2 - 23-27 mmol/L (vii) SO2 - 95-98 % (b) A patient arterial blood gas tested on 03/23/2024 with the following reference intervals: (i) pH - 7.35-7.45 (ii) pO2 - 80-105.0 mmHg (iii) pCO2 - 32.0-45.0 mmHg (iv) BE - 2.0-3.0 mmol/L (v) HCO3 - 22-26 mmol/L (vi) TCO2 - 23-27 mmol/L (vii) SO2 - 95-98 % (3) The

	reports were reviewed with the general supervisor, who stated on 08/28/2024 at 11:30 am, the patient report tested on 12/19/2023 did not include reference intervals for venous Blood Gas testing.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that 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 general supervisor, 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 one of five proficiency testing events reviewed in 2023 and 2024. Findings include: (1) A review of 2023 and 2024 proficiency testing events identified attestation statements had been signed after the graded evaluation had been received for one of ten events reviewed: (a) Third event 2024 Chemistry Core - The sample testing had been completed on 01/29/2024 and the attestation statement had not been signed by the laboratory director until 03/08/2024. (2) The records were reviewed with the general supervisor who stated on 08/27/2024 at 2:00 pm the attestation statement had not been signed timely as stated above.