Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520487	01/10/2023
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the prothrombin time (PT) reagent cross over study documents, the Dade Innovin reagent package insert, a direct observation and an interview with the laboratory manager on 01/10/2023, the laboratory failed to use the correct international sensitivity index (ISI) and normal patient mean for patient International Normalized Ratio (INR) calculations. The findings include: 1. A review of the PT reagent cross over study documents identified a normal patient PT mean of 10.7 for the current Innovin lot number 549783. 2. A review of the Dade Innovin reagent package insert for lot 549783 identified an ISI of 1.08. 3. A direct observation of the ISI in the Sysmex CA620, the laboratory coagulation analyzer, identified an ISI of 1.07 and a patient mean of 10.4. The laboratory failed to use the correct ISI and patient mean to calculate the INR for patient reporting. 4. An interview with the laboratory manger on 01/10/2023 at 08:53 am confirmed that the laboratory was using the incorrect ISI and normal patient mean to calculate patient INRs since the new lot of reagents were put in use on 05/05/2021. 5. The laboratory reports performing 429 PT/INR tests annually.