Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472396	08/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cordell Memorial Hospital	1220 N Glenn English St, Cordell, 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 08/20,21,22/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer, technical consultant, and general supervisor #2 during an exit conference performed at the conclusion of the survey.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with the technical consultant, the facility failed to ensure written policies were followed for preventing transfusion reactions for four of seven units of packed red-blood cells transfused. Findings include: (1) On 08/22/2024 at 1:30 pm, the technical consultant stated that blood transfusions were performed by nursing staff. (2) On 08/22/2024, a review of the hospital policy titled, "Blood Administration Procedure" defined vitals as temperature, blood pressure, pulse and respirations and stated: (a) "Vital signs before initiation of transfusion"; (b) "Check vitals at least every 15 minutes for the first half hour after the start of the transfusion and then every hour after during the transfusion until transfusion is complete". (3) A review of transfusion records for seven units identified the policy had not been followed for four units as follows; (a) Unit #W091024274731 - The unit was started at 11:39 am and vital signs were not taken until 2:09 pm at the end of the transfusion; (b) Unit #W0910290785 - The unit was started at 2:09 pm and vital signs were not taken until 4:20 pm at the end of the transfusion; (c) Unit #W091024215403 - The unit was started at 11:00 pm and vital signs were taken at 11:33 pm, midnight, 12:15 am, and 1:30 am. The transfusion was

	completed at 1:05 am; (d) Unit #W091024230658 - The unit was started at 1:10 am and vital signs were taken at 1:30 am, 2:15 am, and 3:21 am at the conclusion of the transfusion. (4) The records were reviewed with the technical consultant who stated on 08/22/2024 at 01:30 pm, the vital signs had not been documented according to policy.
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 14 of 14 boxes of Triage total 5 quality control materials were stored as required by the manufacturer. Findings include: (1) On 08/20/2024 at 11:00 am observation of the contents of the laboratory freezer identified the following materials: (a) Seven boxes of Triage total 5 quality control materials, level one, lot # C3996AN (b) Seven boxes of Triage total 5 quality control materials, level two, lot # C4002AN (2) The storage requirement, as stated on the bottles for the materials was -20 degrees C (Celsius) or colder; (3) On 08/20/2024 at 11:00 am identified the current temperature reading as -18 degrees C; (4) Observation of the freezer temperature logs from November 1, 2023 to December 31, 2023 identified the following: (a) The temperatures were warmer than -20 degrees C for 60 of 61 days reviewed. (4) The findings were reviewed with the technical consultant who stated on 08/20/2024 at 11:00 am, the freezer temperatures were not within the manufacturer's storage requirements.
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 general supervisors #1 and #2, the laboratory failed to perform calibration verification procedures at least once every six months for the i-STAT1, Cobas Integra, and Cobas E411 test systems during the review period of 08/05/2022 through the current date. Findings include: i-Stat (1) On 08/22/2024 at 2:00 pm, general supervisors #1 and #2 stated that the laboratory performed blood gas (pH, pO2 and pCO2) on the i-STAT1 analyzer (SN375736) using the EG6+ cartridge; (2) A review of records from 08/05/2022 through the current date identified no evidence the calibration verification procedures had been performed for the EG6+ test system; (3) The findings were reviewed with the technical consultant and general supervisor #2, who stated on 08/22/2024 at 2:00 pm, the calibration verification procedures had not been performed every six months as stated above. Cobas Integra (1) On 08/22/2024 at 2:00 pm, the technical consultant stated that the laboratory performed chemistry testing (albumin, bun, calcium, cholesterol, chloride, creatinine, glucose, potassium, lactate, magnesium, sodium, phosphorus, total protein, triglyceride, carbon dioxide, ethanol, ammonia, uric acid, alkaline phosphatase, alt, amylase, AST, creatinine kinase, lactate dehydrogenase, lipase, total bilirubin, and hemoglobin A1c) using the Cobas Integra analyzer. (2) A review of records from 08/05/2022 through the current date identified no evidence that calibration verification procedures had been performed between 1/26/2023 and 05 /21/2024 for the analytes listed above; (3) The findings were reviewed with the technical consultant and general supervisor #2, who stated on 08/22/2024 at 2:00 pm, the calibration verification procedures had not been performed every six months as stated above. Cobas E411 (1) On 08/22/2024 at 2:00 pm, the technical consultant stated that the laboratory performed immunoassay testing (CKMB, troponin-T, myoglobin, ProBNP, TSH, and PSA) using the Cobas E411 analyzer; (2) A review of records from 08/05/2022 through the current date identified no evidence that calibration verification procedures had been performed between 1/26/2023 and 05/21 /2024 for the analytes listed above; (3) The findings were reviewed with the technical consultant and general supervisor #2, who stated on 08/22/2024 at 2:00 pm, the calibration verification procedures had not been performed every six months as stated above.
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 technical consultant, 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 up after the graded evaluation had been received for one of five events reviewed: (a) Third event 2023 Immunology /Immunohematology - The sample testing had been completed on 12/13/2023 and the attestation statement had not been signed by the laboratory director until 04/04/2024. (2) The records were reviewed with the technical consultant who stated on 08/21/2024 at 2:00 pm the attestation statement had not been signed timely as stated above.