Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0445376	10/06/2026
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of iSTAT procedure, review of quality control (QC) for the iSTAT analyzer, observation of cartridges, review of chem 8+ QC log, review patient test numbers, and interview with the general supervisor (GS).the laboratory failed to follow procedure and perform iSTAT QC for CG8+ for 6 patient testing days in 2025 /2026, for iSTAT high sensitivity (HS) troponin for 3 patient testing days in 2026 and failed to follow procedure and document QC for one new iSTAT CG8+ cartridge lot number in 2026. Findings: 1. Review of "ISTAT QUICK GUIDE" procedure states "Chem8+ QC every day of patient testing, new lot or shipment" and "Troponin QC every day of patient testing". 2. Review of chem 8+ patient results showed on the following dates patient results were reported and no QC was performed: 4/7/25 two patients test results reported 4/8/25 two patients test results reported 5/12/25 one patient test results reported 8/25/25 one patient test results reported 6/13/26 one patient test results reported 7/17/26 one patient test results reported 3. Review of HS troponin patient results showed on the following dates patient results were reported and no QC was performed: 5/25/26 two patients test results reported 6/13/26 one patient test results reported 7/9/26 one patient test results reported 4. Observation of iSTAT chem 8+ cartridges showed chem 8+ cartridge lot number H25112 in use since August 2026. 5. Review of chem 8+ QC log showed no documentation of QC for chem 8+ cartridge lot number H25112. 6. Interview with the GS on October 6, 2026 at 11:00 AM confirmed the laboratory failed to follow procedure for iSTAT QC.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 Ortho Vitros 5600 chemistry analyzer operator's guide, January 2026 to date October 6, 2026 laboratory humidity records, Centers for Medicare and Medicaid Services Form 116 (CMS-116) and interview with the general supervisor (GS) #1, the laboratory failed to ensure the humidity was maintained for 29 of 279 days. Findings: 1. Review of the Ortho Vitros 5600 chemistry analyzer operator's guide states "Site Relative humidity: 15-75% RH non-condensing". 2. Review of the laboratory humidity records shows that the humidity in the laboratory where the Ortho Vitros 5600 is located was out of range for 29 of 279 days from January 2026 to date October 6, 2026. 3. Review of CMS-116 showed the laboratory performs approximately 60,000 chemistry patient tests annually. 4. Interview with the GS #1 on October 6, 2026 at 11:30 AM confirmed the laboratory failed to ensure the humidity was maintained for 29 days.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of blood gas individualized quality control plan (IQCP) for the iStat blood gas analyzer, review of January 2025 to date October 6, 2026 iStat quality control (QC), patient results and interview with the general supervisor (GS), the laboratory failed to ensure that the IQCP for the iStat blood gas analyzer was followed for 2 of 21 months. Findings: 1. Review of blood gas procedure "Individualized Quality Control Plan (IQCP) for the Abbott i-STAT Analyzer" stated "Currently, we perform QC that meets manufacturer recommendations, by doing 2 levels of liquid QC every month and with each new lot shipment of cartridges". 2. Review of iStat blood gas analyzer QC showed no QC was performed in October 2025 or May 2026.

	3. Review of iStat blood gas analyzer patient results showed approximately 957 patient results annually. 4. Interview with the GS on October 6, 2026 at 11:00 AM confirmed the laboratory failed to ensure the iStat IQCP was followed.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of August 2026 Sediplast Westergren Erythrocyte Sedimentation Rate (ESR) quality control records, and patient results and interview with general supervisor (GS) #1, the laboratory failed to include two control materials of different concentrations each day of patient testing for 19 of 19 ESR testing days. Findings: 1. Review of August 2026 Sediplast Westergren ESR QC and patient results showed: 08 /01/2026 ESR resulted on one patient and no QC performed 08/04/2026 ESR resulted on seven patients and no QC performed 08/05/2026 ESR resulted on six patients and no QC performed 08/06/2026 ESR resulted on three patients and no QC performed 08 /07/2026 ESR resulted on one patient and no QC performed 08/09/2026 ESR resulted on one patient and no QC performed 08/10/2026 ESR resulted on two patients and no QC performed 08/11/2026 ESR resulted on two patients and no QC performed 08/13 /2026 ESR resulted on two patients and no QC performed 08/14/2026 ESR resulted on one patient and no QC performed 08/18/2026 ESR resulted on one patient and no QC performed 08/19/2026 ESR resulted on two patients and no QC performed 08/20 /2026 ESR resulted on four patients and no QC performed 08/21/2026 ESR resulted on two patients and no QC performed 08/26/2026 ESR resulted on three patients and no QC performed 08/27/2026 ESR resulted on one patient and no QC performed 08/28 /2026 ESR resulted on three patients and no QC performed 08/29/2026 ESR resulted on one patient and no QC performed 08/31/2026 ESR resulted on one patient and no QC performed 2. Review of patient results showed that the laboratory performs approximately 528 ESR patient tests annually. 3. Interview with the GS #1 on October 6, 2026 at 10:30 AM confirmed the laboratory failed to include two control materials of different concentrations each day of patient testing.
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. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of Sysmex CA-660 coagulation analyzer quality control (QC), patient results and interview with the general supervisor (GS), the laboratory failed to include two levels of control material each 8 hours of operation for d-dimer for 1 of 30 patient testing days in September 2026. Findings: 1. Review of laboratory procedure "D-Dimer - Sysmex Ca660" states "Innovance D-Dimer controls must be tested every 8 hours of patient testing on each testing day." 2. Review of the Sysmex CA-660 coagulation analyzer quality control (QC) for September 2026 showed QC was not performed on September 4, 2026. 3. Review of patient results showed one patient d-dimer result was released on

	September 4, 2026, when QC was not performed. 4. Interview with the GS on October 6, 2026, at 10:30 AM confirmed the laboratory failed to perform two levels of d-dimer QC each 8 hours of operation.