Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472396	08/07/2026
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 08/05/206 though 08/07/2026. Standard-level deficiencies were cited.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to review and evaluate proficiency testing results for one of five Hematology Proficiency testing events reviewed in 2025 and 2026. Findings include: (1) On 08/05/2026, a review of Hematology Proficiency testing records for five events (First 2025, Second 2025, Third 2025, First 2026, and Second 2026) identified the following failure with no evidence that a corrective action had been documented as performed: (a) Second 2025 Event - The laboratory attained a score of 60% for Blood Cell Identification (Sample BCI-06 and Sample BCI-07). (2) Interview with technical consultant #1 on 08/05/2026 at 03:00 pm confirmed a corrective action had not been taken and documented for the failure.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical

	consultant #2, the laboratory failed to verify the accuracy for one of one analyte at least twice annually during the review period of January 2025 through the current date. Findings include: (1) On 08/05/2026 at 12:09 pm, technical consultant #1 and technical consultant #2 stated the laboratory performed D-Dimer testing using Quidel Triad MeterPro analyzer; (2) A review of 2025 and 2026 proficiency testing records identified the laboratory had not enrolled and participated in proficiency testing for the above analyte, therefore, it was determined the laboratory must verify the accuracy of the testing at least twice annually; (3) Interview with technical consultant #1 and technical consultant #2, on 08/06/2026 at 09:55 am confirmed the laboratory did not have a method in place to verify the accuracy of D-Dimer testing twice annually and the accuracy of the testing had not been verified during 2025 through the current date.
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 a review of manufacturer's instructions, observation, and interview with technical consultant #2, the laboratory failed to ensure the i-Stat EG7+ cartridges and the Hemochron PT cuvettes had not exceeded the room temperature expiration date. Findings include: I. I-STAT EG7+ CARTRIDGES (1) On 08/05/2026 at 12:08 pm, technical consultant #2 stated the laboratory performed Blood Gas (pH, pO2, and pCO2) testing using the i-STAT 1 analyzer serial number 375736 and the EG7+ cartridge; (2) Observation of the laboratory on 08/05/2026 at 12:08 pm identified two Abbott EG7+ cartridges (Lot #N26112) stored at room temperature, without documentation of when they were removed from refrigeration; (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for 2 months. (4) The findings were reviewed with technical consultant #2 who stated on 08/05/2026 at 12: 10 pm, the cartridges had not been dated to ensure they would not be used beyond the room temperature storage expiration date. II. HEMOCHRON PT CUVETTES (1) On 08/05/2026 at 12:06 pm, technical consultant #2 stated the laboratory performed fingerstick Prothrombin Time (PT) testing using the Hemochron Signature Elite analyzer and the Hemochron PT test cuvette; (2) Observation of the draw room on 08 /05/2026 at 12:06 pm identified the following: (a) Five Hemochron test cuvettes (lot #G5JPT012) being stored at room temperature. (3) Review of the manufacturer's package insert under the section, "Storage and Stability" stated "Room temperature re-dating is allowed up to a maximum of 12 weeks, but must never exceed the marked expiration date. Re-dating is necessary if stored at room temperature and the new expiration date should be indicated on the "Performance Verified" label contained in the cuvette box". (4) The findings were reviewed with technical consultant #2 who stated on 08/05/2026 at 12:10 pm, the test cuvettes had not been dated to ensure they would not be used beyond the room temperature storage expiration date.
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 technical consultant #1 and technical consultant #2, the laboratory failed to utilize the demonstrated reportable ranges for one of six analytes reviewed for the Beckman Coulter Access 2 test system, and for one of six analytes reviewed for the Beckman Coulter DxC AU 500 test system. Findings include: I. B-TYPE NATRIURETIC PEPTIDE (BNP) (1) On 08/05/2026 at 11:56 am, technical consultant #1 and technical consultant #2 stated the laboratory began using the Beckman Coulter Access 2 analyzer to perform immunoassay testing which included the analyte BNP on 10/23/2024; (2) A review of the performance specifications records identified the laboratory had demonstrated the following reportable range for one of six analytes reviewed: (a) BNP - 0.00 to 4688 ng/dL (3) Interview with technical consultant #1 and technical consultant #2 on 08/06/2026 at 01:50 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) BNP - 1.00 to 5000 ng/dL. II. HEMOGLOBIN A1C (1) On 08/05/2026 at 11:54 am, technical consultant #1 and technical consultant #2 stated the laboratory began using the Beckman Coulter DxC AU 500 analyzer to perform routine chemistry testing which included the analytes Hemoglobin A1c (HbA1c) on 12/24/2024; (2) A review of the performance specifications records identified the laboratory had demonstrated the following reportable range for one of six analytes reviewed: (a) HbA1c - 4.90 to 19.94 % (3) Interview with technical consultant #1 and technical consultant #2 on 08/06/2026 at 02:30 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) HbA1c - 4.00 to 19.4 %.
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 technical consultant #1 and technical consultant #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for one of three analyzers reviewed from May through June 2026. Findings include: (1) On 08/05/2026 at 09:38 am, technical consultant #1 and technical consultant #2 stated the laboratory performed Prothrombin Time/International Normalized Ratio (PT/INR) and Partial Thromboplastin Time (PTT) testing using the Sysmex CA 600 analyzer; (2) On 08/07/2026, a review of the manufacturer's maintenance log showed the following required daily maintenance procedures: (a) Clean sample probe (b) Discard used reaction tubes (c) Dispose of waste (d) Remove dew from reagent rack (3) A review of maintenance logs from May through June 2026 identified daily maintenance had not been documented as performed as follows: (a) May 14, 18, 19, 22, 27 (b) June

