Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472396	08/04/2022
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 08/02,03,04/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant and laboratory manager at the conclusion of the survey.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 follow the manufacturer's instructions for performing maintenance procedures for one of three analyzers. Findings include: (1) On 08/02/2022 at 11:50 am, the technical consultant stated the laboratory performed CKMB (Creatine Kinase Isoenzyme), Myoglobin, Pro-BNP (B-type natriuretic peptide), PSA (Prostate Specific Antigen), Troponin T, and TSH (Thyroid Stimulating Hormone) testing using the Cobas e411 analyzer; (2) On 08/04/2022, a review of the manufacturer's maintenance log showed the following manufacturer required weekly maintenance procedures: (a) Clean Incubator and Aspiration Station (b) Clean Sipper probe (3) A review of maintenance logs in October 2021, November 2021, March 2022, and July 2022 revealed the weekly maintenance had not been documented as performed between 10/01/2021 and 11/05/2021; (4) The records were reviewed with the technical consultant who stated on 08/04/2022 at 11:41 am, the above maintenance had not been documented as performed.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. 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 perform function checks as defined by the manufacturer for the iSTAT 1 analyzer 19 of 19 months reviewed. Findings include: (1) On 08/02/2022 at 11:00 am, the technical consultant stated the laboratory performed Blood Gas (pH, pCO2, and pO2) testing using two the iSTAT 1 analyzer and the EG6+ cartridge; (2) A review of the manufacturer's instructions contained in the "iSTAT 1 System Manual" on page 14-2 stated "Check thermal contral system every six months"; (3) On 08/03/2022, a review of records from January 2021 through July 2022 revealed no evidence the thermal probe checks had been performred during the review period; (4) The findings were reviewed with the technical consultant who stated on 08/03/2022 at 11:56 am, the thermal probe checks had not been performed every six months.
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 the technical consultant, the laboratory failed to perform calibration verification procedures at least once every 6 months for 27 of 27 analytes. Findings include: (1) On 08/02/2022 at 11:50 am, the technical consultant stated Albumin, Alcohol, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), CO2, Direct Bilirubin, Total Bilirubin, Calcium, Potassium, CK (Creatine Kinase), Chloride, Sodium, Creatinine, Glucose, Lactic Acid, Lipase,

	LD (Lactate Dehydrogenase), Magnesium, Phosphorus, Total Protein, Total Cholesterol, Triglyceride, and Uric Acid testing were performed using the Cobas Integra 400 analyzer; (2) On 08/04/2022, a review of 2022 calibration records revealed that calibration procedures for the above analytes had been performed with two levels of calibrators. Since the calibration procedures included only two levels, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of calibration verification records performed during 2021 through the current date revealed that calibration verification had not been performed as follows: (a) Albumin, Alcohol, Alkaline Phosphatase, ALT, Ammonia, Amylase, AST, BUN, CO2, Direct Bilirubin, Total Bilirubin, Calcium, Potassium, Chloride, Sodium, Creatinine, Glucose, Lactic Acid, Lipase, LD, Magnesium, Phosphorus, Total Protein, Total Cholesterol, Triglyceride, and Uric Acid - Between 02/12/2021 and 02/10/2022; (b) CK - Since 02/12/2021 (4) The records were reviewed with the technical consultant who stated on 08/04/2022 at 11:28 am, calibration verification had not been performed as stated above.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure quality control results were acceptable before reporting patient test results for pO2 and Oxygen Saturation testing for one of 11 patients reviewed. Findings include: (1) On 08/02/2022 at 11:30 am, the technical consultant stated the following: (a) The laboratory performed arterial and venous blood gas (pH, pCO2, pO2) testing using the EG6+ cartridge and iSTAT 1 analyzer; (b) An IQCP (Individualized Quality Control Program) had not been developed for the test system and the laboratory performed two levels of QC (Quality Control) materials each eight hours of patient testing. (2) On 08/03/2022, a review of QC and patient testing records for testing performed in June 2021, November 2021, January 2022, and May 2022 revealed the results for level one QC for pO2 and Oxygen Saturation was not acceptable for one of 11 patients reviewed as follows: (a) 06/22/2021 - A patient venous blood gas had been tested at 01:56 pm. Although two levels of QC materials had been tested (level one was tested at 01:17 pm and level three was tested at 01:21 pm), the pO2 and Oxygen Saturation results for level one were suppressed (the results were replaced with ***). There was no indication the sample had been retested to ensure acceptable results prior to reporting patient testing. (4) The records were reviewed with the technical consultant who stated on 08/03/2022 at 01:27 pm, the patient Blood Gas results had been reported when level one QC results were not acceptable for pO2 and Oxygen Saturation as stated above.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21

	CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to have procedures to detect an ABO incompatibility between the donor's cell type and the recipient serum or plasma type for 14 of 22 units crossmatched. Findings include: (1) On 08/02/2022 at 11:20 am, the technical consultant stated the Ortho MTS Anti-IgG gel cards were used to perform patient antibody screen and compatibility testing; (2) On 08/03/2022 a review of the manufacturer's instructions contained in the package insert for the MTS Anti-IgG gel cards stated, "The MTS Anti-IgG Gel Test System can be used in both direct and indirect antiglobulin test systems to detect the presence or absence of IgG on human red blood cells"; (3) A review of patient compatibility testing performed from 11/13 /2021 through 07/26/2022 revealed for 14 of 22 units crossmatched, the laboratory exclusively used the Anti-IgG gel cards to perform patient compatibility testing, and therefore, did not include a method to detect ABO incompatibilities based on IgM antibodies (in order to achieve this, an immediate spin crossmatch, containing the donor's red blood cells and the recipient's serum or plasma, or an electronic crossmatch must be performed in conjunction with the IgG crossmatch); (4) The findings were reviewed with the technical consultant who stated on 08/03/2022 at 04: 00 pm, an immediate spin crossmatch (using the buffer gel card or tube method) had not been performed for the 14 units crossmatched; (5) The specific days of testing were: (a) 04/17/2022 - one unit crossmatched (b) 05/12/2022 - two units crossmatched (c) 05/17/2022 - one unit crossmatched (d) 05/27/2022 - two units crossmatched (e) 06 /07/2022 - two units crossmatched (f) 06/13/2022 - two units crossmatched (g) 07/13 /2022 - two units crossmatched (h) 07/26/2022 - two units crossmatched NOTE: The following reference was published in the CLIA Network Newsletter dated July-August 2009: "The gel card only detects incompatibility based on IgG antibodies. It does not detect incompatibility based on IgM antibodies, which is important in determining ABO compatibility. Therefore, the use of the gel card alone is not adequate to demonstrate incompatibility between the donor's cell type and the recipient's serum type, and the laboratory must also perform an immediate spin or electronic crossmatch to determine ABO compatibility." NOTE: The Interpretive Guidelines at 493.1271 require standard operating procedures for compatibility testing: "Procedures to demonstrate incompatibility between the donor's cell type and the recipients's serum or plasma type. These procedures may consist of a serologic crossmatch, or a computer crossmatch."
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The

	laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 written policies and interview with the technical consultant, the laboratory failed to ensure that written policies provided safety for individuals being transfused for three of three patients reviewed. Findings include: (1) On 08/02/2022 at 11:20 am, the technical consultant stated the laboratory stored units of PRBC's (packed red blood cells) in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 08/03/2022, a review of the hospital policy titled, "Blood Administration Protocol" stated the following: (a) "Check for signed consent for transfusion"; (b) Check vital signs 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 infusion is complete". (3) A review of records for three patients receiving transfusions in April and July 2022 revealed the policy had not been followed as follows: (a) Patient #9693 - Transfused with one unit of PRBC's (unit #W091022174886) on 04/17/2022. There was no evidence the vitals had been taken every 15 minutes for the first half hour. The vitals had not been taken between 11:05 am and 11:35 am; (b) Patient #726 - Transfused with two units of PRBC's on 07/13,14/2022. There was no evidence of a signed consent in the patient records; (c) Patient #11828 - Transfused with two units of PRBC's on 07/26/2022. For one of two units (W091022272907), there was no evidence the vitals had been taken every 15 minutes for the first half hour. The vitals had not been taken between 11:40 am and 12:40 pm. (4) The records were reviewed with the technical consultant who stated on 08/03/2022 at 02:30 pm, the policy had not been followed as stated above. NOTE: D5559 was cited on the recertification survey performed on 10/05,06/2020
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. (c) The laboratory must document all analytic systems assessment activities. 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 for the Med Tox Profile II analyzer for two of three years. Findings include: (1) On 08/03/2022 at 10:00 am, the technical consultant stated the following: (a) Urine Drug Screen testing was performed on the Med Tox Profile II analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) A review of the QA (Quality Assessment) portion of the IQCP included a schedule for evaluating the QCP (Quality Control Plan) annually to ensure they continued to provide accurate and reliable results; (3) A review of records from January 2020 through July 2022 revealed an annual review of the QCP had not been performed since 01/07/2020; (4) The records were reviewed with the technical consultant who stated on 08/03/2022 at 01:30 pm, the QA reviews had not been performed.

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 technical consultant, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On 08/02/2022 at 11:15 am, the technical consultant stated CBC (Complete Blood Count) testing was performed using the Sysmex 1000i analyzer; (2) On 08/03/2022, two patient CBC reports were reviewed - the first report was for an adult male patient with the testing performed on 03/29/2022 at 08:19 am; the second report was for an adult female patient with the testing performed on 07/01/2022 at 07:27 am. Both reports included the same reference intervals for the CBC parameter of Hemoglobin which was 11.8-15.8 gm/dl; (3) The reports were reviewed with the technical consultant who stated on 08/03/2022 at 12:13 pm, the patient reports did not include a gender specific reference range for Hemoglobin.