Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 27D0409886	**(X3) Date Survey Completed** 06/24/2021
Name of Provider or Supplier Colstrip Medical Center	**Street Address, City, State** 6230 Main Street, Colstrip, 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**
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 observation, review of laboratory records and interview with General Supervisor (GS) #1, the laboratory failed to perform preventative maintenance (PM) for 1 of 2 centrifuges for years 2019 and 2020. Findings: 1. Observed two centrifuges in the laboratory, each with a calibration sticker. The calibration sticker for the UNICO PowerSpin LX Centrifuge was dated 4/16 (month /year) by BTM 2. No PM or calibrations records for the UNICO PowerSpin LX Centrifuge were available for review for years 2019 and 2020. 3. Interview with GS #1 on 6/24/2021 at 10:15 AM confirmed the laboratory failed to perform preventative maintenance for 1 of 2 centrifuges for years 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 IQCP Quality Control Plan, calibration records for the Abbott i-STAT Analyzer for CHEM8+ cartridge (analytes: Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Urea Nitrogen (BUN), Creatinine, Hematocrit), and i-STAT Troponin cartridge (analyte Troponin), and interview with the General Supervisor (GS) #1, the laboratory failed to perform at least a three point (a minimal, mid-point, and maximum) calibration verification every six months for years 2019 and 2020. Findings: 1. Review of 2019 and 2020 calibration records for Abbott i-STAT analyzer for Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Urea Nitrogen (BUN), Creatinine, Hematocrit and Troponin, revealed the laboratory failed to perform a calibration verification including, at least, a minimal, midpoint, and maximum value for each analyte, every six months for years 2019 and 2020 2. Review of IQCP Quality Control Plan for i-STAT Troponin revealed Calibration Verification should be performed with a linearity kit every 6 months. 3. Interview with the GS #1 on June 24, 2021 at 9:24 AM, confirmed the laboratory failed to perform at least a three point calibration verification for Sodium, Potassium, Chloride, Ionized Calcium, Glucose, Urea Nitrogen (BUN), Creatinine, Hematocrit and Troponin, on the i-STAT analyzer every six months for years 2019 and 2020.