Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445376	09/19/2022
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
D0000	A recertification survey was completed on September 19, 2022. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F. R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1441 Condition: Laboratory Director
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the Bio-Rad Liquichek Immunoassay Plus Control package insert, review of the Bio-Rad Liquichek Cardiac Markers Plus Control LT package insert, review of the Bio-Rad Liquid Unassayed Multiqual Control package insert, review of laboratory temperature logs, observation of chemistry refrigerator, review of the performance verification procedures for the Sysmex XN-350 hematology analyzer, review of calibration records for the Ortho Diagnostics Vitros 5600 chemistry analyzer and iStat blood gas analyzer, review of Sysmex XN-350 hematology analyzer quality control (QC), review of Sysmex XN-L check hematology QC package insert, review of blood gas individualized quality control plan (IQCP), review of 2021/2022 blood gas quality control (QC), review of Ortho Diagnostics Vitros 5600 chemistry analyzer quality control (QC), review of Meditech LIS for blood bank, review of patient history with prior antibodies, review of blood bank procedures, review of blood bank quality control (QC) logs, review of blood bank alarm test logs, lack of blood bank alarm test logs for 2021, review of patient results,

	and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to follow manufacturer's instructions for reagent storage for 38 of 44 days in 2022 (Refer to D5411); the laboratory failed to discard expired chemistry reagents (Refer to D5417); the laboratory failed to verify performance specifications prior to reporting patient test results (Refer to D5421); the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range (Refer to D5439); the laboratory failed to ensure hematology QC detects immediate errors that occur (Refer to D5441); the laboratory failed to ensure the IQCP was followed for 11 of 21 months (Refer to D5445); the laboratory failed to include two control materials of different concentrations for alkaline phosphatase, cholesterol and alanine transaminase (ALT) for 20 of 135 patient testing days (Refer to D5447); the laboratory failed to establish criteria for acceptability of control materials providing quantitative results (Refer to D5469); the laboratory failed to ensure patients with prior antibodies were checked before compatibility testing occurred and failed to document quality control for three patient testing days in 2022 (Refer to D5551); and the laboratory failed to perform refrigerator alarm checks according to the laboratory's established procedure (Refer to D5555).
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 observation of chemistry freezer, review of the Bio-Rad Liquichek Immunoassay Plus Control package insert, Bio-Rad Liquichek Cardiac Markers Plus Control LT package insert, Bio-Rad Liquid Unassayed Multiqual Control package insert, laboratory temperature logs, and interview with the general supervisor (GS) #1, the laboratory failed to follow manufacturer's instructions for reagent storage for 38 of 44 days in 2022. Findings: 1. Observation of the chemistry freezer showed Bio-Rad Liquichek Immunoassay Plus controls, Bio-Rad Liquichek Cardiac Markers Plus controls and Bio-Rad Liquid Unassayed Multiqual controls stored in freezer. 2. Review of the Bio-Rad Liquichek Immunoassay Plus Control package insert states, "Storage and stability: This product will be stable until the expiration date when stored unopened at -20C to -70C." 3. Review of the Bio-Rad Liquichek Cardiac Markers Plus Control LT package insert states, "Storage and stability: This product will be stable until the expiration date when stored unopened at -20C to -70C." 4. Review of the Bio-Rad Liquid Unassayed Multiqual Control package insert states, "Storage and stability: This product will be stable until the expiration date when stored unopened at -20C to -70C." 5. Review of laboratory temperature logs for August to date September 2022 showed the laboratory freezer digital temperature was not within acceptable range for 14 for 44 days and the inside freezer temperature was not within acceptable range for 38 of 44 days. 6. Interview with the GS #1 on September 13, 2022 at 2:30 PM, confirmed the laboratory failed to follow manufacturer's instructions for reagent 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 chemistry refrigerator and interview with the general supervisor (GS) #1, the laboratory failed to discard expired chemistry reagents. Findings: 1. Observation of the chemistry refrigerator showed: Two boxes of Vitros NT-proBNP range verifier lot #1780, expiration date August 11, 2022 still in use. One box of Vitros CKMB range verifier lot # 0438, expiration date August 6, 2022 still in use. 2. Interview with the GS #1 on September 13, 2022 at 1:15 PM confirmed the laboratory failed to discard expired chemistry reagents.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 review of the performance verification procedures for the Sysmex XN-350 hematology analyzer and interview with the general supervisor (GS) #1, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Sysmex XN-350 hematology analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing in February 2022. 2. Review of patient results from February 2022 to date September 13, 2022 showed 2637 complete blood count (CBC) patient results were reported. 3. Interview with the GS #1 on September 13, 2022 at 2:30 PM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
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 review of 2021 to date September 13, 2022 calibration records for the Ortho Diagnostics Vitros 5600 chemistry analyzer, iStat blood gas analyzer and interview with the general supervisor (GS) #1, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of the Vitros 5600 calibration records for 2021 through February 2022 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: sodium, potassium and chloride. 2. Review of the iStat blood gas calibration records for June 2021 showed no calibration that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: pH, pCO2 and pO2. 3. Interview with the GS #1 on September 13, 2022 at 2:00 PM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for sodium, potassium, chloride, pH, pCO2 and pO2.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Sysmex XN350 hematology analyzer quality control (QC), Sysmex XN-L check hematology QC package insert, and interview with the general supervisor (GS) #1, the laboratory failed to ensure hematology QC detects immediate errors that occur. Findings: 1. Review of Sysmex XN350 showed a new lot # of QC started on September 12, 2022 with ranges that do not match the package insert.

