Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445376	05/01/2018
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and patient records for 2017 and interview with the general supervisor, the laboratory failed to verify the accuracy of the Leuko-EZ Vue test at least twice annually. Findings: 1. Review of PT records for 2017 revealed the laboratory did not verify the accuracy of the moderately complex Leuko-EZ Vue test (a marker for fecal leukocytes and indicator of intestinal inflammation) at least twice annually for 2017. 2. Review of patient records for 2017 revealed the laboratory performed the Leuko-EZ Vue test on seven patients. 3. Interview with the general supervisor on May 1, 2018 at 2:00 PM confirmed the laboratory failed to verify the accuracy of the Leuko-EZ Vue test at least twice annually during 2017.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, documentation of freezer temperatures and observation of quality control (QC) material stored in the freezer revealed, and interview with the general supervisor, the laboratory failed to follow the manufacturer's instructions for storage of control material for 6 of 121 testing days since January 1, 2018 through May 1, 2018. Findings: 1. Review of the manufacturer's instructions for Bio-Rad liquid unassayed Multiqual control showed controls must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 2. Review of the laboratory's temperature chart showed a defined acceptable range of minus 18 degree C or below. 6 of 121 testing days failed to meet the manufacturer's required minus 20 to minus 70 degree C range. 3. Observation of the laboratory freezer showed 2 boxes of Bio-Rad Multiqual unassayed control level I(lot# 47971)control currently in use in the laboratory. 4. Interview with the general supervisor on May 1, 2018 at 11:00 AM confirmed the laboratory failed to properly monitor the freezer and store QC materials per manufacturer's instructions.
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 coagulation plasma calibration materials on May 1, 2018 and interview with the general supervisor, the laboratory failed to ensure four of four boxes of calibration materials did not exceed the expiration date. Findings: 1. Observation of four boxes of Hemosil (coagulation) plasma calibration materials, lot number N0154106, revealed an expiration date of January 2018 and were available for use. 2. Interview with the general supervisor on May 1, 2018 at 10:00 AM confirmed the calibration materials expired and were available for coagulation calibration procedures. 38475 Based on observation of chemistry calibration reagents and interview with the general supervisor the laboratory failed to ensure that all calibrators in use had not exceeded their expiration date. Findings: 1. Observation of Vitros chemistry liquid performance verifier showed level 1 lot # 170929 expired 9/29 /17 and level 11 lot # 170930 expired 9/29/17 and were still available for use. 2. Interview with the general supervisor on May 1, 2018 at 11:30 AM confirmed the laboratory failed to ensure that all calibrators in use had not exceeded their expiration date.
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 patient test reports, laboratory procedure manuals and interview with the general supervisor, the laboratory failed to ensure pertinent normal values as determined by the laboratory were available for interpretation. Three of three selected

	patient test reports generated by the laboratory information system on May 1, 2018 revealed differences between normal values for BUN and urine microscopic white blood cells (WBC) included on test reports and those stated in the approved procedure manual Findings: 1. The differences between BUN and urine microscopic (WBC) normal values included on patient test reports and those included in the procedure manual approved by the director are as follows: Normal values included on patient test reports: Blood Urea Nitrogen (BUN) 7-25 mg/dl (male/female) Urine Microscopic : 3-5 WBC / HPF Normal values included in the approved chemistry and urinalysis procedure manual: BUN 9-20 mg/dl (male) BUN 7-17 mg/dl (female) Urine Microscopic : 0-5 WBC / HPF 2. Interview with the general supervisor on May 1, 2018 at 2:00 PM confirmed the normal values determined by the laboratory and approved by the laboratory director differed from those included on the test reports.