Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445376	10/14/2020
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2018, 2019 and 2020 blood gas quality control (QC) records and interview with testing personnel #6, the laboratory failed to retain blood gas QC for at least 2 years. Findings: 1. Review of blood gas QC showed no documentation of blood gas QC from January 2018 to November 2018. 2. Interview with testing personnel #6 on October 14, 2020 at 11:00 AM confirmed the laboratory failed to retain blood gas QC for at least 2 years.
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 ACL Elite analyzer, Vitros 5600 chemistry analyzer and the i-Stat blood gas analyzer, the laboratory failed to verify normal patient range (Refer to D5411), failed to follow manufacturer's instructions (Refer to D5415), failed to

	perform preventative maintenance (Refer to D5429), failed to perform calibration (Refer to D5439) and failed to perform instrument comparisons (Refer to D5775).
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 manufacturer's product insert, lack of documentation of normal patient Protime mean study and interview with testing personal (TP) #1 the laboratory failed to verify normal patient Protime mean study. Findings: 1. Review of manufacturer's product insert for HemosiL reagent states "each laboratory should verify its own normal range for Protime, international normailized ratio (INR) results." 2. No documentation was available to show the laboratory performed a normal patient Protime mean study. 3. Interview with TP #1 on October 14, 2020 at 0930 AM confirmed the laboratory did not have documentation proving they verified the normal patient Protime result used in conjunction with the international standard index to calculate INR.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of manufacturer's product insert, procedure manual and interview with testing personal (TP) #1, the laboratory failed to follow manufacturer's storage requirements for HemosIL controls. Findings: 1. Review of manufacturer's product insert stated "HemosIL controls after reconstitution, are stable for 8 hours at 2-8 degrees Celsius in the original vial." 2. Procedure manual stated "reconstituted controls in original vials are stable for 8 hours when stored at 2-8 degrees Celsius." Observation revealed two controls aliquoted and stored in the freezer. 3. Interview with TP #1 October 14, 2020 at 9:30 AM confirmed the laboratory was aliquoting controls after reconstitution and freezing for later use.
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 manufacturer's preventive maintenance (PM) procedure, lack of PM documentation and interview with the general supervisor (GS) the laboratory failed to perform PM procedures for blood bank cell washer for years 2018, 2019 and 2020. Findings: 1. Review of manufacturer's PM procedure checks included, "daily inspect tubing and conections, inspect interior bowl, check saline fill volume, weekly flush tubing with a 1:10 solution of household bleach, clean the rotor and solenoid plunger and three months check motor speed.". 2. No documentation was available for PM checks for years 2018, 2019 and 2020, 3. Interview with the GS October 14, 2020 at 9: 40 AM the laboratory failed to follow manufacturer's PM procedures for daily, weekly, and three month intervals in 2018, 2019 and 2020.
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 calibration records for the Vitros 5600 analyzer, i-Stat analyzer and interview with the general supervisor #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 2018 and to date October 14, 2020 for the analyte hemoglobin A1C showed the laboratory failed to perform calibration verification which included at least a minimal value, a mid-point value and a maximum value near the upper limit at least once every six months. 2. Review of the i-Stat blood gas analyzer calibration records for 2018 to date October 14, 2020 for the analytes: pH, pCO2 and pO2 showed the laboratory failed to perform calibration verification which included at least a minimal value, a mid-point value and a maximum value near the upper limit at least once every six months. 2. Interview with general supervisor #1 on October 14, 2020 at 11:30 AM confirmed the laboratory failed to perform calibration verification procedure for hemoglobin A1C and blood gases at least once every six months.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of lack of i-Stat instrument comparison's in 2018, 2019 and interview with the general supervisor #1, the laboratory failed to evaluate and define the relationship between analyzers performing blood gases twice a year. Findings: 1. Review of 2018 and 2019 i-Stat instrument comparison's for analytes: pH, pCO2 and pO2 showed the laboratory failed to evaluate and define the relationship between two i-Stat analyzers twice a year. 2. Interview with the general supervisor #1 on October 14, 2020 at 12:15 PM confirmed, the laboratory failed to evaluate and define the relationship between two i-Stat analyzers twice a year.
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 i-Stat blood gas analyzer, Immunohematology the laboratory director failed to verify i-stat verification (Refer to D6086), failed to review proficiency testing results (Refer to D6091), failed to ensure blood bank quality control (Refer to D6093) and failed to ensure i-Stat competencies (Refer to D6103).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of blood gas i-Stat verification and interview with general supervisor (GS) #1, the laboratory director failed to perform reportable range of the test results for i-Stat blood gases and failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. Findings: 1. Review of the i-Stat verification from June 2018 showed no verification of reportable range of the test results for the i-Stat and no verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for analytes; pH, pCO2 and pO2. 2. Interview with the GS #1 on October 14, 2020 at 11:30 AM confirmed the laboratory director failed to ensure verification procedures were adequate for the i-Stat blood gas analyzer.

D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 2019, 2020 Proficiency testing (PT) and interview with the general supervisor (GS) #1, the laboratory director failed to ensure 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. Findings: 1. Review of 2019, 1st event chemistry PT showed "not graded" for all samples of blood gases for pCO2, pH and pO2 and laboratory director failed evaluate. 2. Review of 2019, 1st event hematology PT showed BCI-04, BCI-05 "unacceptable" and laboratory director failed to identify any problems that require corrective action. 3. Interview with the GS #1 on October 14, 2020 at 11:30 AM confirmed the laboratory director failed to ensure all PT reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of 2020 immunohematology quality control (QC), patient blood bank logs and interview with the general supervisor (GS) #1, the laboratory director failed to ensure blood bank QC was maintained and to identify failures in quality as they occur. Findings: 1. Review of blood bank QC on July 14, 2020 showed no QC performed on July 14, 2020. 2. Review of blood bank patient logs on July 14, 2020 showed one patient retyped. 3. Review of blood bank documents showed lack documentation to identity failures in quality when they occurred on July 14, 2020. 4. Interview with the GS #1 on October 14, 2020 at 11:00 AM confirmed the laboratory director failed to ensure blood bank QC was maintained and to identify failures in quality as they occur.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: Based on review of 2018, 2019, 2020 competencies and interview with the general supervisor (GS) #1, the laboratory director failed to ensure two of two moderate complexity testing personnel (TP) maintained competency. Findings: 1. Review of 2018 and 2019 competencies showed no documentation of competency for TP #5 by qualified staff. 2. Review of 2019 competencies showed no documentation of competency for TP #6 by qualified staff. 3. Interview with the GS #1 on October 14, 2020 at 11:30 AM confirmed the laboratory director failed to ensure moderate complexity TP maintained competency.