	Review of Sysmex XN350 QC ranges showed: Level 1 WBC 0..00-4.80 RBC 0.00-4.45 HGB 0.0-10.8 HCT 0.0-31.6 MCV 0.0-138.6 PLT 0-90 Level 2 WBC 0.00-13.76 RBC 0.00-8.62 HGB 0.0-25.6 HCT 0.0-72 MCV 0.0-167.0 PLT 0-472 Level 3 WBC 0.00-32.82 RBC 0.00-10.44 HGB 0.0-33.6 HCT 0.0-92.0 MCV 0.0-176.2 PLT 0-1200 2. Review of Sysmex XN-L Check hematology control package insert showed: Level 1; WBC 2.07-2.80 RBC 2.18-2.41 HGB 5.2-5.7 HCT 14.7-16.9 MCV 64.9-73.2 PLT 35-82 Level 2: WBC 6.40-7.82 RBC 4,21-4.56 HGB 12.5-13.6 HCT 34.3-38.6 MCV 78.1-88.1 PLT 202-285 Level 3: WBC 15.30-18.32 RBC 5.11-5.54 HGB 16.3-17.7 HCT 43.6-49.2 MCV 82.0-92.4 PLT 511-650 3. Interview with GS #1 on September 13, 2022 at 11:00 AM, confirmed the laboratory failed to ensure hematology QC detects immediate errors that occur.
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 review of the blood gas individualized quality control plan (IQCP), review of 2021/2022 blood gas quality control (QC), and interview with the general supervisor (GS) #1, the laboratory failed to ensure the IQCP was followed for 11 of 21 months. Findings: 1. Review of the blood gas IQCP states "Two levels of QC will be analyzed monthly." 2. Review of 2021 blood gas QC showed no monthly QC was performed in January, February, March, April, May, June, July, September, October, November and December for the analytes PH, PO2, and PCO2. 3. Interview with the GS #1 on September 13, 2022 at 11:00 AM confirmed the laboratory failed to perform monthly QC for blood gases.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Ortho Diagnostics Vitros 5600 chemistry analyzer quality control (QC) from May 1, 2022 to date September 13, 2022, patient results, and interview with the general supervisor (GS) #1, the laboratory failed to include two control materials of different concentrations for alkaline phosphatase (ALP), cholesterol, and alanine transaminase (ALT) for 20 of 135 patient testing days. Findings: 1. Review of Ortho Diagnostics Vitros 5600 chemistry analyzer QC results

	from May 1, 2022 to date September 13, 2022 showed two acceptable levels of ALP QC were not performed on August 8, 2022, August 22, 2022, July 3, 2022, July 2, 2022, June 19, 2022, June 13, 2022, June 4, 2022, May 14, 2022, May 5, 2022 and May 3, 2022. 2. Review of patient results showed the laboratory reported 80 ALP patients while QC was not acceptable. 3. Review of Ortho Diagnostics Vitros 5600 chemistry analyzer QC results from May 1, 2022 to date September 13, 2022 showed two acceptable levels of cholesterol QC were not performed on May 19, 2022, May 18, 2022, May 14, 2022 and May 1, 2022. 4. Review of patient results showed the laboratory reported 5 cholesterol patients while QC was not acceptable. 5. Review of Ortho Diagnostics Vitros 5600 chemistry analyzer QC results from May 1, 2022 to date September 13, 2022 showed two acceptable levels of ALT QC were not performed on August 29, 2022, June 27, 2022, June 26, 2022, June 25, 2022, June 20, 2022, and May 8, 2022. 6. Review of patient results showed the laboratory reported 52 ALT patients while QC was not acceptable. 7. Interview with the GS #1 on September 13, 2022 at 2:30 PM confirmed the laboratory failed to include two control materials each day of patient testing for ALP, cholesterol and ALT each day of patient testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview with testing personnel (TP) #2, review of Ortho Diagnostics Vitros 5600 quality control (QC) records, and interview with the general supervisor (GS) #1, the laboratory failed to establish criteria for acceptability of control materials providing quantitative results for 43 of 43 analytes. Findings: 1. Interview with TP #2 confirmed the laboratory uses Bio-Rad unassayed multiqual quality control (QC), Bio-Rad Liquichek Cardiac Markers Plus Control LT QC, and Bio-Rad Liquichek Diabetes Control QC for their Vitros 5600. The laboratory did not have copies of QC package inserts. TP #2 and GS #2 did not know how Vitros 5600 QC ranges were established. 2. Review of the Ortho Diagnostics Vitros 5600 QC records showed the laboratory did not establish and define statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC results reported on the chemistry analyzer for the analytes: aspartate aminotransferase, alanine aminotransferase, albumin, alkaline phosphate, alcohol, acetaminophen, amylase, beta HCG quantitative, calcium, carbamazepine, cholesterol, chloride, creatinine, creatinine kinase, creatinine kinase MB, digixon, direct bilirubin, direct high density lipoprotein, enzymatic CO2, free thyroxine, gentamicin, glucose, lactate, lipase, low density lipoprotein, magnesium, myoglobin, NT-proB-type natriuretic peptide,

