Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445376	05/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cedar County Memorial Hospital	1401 S Park St, Eldorado Springs, MO	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on lack of laboratory procedures and interview with the testing personnel (TP) #2, the laboratory failed to provide a procedure for acceptability of quality control (QC) results and reference intervals (normal values) for tests performed on the Ortho Vitros 5600 chemistry analyzer. Findings: 1. Lack of the laboratory procedures showed no procedure for acceptability of QC results and no procedure for laboratory reference intervals (normal values) for tests performed on the Ortho Vitros 5600 chemistry analyzer. 2. Interview with the TP #2 on May 16, 2023 at 10:30 AM confirmed the laboratory failed to provide a procedure for acceptability of QC results

	and reference intervals (normal values) for tests performed on the Ortho Vitros 5600 chemistry analyzer.
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 review of the blood collection tube labeling, temperature log sheet and interview with the testing personnel (TP) #2, the laboratory failed to follow manufacturer's instructions for storage for 30 of 209 days from October 2022 to date May 16, 2023. Findings: 1. Review of the blood collection tube package label states the storage requirements are from 4C to 25C. 2. Review of the temperature log sheets from October 2022 to date May 16, 2023, showed the temperature did not fall within the stated parameters on log sheet. For the following days: 2022 December: 6, 7, 24, and 26 2023 January: 24, 25, and 26 February: 2, 3, 8, 11, 13, 17, 21, 25, 26, and 27 March: 18, 19, 21, and 23 April: 1, 10, 19, 20, 27, and 28 May: 1, 6, and 16 3. Interview with the TP #2 on May 16, 2023 at 10:30 AM, confirmed the laboratory failed to follow manufacturer's instructions for blood collection tube storage.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation of the laboratory refrigerator and interview with the testing personnel (TP) #1, the laboratory failed to ensure the laboratory's quality control and reagents were not used when they had exceeded their expiration date. Findings: 1. Observation of the laboratory refrigerator showed the following quality control and reagents still in use: Validate GC3 Test Set lot #10597111 expiration date 04/24/2023 Validate GC4 Test Set lot #10611075 expiration date 03/15/2023 Pooled Cells for Serum Group - included in set A1 Cells lot #111433 expiration date 12/30/2022 B Cells lot #113433 expiration date 12/30/2022 Cor QC Test Set lot #43329 expiration date 12/30/22 - included in set Cor QC Cells lot #43329 expiration date 12/30/2022 Cor QC Reagent Antiserum lot #134046-1 expiration date 3/30/2023 Antibody Screen Set lot #43326 exp 12/30/2022 - included in set Panoscreen Level I lot #43326 expiration date 12/30/2022 Panoscreen Level II lot #43326 expiration date 12/30/2022 Immucor Checkcell lot #39300 expiration date 12/02/2022 Immucor Checkcell lot #43330 expiration date 12/12/2022 CLOtest Reagent Urease Type III lot # 41029 expiration date 04/25/2023 2 boxes of Sysmex CA Clean I lot # A2049 expiration date 05/09/2022 2. Interview with TP #1 on May 16, 2023 at 10:30 AM confirmed the laboratory failed to ensure the laboratory's quality control and reagents were not used when they had exceeded their expiration date.

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. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Sysmex CA-660 analyzer quality control (QC), patient results and interview with testing personnel (TP) #1, the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time (PT) and activated partial thromboplastin time (aPTT) for 7 of 136 testing days from January 1, 2023 to date May 16, 2023. Findings: 1. Review of laboratory procedure "Protime/INR-Sysmex Ca660" states, "Run controls every day patients are reported, Q 8 hours." 2. Review of Sysmex CA-660 analyzer QC from January 1, 2023 to date May 16, 2023. showed QC was not performed every 8 hours on the following days: February 7, 2023 February 10, 2023 March 6, 2023 March 13, 2023 March 14, 2023 March 28, 2023 May 14, 2023 3. Review of patient results showed 9 PT patient results and 1 aPTT patient result were released when QC was not performed. 4. Interview with TP #1 on May 16, 2023 at 11:30 AM confirmed the laboratory failed to perform two levels of PT and PTT QC each 8 hours of operation.
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 review of blood gas procedure, blood gas patient report, and interview with the testing personnel (TP) #1, the laboratory failed to ensure the blood gas procedure reference ranges matched the reference ranges on the blood gas patient report. Findings: 1. Review of the blood gas procedure showed the reference ranges as: PO2: 80-100 mmHg HCO3: +/- 2 mmol/L O2 Sat: 92-98.5% 2. Review of the blood gas patient report showed the reference ranges as: PO2: 80-105 mmHg HCO3: -2 to 3 O2 Sat: 95-98% 3. Interview with the TP #1 on May 16, 2023 at 10:30 AM confirmed that the blood gas procedure reference ranges did not match the blood gas patient report reference ranges.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of blood bank procedures, review of proficiency testing, and

