Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472396	10/06/2020
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 10/05/2020 and 10/06/2020. The findings were reviewed with hospital administrator/director of nursing, quality /infection control/case management, laboratory/radiology manager, and the technical consultant during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. 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 Mycoplasma testing for 1 of 3 days. Findings include: (1) On 10/05/2020 at 11:45 am, the technical consultant stated to the surveyor the ImmunoCard Mycoplasma test kit was used to detect IgM to Mycoplasma pneumoniae in patient serum samples; (2) The surveyor reviewed the manufacturer's instructions (package insert) for the test kit. The section titled, "Test Procedure" stated "Incubate 2 minutes at 22-25 degrees C"; (3) The surveyor reviewed 3 patient reports (testing performed 09/08/2020, 09/11/2020, 10/05/2020) and laboratory temperature logs. The review showed the laboratory had not followed the manufacturer's instructions for incubating at the specified temperature for 1 of 3 patients. The room temperature for the patient tested on 09/08 /2020 had been documented as 20 degrees C (Centigrade); (4) The surveyor reviewed the findings with the technical consultant, who stated on 10/05/2020 at 05:15 pm, the laboratory had not followed the manufacturer's instructions.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 perform quality control as stated in the IQCP for PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing on the Hemochron Signature+ analyzer for 1 of 9 months. Findings include: (1) On 10/05/2020 at 11:45 am, the technical consultant stated to the surveyor: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Hemochron Signature+ analyzer; (i) Two levels of quality control materials were tested monthly, according to the laboratory IQCP (Individualized Quality Control Plan); (ii) The results for two levels of control materials must be acceptable in order to report patient results. (2) The surveyor reviewed PT/INR and PTT quality control records for testing performed from January 2020 through September 2020. The following was identified for 1 of 9 months: (a) Level 2 PTT - not documented as performed between 04/15/2020 and 06/16/2020. (3) The surveyor reviewed the records with the technical consultant, who stated on 10/06/2020 at 11:10 am quality control had not been performed as stated in the IQCP.
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 7 of 16 packed red blood cell units. Findings include: (1) On 10/05/2021 at 12:25 pm, the technical consultant stated the laboratory stored units of PRBCs (packed red blood cells) in the blood bank refrigerator. The units were to be used for patient transfusions; (2) The surveyor reviewed the Nursing Policy and

	Procedure regarding blood administration. The policy titled, "Blood Administration Procedure" stated the following: (a) "1. Explain procedure to patient. Check for signed consent for transfusion. Advise patient to report any chills, itching, rash, or unusual symptoms immediately."; (b) "7. Take Baseline set of vital signs before beginning transfusion."; (c) "8. Start infusion of the blood product." (i) "e. 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.". (d) "10. Blood has been infusing for more than 4 hours must be discontinued to prevent the risk of bacterial contamination." (3) The surveyor reviewed transfusions between 03/09/2020 through 09/28/2020 (a total of 16 units) and identified the following: (a) Consent form for 1 of 5 patients had not been signed by the physician (1) Patient # 263184153 - Transfusions performed on 03/09/2020, 04/06/2020, 05/11/2020, 06/16/2020, 07/07 /2020, 08/03/2020, 08/24/2020, 09/28/2020. (b) Start time of the infusion (1) Patient # 263184153 - Transfused with 1 unit of PRBCs (unit# W091020300203) on 08/03 /2020. There was no documentation indicating the start time of the infusion. (c) Vital signs at least every 15 minutes for the first half hour (1) Patient # 263184153 - Transfused with 1 unit of PRBCs (unit# W091020268122) on 08/03/2020 with a start time of 01:15 pm and vitals taken at 01:30 pm and 02:30 pm (1 hour later); (2) Patient # 263184153 - Transfused with 1 unit of PRBCs (unit# W091020312914) on 08/24 /2020 with a start time of 10:05 am and vitals taken at 10:20 am and 11:20 am (1 hour later); (3) Patient # 263184153 - Transfused with 1 unit of PRBCs (unit# W091020294013) on 08/24/2020 with a start time of 12:55 pm and vitals taken at 01: 10 pm and 02:10 pm (1 hour later); (4) Patient # 263184153 - Transfused with 1 unit of PRBCs (unit# W091020279261) on 09/28/2020 with a start time of 10:00 am and vitals taken at 10:14 am and 11:14 am (1 hour later); (5) Patient # 263184153 - Transfused with 1 unit of PRBCs (unit# W091020245051) on 09/28/2020 with a start time of 03:24 pm and vitals taken at 03:39 pm and 04:39 pm (1 hour later); (d) Infusion lasting longer than 4 hours for 1 of 5 patients (1) Patient # 263184153 - Transfused with 1 unit of PRBCs (unit# W091020186830) on 04/06/2020 with a start time of 12:08 pm and end time of 04:38 pm (4 hours and 30 minutes). (4) The above transfusion records were reviewed with the technical consultant on 10/06/2020 who stated at 01:35 pm the records did not follow the blood administration policy as indicated above.
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 Hemochron Signature+ coagulation analyzer for 1 of 2 years. Findings include: (1) On 10/05/2020 at 11:45 am, the technical consultant stated to the surveyor: (a) PT /INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Hemochron Signature+ analyzer; (b) IQCP's (Individualized Quality Control Plan) had been developed for the test systems. (2) The surveyor reviewed the IQCP. 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) The surveyor reviewed 2019 and 2020 records and could not locate the QA review for 2019; (4) The surveyor reviewed the records with the technical consultant, who stated on 10/05/2020 at 04:50 pm, the 2019 QA review had not documented as 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 10/05/2020 at 11:45 am, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed using the Sysmex 1000i analyzer; (2) The surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 06/03/2020 at 07:09 am; the second report was for an adult female patient with the testing performed on 06/03/2020 at 09:52 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), which were: (a) RBC - 4.20 - 6.10 X 10E12/L. (3) The surveyor reviewed the findings with the technical consultant, who stated on 10/06/2020 at 02:30 pm the patient reports did not include gender specific reference ranges as indicated above. NOTE: Routinely, female reference intervals for the RBC's are lower than male reference intervals.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory/radiology manager and the technical consultant, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 1 of 5 testing persons. Findings include: (1) On 10/05/2020 at 11:45 am, the technical consultant stated to the surveyor PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing were performed on the Hemochron Signature+ analyzer; (2) The surveyor then reviewed the 2018, 2019, and 2020 personnel records for 5 persons performing PT/INR and PTT testing in the laboratory. The records showed that an evaluation had been performed as follows: (a) Testing Person #5 - Performed on 05/01/2020 (3) There was no evidence the evaluation, performed for the above person, included an assessment of PT/INR and PTT testing; (4) The surveyor reviewed the findings with the laboratory/radiology manager and the technical consultant, who stated on 10/05/2020 at 12:30 pm the above evaluation did not include an assessment of PT/INR and PTT testing as indicated above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's 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 interview with the technical consultant, the technical supervisor failed to ensure testing persons performing high complexity testing had been evaluated at least annually for 2 of 4 testing persons. Findings include: (1) On 10 /05/2020, the surveyor reviewed personnel records for 4 persons who performed testing in 2018, 2019, and 2020. For 2 of the 4 persons (testing person #3 and testing person #4), there was no evidence annual evaluations had been performed in 2018; (2) The surveyor reviewed the findings with the technical consultant who stated on 10/05 /2020 at 12:32 pm the annual evaluations had not been performed as indicated above. High Complexity Testing Includes: 1. Crossmatches, including ABO/Rh typing, Antibody screens, Compatibility testing using the Ortho MTS Gel system