Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0652475	08/24/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mccone County Health Center	605 Sullivan Avenue, Circle, MT	

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
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 the calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes of sodium, potassium, and chloride, and interview with the Laboratory Director (LD) #1, the laboratory failed to perform at least a three point (a minimal, mid-point, and maximum) calibration verification every six months. Findings: 1. Review of 2019 and 2020 calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes: sodium, potassium, and chloride,

	revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Interview with the LD #1 on August 24, 2021 at 9:03 AM confirmed the laboratory failed to perform at least a three-point calibration for sodium, potassium, and chloride on the Siemens Dimension EXL 200 chemistry analyzer every six months.
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 record review, policy manual, and interview with Laboratory Director (LD) #1, the laboratory failed to run two levels of control materials each day of patient testing for the i-STAT CHEM8+ cartridge with the Abbott i-STAT 1 System for analytes sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide for year 2020. Findings: 1. Review of QC records for CHEM8+ cartridge for chemistry analysis lacked two levels of controls for each day of patient testing for analytes sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, and total carbon dioxide for year 2020. 2. Review of Chemistry Testing Using i-STAT Clinical Analyzer states "External controls (3 levels) must be run with each new shipment and /or lot number of cartridges or as needed to verify the system integrity and operator proficiency" 3. No Individualized Quality Control Plan (IQCP) procedure was available for review. 4. Interview with LD#1 on August 24, 2021 at 8:40 AM confirmed the laboratory failed to run two levels of controls each day of patient testing on the i-STAT analyzer for the CHEM8+ cartridge in year 2020 or have an IQCP for alternative QC practices.
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 record review of instrument comparison documentation and interview with Laboratory Director (LD) #1, the laboratory failed to perform instrument comparison for analyzers, Abbott i-STAT 1 System and the Siemens Dimension EXL for analytes sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, and total carbon dioxide and analyzers, Sysmex XS-1000i and the Abbott iSTAT 1 system for analyte hematocrit two times a year. Findings: 1. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for Abbott i-STAT 1 System and the

	Siemens Dimension EXL for analytes sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, and total carbon dioxide for year 2020. 2. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for the Sysmex XS-1000i and the Abbott iSTAT 1 system for analyte hematocrit for year 2020. 3. Interview with LD #1 on August 24, 2021 at 9:10 AM confirmed the laboratory failed to perform twice a year instrument comparison.