	interviews, the laboratory failed to meet the condition of laboratory director (LD). The LD failed to provide the overall oversight of the laboratory (Refer to D6004); failed to ensure the "Blood Product Log Sheet" was completed according to procedure (Refer to D6007); failed ensure the patient's "Routine Blood Usage Log" was completed according to procedure (Refer to D6014); and failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action (Refer to D6018).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on interview, observation of blood bank, review of "Blood Product Log Sheet", "Routine Blood Usage Log", and interview with testing personnel (TP) # 1, the laboratory director (LD) failed to provide overall operation of the laboratory. Findings: 1. Interview with TP # 2 stated "Blood bank procedures are very confusing. At one point we put blood bank documentation in Meditech, then we were told to stop and now we are trying to put back in. We have had a lot of changes". 2. Observation of blood bank showed disorganization of paperwork. The "Blood Product Log Sheet" did not match "Routine Blood Usage Log". 3. Review of the "Blood Product Log Sheet" showed 3 units of packed red blood cells (PRBC) transfused to a patient with no documentation (Refer to D6007). 4. Review of patient's "Routine Blood Usage Log" showed the LD failed to ensure the log was filled out properly (refer to D6014). 5. The laboratory could not provide how many patients were transfused units. 6. Interview with TP #1 on May 16, 2023 at 10:30 AM confirmed, the LD failed to provide overall operation of the laboratory.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by:

	Based on interview, review of blood bank procedures, "Blood Product Log Sheet", and interview with testing personnel (TP) # 1, the laboratory director (LD) failed to ensure testing personnel performed all aspects for preanalytic, analytic and postanalytic phases for blood bank transfusion paperwork for 3 of 23 units of packed red blood cells (PRBC) transfused from November 2022 to date May 16, 2023.. Findings: 1. Interview with TP # 2 stated "Blood bank procedures are very confusing. At one point we put blood bank documentation in Meditech, then we were told to stop and now we are trying to put back in. We have had a lot of changes". 2. Review of blood bank "Blood Bank General Policy" procedure revealed "Lab will maintain a binder that includes a Blood bank Inventory Log, Transfusion log, quarterly checks of blood bank refrigerator high and low alarms and patient records for transfusions". Review of "Blood Products Ordered Routine" stated "There needs to be a blood usage log for each unit ordered. Most recent CBC results. Patient specimens (2 lavender and 1 serum no gel) properly labeled" (send reference lab for crossmatch). "Retain all paperwork.". 3. Review of the "Blood Product Log Sheet" showed a PRBC unit of blood transfused to a patient with no documentation on the "Routine Blood Usage Log", no CBC results, and no documentation of blood sent to reference lab for crossmatch testing on: 5/9/23 a patient was transfused unit # W045123123563 5/29/23 a patient was transfused unit # W045123552005 5/29/23 a patient was transfused unit # W045123251962 4. The laboratory could not provide how many patients were transfused units. 5. Interview with TP #1 on May 16, 2023 at 9:00 AM confirmed the LD failed to ensure testing personnel performed all aspects for preanalytic, analytic and postanalytic phases for blood bank transfusion paperwork.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of blood bank procedures, "Routine Blood Usage Log", and interview with testing personnel (TP) # 1, the laboratory director (LD) failed to ensure blood bank procedures for emergency release packed red blood cells (PRBC) and non emergency PRBC were followed as required for accurate and reliable results for two of nineteen patients from November 2022 to date May 16, 2023. Findings: 1. Review of blood bank procedure "Blood Products Ordered Routine" stated "There needs to be a blood usage log for each unit ordered. Most recent CBC results. Patient specimens (2 lavender and 1 serum no gel) properly labeled" (send to reference lab for crossmatch). "Retain all paperwork." 2. Review of patient's: "Routine Blood Usage Log" showed: one patient's paperwork from 11/17/22 had the wrong patient's date of birth and no CBC results one patient's paperwork from 12/8/22 had no identification for unit of blood given (should be documented on the Routine Blood Usage Log per laboratory procedure), no crossmatch information and no CBC results 3. Interview with TP #1 on May 16, 2023 at 9:00 AM confirmed the LD failed to ensure blood bank procedures were followed as required for accurate and reliable results.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the 2022/2023 proficiency testing (PT) records and interview with testing personnel (TP) #1, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of 2022 Hematology/Coagulation- third event showed no review by the appropriate staff to evaluate the laboratory's performance. 2. Review of the 2023 Hematology/Coagulation- first event showed the laboratory obtained a "not graded" result for activated partial thromboplastin (aPTT), samples COA 01-05 and gastric pH, sample GOB-02. The laboratory could not provide documentation to show appropriate staff evaluated the "not graded" results to identify any problems that may require corrective action. 3. Interview with TP #1 on May 16, 2023 at 11:00 AM confirmed, the laboratory director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of competencies and interview with testing personnel # 1 , the technical consultant (whom is also the laboratory director) failed to identify training needs for one of nine testing personnel in 2023. Findings: 1. Review of laboratory competencies showed no documentation of initial training for testing personnel # 9. 2. Interview with testing personnel #1 on May 16, 2023 at 11:00 AM confirmed the technical consultant failed to identify initial training needs for one testing personnel.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by:

	Based on review of the performance evaluations and interview with testing personnel #1, the technical consultant (whom is also the laboratory director) failed to evaluate and document performance evaluations at least semiannually during the first year for one of nine testing personnel. Findings: 1. Review of performance evaluations showed no semiannual performance evaluation was documented for testing personnel #6. 2. Interview with testing personnel #1 on May 16, 2023 at 11:00 AM confirmed the technical consultant did not evaluate and document the semiannual performance evaluation for testing personnel #6.