	phosphorus, potassium, prostate specific antigen, phenytoin, salicylate, sodium, thyroid stimulating hormone, total bilirubin, total protein, triglyceride, troponin, urea, uric acid, vancomycin and valproic acid. From January 2021 to date September 13, 2022, the laboratory performed 371,500 patient chemistry tests. 3.Interview with the GS #1 on September 13, 2022 at 1:00 PM, confirmed the laboratory failed to establish criteria for acceptability of chemistry control materials providing quantitative results.
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 interview with testing personnel (TP) #4, review of Meditech LIS for blood bank, patient history with prior antibodies files, and interview with the general supervisor (GS) #1, the laboratory failed to ensure patients with prior antibodies were checked before compatibility testing was performed. Findings: 1. Interview with TP #4 stated before compatibility testing is performed patient history is checked in Meditech LIS system. 2. Review of the Meditech LIS system showed laboratory starting using the Meditech LIS system in 2018. 3. Review of the patient history in a paper file located in blood bank showed four patients with prior antibodies from 2014 to present September 13, 2022. No patient history could be provided previous to July 30, 2014. From January 2021 to date September 13, 2022 the laboratory performed 148 blood bank patients. 4. Review of the Community Blood Center of the Ozarks antibody consultation report showed one of four patient's were not entered into the Meditech LIS system. The patient from "7-13-14" had a "Warm auto-immune antibody" and was not entered into the Meditech LIS system. 5. Interview with the TP #4 and GS #1 on August 13, 2022 at 10:30 AM confirmed the laboratory failed to ensure patients with prior antibodies were checked before compatibility testing was performed. 44735 Based on review of blood bank procedures, blood bank patient logs, blood bank quality control (QC) logs, and interview with the general supervisor (GS) #1, the laboratory failed to document quality control (QC) for three patient testing days in 2022. Findings: 1. Review of the laboratory's blood bank policy "Quality Control Policies" states, "QC- Reagent QC must be performed on each day of use." 2. Review of 2022 blood bank patient testing logs showed patient testing was performed on January 22, 2022, May 7, 2022 and July 9, 2022. 3. Review of 2022 blood bank QC logs show no documented QC on January 22, 2022, May 7, 2022 and July 9, 2022. 4. Review of blood bank patient logs showed three units of blood were transfused to patients while blood bank QC was not documented. 5. Interview with the GS #1 on September 13, 2022 at 2:30 PM, confirmed the laboratory failed to document quality control for three patient testing days in 2022.
D5555	IMMUNOHEMATOLOGY

	CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 review of blood bank expected refrigerator temperature range, blood bank refrigerator continuous temperature monitoring by a recording thermograph, and interview with the general supervisor (GS) #1, the laboratory failed to accurately monitor the blood bank refrigerator temperature for 14 of 21 months. Findings: 1. Review of blood bank refrigerator acceptable temperature ranges showed acceptable ranges as 2 degrees Celsius to 6 degrees Celsius. 2. Review of blood bank refrigerator continuous temperature monitoring by a recording thermograph showed a continuous temperature reading of "10" for August 2021 to date September 13, 2022. 3. Interview with the GS #1 on September 13, 2022 at 11:00 AM confirmed the laboratory failed to accurately monitor the blood bank refrigerator. 44735 Based on review of the blood bank procedures, blood bank alarm test log, lack of blood bank alarm test logs for 2021, and interview with the general supervisor (GS) #1, the laboratory failed to perform refrigerator alarm checks according to the laboratory's established procedure. Findings: 1. Review of blood bank procedure "Blood Bank Refrigerator Alarm Testing" states, "To check the high activation temperature: (5.5 degree Celsius)." 2. Review of blood bank alarm test log showed in quarter 1 of 2022 on January 22, 2022, the refrigerator starting temperature was 6 degrees Celsius and the refrigerator high alarm when it sounded at the nurse's station was 5.5 degrees Celsius. 3. Review of blood bank procedure "Blood Bank Refrigerator Alarm Testing" states, "Both the high and low activation temperatures are checked and documented at least on a quarterly basis using the Blood Bank Refrigerator Alarm Verification Form." 4. The laboratory did not have documentation for quarterly refrigerator alarm inspections during 2021. 5. Interview with the GS #1 on September 13, 2022 at 2:30 PM confirmed, the laboratory failed to perform blood bank refrigerator alarm inspections according to the laboratory's established procedure.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of blood bank quality control (QC), blood bank antibody history check, Vitros 5600 chemistry analyzer QC, iSTAT blood gas analyzer QC, Sysmex XN-350 hematology QC, freezer temperatures, observation of reagents, Sysmex XN-350 performance verification, chemistry and blood gas calibration verification, blood bank alarm checks, blood bank refrigerator temperature and interviews, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The LD failed to ensure the overall operation of the laboratory was appropriate for

	reporting accurate results (Refer to D6079); the LD failed to ensure the laboratory maintained acceptable levels of analytical performance (Refer to D6095).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 review of blood bank quality control (QC), blood bank antibody history check, Vitros 5600 chemistry analyzer QC, iSTAT blood gas analyzer QC, Sysmex XN-350 hematology QC, freezer temperatures, observation of reagents, Sysmex XN-350 performance verification, chemistry and blood gas calibration verification, blood bank alarm checks, blood bank refrigerator temperature and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure the overall operation of the laboratory was appropriate for reporting accurate results. Findings: 1. Review laboratory QC showed the LD failed to ensure QC was performed appropriately for blood bank, chemistry, blood gases and hematology (Refer to D5551, D5469, D5447, D5445 and D5441). 2. Review of temperatures logs and reagents showed the LD failed to ensure freezer temperatures were within acceptable limits and reagents were not used past expiration (Refer to D5411 and D5417). 3. Review of Sysmex XN-350 showed the LD failed to ensure performance verification was acceptable before patient testing started (Refer to D5421). 4. Review of chemistry and blood gas calibration verification showed the LD failed to ensure calibration verification was performed every six months (Refer to D5439). 5. Review of blood bank alarm checks and temperature logs showed the LD failed to ensure blood bank refrigerator alarm checks and temperature were documented appropriately (Refer to D5555). 6. Interview with GS #1 on September 13, 2022 at 2:30 PM confirmed the laboratory director (LD) failed to ensure the overall operation of the laboratory was appropriate for reporting accurate results.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of blood bank quality control (QC), blood bank antibody history check, Vitros 5600 chemistry analyzer QC, iSTAT blood gas analyzer QC, Sysmex XN-350 hematology QC and interview with the general supervisor (GS) #1, the laboratory director (LD) failed to ensure the laboratory maintained acceptable levels

	of analytical performance. Findings: 1. Review of blood bank patient logs showed three units of blood were transfused to patients while blood bank QC was not documented on January 22, 2022, May 7, 2022 and July 9, 2022 (Refer to D5551). 2. Review blood bank history check and Community Blood Center of the Ozarks antibody consultation report showed one of four patient's were not entered into the medi-tech LIS system. The patient from "7-13-14" had a "Warm auto-immune antibody" and was not entered into the medi-tech LIS system. No patient history could be provided previous to July 30, 2014. From January 2021 to date September 13, 2022 the laboratory performed 148 blood bank patients (Refer to D5551). 3. Review of Ortho Diagnostics Vitros 5600 quality control (QC) record showed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results for 43 of 43 analytes (Refer to D5469). 4. Review of Ortho Diagnostics Vitros 5600 quality control (QC) record showed the laboratory failed to include two control materials of different concentrations for alkaline phosphatase, cholesterol and alanine transaminase (ALT) for 20 of 135 patient testing days (Refer to D5447). 5. Review of 2021 blood gas QC showed no monthly QC was performed in January, February, March, April, May, June, July, September, October, November and December for the analytes PH, PO2 and PCO2 (Refer to D5445). 6. Review of Sysmex XN-350 hematology analyzer QC showed hematology ranges failed to ensure hematology QC detects immediate errors that occur. (Refer to D5441) 7. Interview with GS #1 on September 13, 2022 at 11:00 AM confirmed the LD failed to ensure the laboratory maintained acceptable levels of analytical performance..