	7 (Dispose of waste and removal of dew from reagent rack not performed) (c) June 19, 29 (4) The records were reviewed with technical consultant #1 and technical consultant #2 who stated on 08/07/2026 at 01:45 pm, the daily maintenance procedures had not been documented as performed as stated above.
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 technical consultant #1 and technical consultant #2, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly during the review period of January 2025 through the current date. Findings include: (1) On 08/05/2026 at 11:55 am, technical consultant #2 stated the following: (a) Urine sediment examinations were performed by the laboratory; (b) The specimens were processed in the TD4C centrifuge at a speed of 1800 revolutions per minute (rpm) for 10 minutes. (2) A review of the procedure titled, "Centrifuge Function Check Procedure" stated the following: (a) Centrifuge speed and time check will be performed by a contracted biomedical engineer annually; (b) The centrifuge will be checked with an acceptable limit of 1500-2000 rpm and +/- 10 seconds at 10 minutes. (3) A review of centrifuge function check records from January 2025 through the current date identified no evidence the function check had been documented as performed; (4) The records were reviewed with technical consultant #1 and technical consultant #2, who stated on 08/05 /2026 at 03:55pm, the laboratory had not followed their policy for the function checks.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #2, the laboratory failed to perform two levels of quality control materials each eight hours of patient D-dimer testing for one of 14 days reviewed from February through June 2026. Findings include: (1) On 08/05/2026 at 12:09 pm, technical consultant #1 and technical consultant #2 stated the following: (a) The laboratory performed D-dimer testing using the Quidel Triage MeterPro analyzer; (b) The laboratory performed two levels of Quality Control (QC) materials each eight hours of patient testing; (c) An Individualized Quality Control Plan (IQCP) had not been developed for the test system. (2) On 08/06/2026, a review of QC and patient testing records for fourteen days during the review period of February through June 2026 identified the following: (a) Patient test had been performed on 03/03/2026 at 01:10

	am and at 03:40 am; (b) There was no documentation to show two levels of QC had been performed since 02/25/2026. (3) The records were reviewed with technical consultant #1 and technical consultant #2 who stated on 08/06/2026 at 10:30 am, two levels of QC materials had not been performed 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, written policy, and interview with the technical 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 five of five emergency releases reviewed. Findings include: (1) On 08/07/2026 at 9:00 am, the technical supervisor stated the laboratory maintained units packed red blood cells of (PRBC's). The units were to be used for patient transfusions; (2) On 08/08/2026 a review of the policy titled, "Emergency Transfusion Request" required an Emergency Release form be completed which stated, "I believe this patient's life will be in jeopardy without an emergency transfusion". The form included a space for the medical provider's signature; (3) A review of documentation of emergency issue identified the following for five of five patient records: (a) Two units of type O packed red blood cells had been released to a patient on 06/18/2025. The "Emergency Transfusion Request" form appeared to be signed by a mid-level provider and not a physician; (b) One unit of type O packed red blood cells had been released to a patient on 05/27/2026. The "Emergency Transfusion Request" form appeared to be signed by a mid-level provider and not a physician; (c) One unit of type O packed red blood cells had been released to a patient on 05/06/2025. The "Emergency Transfusion Request" form appeared to be signed by a mid-level provider and not a physician. (4) The documentation was reviewed with the technical supervisor who stated on 08/07/2026 at 11:00 am, the emergency releases had not been signed by a physician.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of records and interviews with the technical supervisor and general supervisor #2, the technical supervisor failed to ensure personnel performing high complexity testing had been evaluated at least annually for one of five persons during the review period of January 2025 through the current date. Findings include: (1) On 08/05/2026 a review of personnel records for five persons performing high complexity testing from January 2025 through the current date identified no evidence an annual competency evaluation had been performed for one of five testing persons

	as follows: (a) Testing Person #1 - no evidence competency assessment had been performed to date. (2) The records were reviewed with the technical supervisor and general supervisor #2 who stated on 08/05/2026 at 11:41 am the annual evaluation had not been performed.