Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042064	07/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Benefis Teton Medical Center	915 4th Street Nw, Choteau, 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 Xpand Plus chemistry analyzer for the analytes of sodium, potassium, and chloride, and interview with the Technical Supervisor (TS) #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 Xpand Plus 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 TS #1 on July 27, 2021 at 9:30 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.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on review of the blood bank procedure manual, documentation of 2019, 2020 blood bank refrigerator alarm checks, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform and document regular alarm inspection checks for 1 of 1 blood bank refrigerator. Findings: 1. Review of the TMC Blood Banking Procedure Manual revealed "3.7 Alarm checks are at least quarterly and recorded on the monthly temperature charts." 2. Review of the 2019, 2020 documentation for alarm checks revealed the laboratory failed to perform alarm checks quarterly for year 2020. 3. Interview with the TS #1 on July 27, 2021 at 2:20 PM confirmed the laboratory failed to regularly perform and document the alarm checks every 3-4 months to monitor proper blood and blood product storage temperatures.