Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520487	04/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Caribou Medical Center	300 South 3rd West, Soda Springs, ID	

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
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a random review of immunohematology quality control (QC) records, patient records and an interview with the laboratory manager on 4/20/2021, the laboratory failed to document control material results with graded or titered reactivity and include negative control material. The findings include: 1. A random record review of immunohematology QC and patient records for 2019, 2020 and 2021 identified that the laboratory failed to document positive QC (1-4+) and negative QC on 12/20/2019, 7/26/2020 and 10/13/2020 as required by regulation for ABO and Rh type, antibody screen and crossmatch testing. 2. One ABO and Rh type, antibody screen and crossmatch was performed on 12/20/2019. One ABO and Rh type, antibody screen and crossmatch was performed on 7/26/2020. One ABO and Rh type, antibody screen and crossmatch was performed on 10/13/2020. 3. An interview with the laboratory manager on 4/20/2021 at 10:00 am confirmed that immunohematology QC was not documented on 12/20/2019, 7/26/2020 and 10/13/2020.
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. (d)

	The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a random record review of Quality Control (QC) documentation, instrument printouts and an interview with the laboratory manager on 4/19/2021 the laboratory failed to successfully perform two levels of of control material each 8 hours of operation. The findings include: 1. A random record review of QC documents and instrument printouts from the Sysmex CA-600 for 2019, 2020 and 2021 identified that the laboratory failed to perform two levels of QC for prothrombin time (PT) on 2/6 /2021. The laboratory performed one patient PT test on 2/6/2021. 2. An interview with the laboratory manager on 4/19/2021 at 3:18 pm confirmed that the laboratory failed to perform PT QC on 2/6/2021.