Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042064	04/25/2023
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
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation, review of maintenance documentation, policy and procedure manual, and interview with Technical Supervisor (TS) #1, the laboratory failed to perform annual certification for one of one biological fume hood from April 25, 2021, to April 25, 2023. Findings: 1. Observed one biological fume hood in the laboratory with a function check sticker dated 4/9/2018. No other function check sticker or certification records were available for review from April 25, 2021, to April 25, 2023. 2. No policy or procedure dictating the frequency of certification for the biological fume hood was available for review. 3. Interview with TS #1 on April 25, 2023 at 2: 00 PM, confirmed the laboratory failed to have the biological fume hood certified for years 2021 and 2022.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When

	control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records, policies and procedures, and an interview with the technical supervisor (TS) #1, the laboratory failed to verify the new lots of hematology quality control material performed on the Sysmex XN 450 analyzer prior to patient testing from April 25, 2021 to April 25, 2023. Findings: 1. No concurrent studies of lot-to-lot changes to verify that the Sysmex XN 450 quality control materials (levels 1, 2, and 3) met acceptability requirements prior to patient testing were available for review from April 25, 2021, to April 25, 2023. 2. The laboratory failed to have in their procedures how to verify new lots of quality control material performed on the Sysmex XN 450 hematology analyzer. 3. Based off the test volume sheet, 2098 complete blood count (CBC) patient tests were performed from April 25, 2022 to April 25, 2023 (12 months). 4. An interview with (TS) #1 on April 25, 2023, at 3:17 PM, confirmed the laboratory failed to verify new lots of QC material for the hematology analyzer from April 25, 2021, to April 25, 2023.