

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0042064	(X3) Date Survey Completed 03/04/2025
Name of Provider or Supplier Benefis Teton Medical Center	Street Address, City, State 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a record review, observation, and interview with the technical supervisor (TS) #1, the laboratory failed to follow the manufacturer's instructions for use and verify the mean normal prothrombin time (MNPT) for the new lot of Dade Innovin Reagent used to calculate International Normalized Ratio (INR) on their Sysmex CA-600 coagulation instrument from March 01, 2024, to March 04, 2025. Findings: 1. An observation of one Sysmex CA-620 coagulation instrument in the laboratory on March 04, 2025, at 1:45 PM had the following values entered: Dade Innovin lot # 564628, expiration date 8/25/25, International Sensitivity Index (ISI) value of 1.04 and MNPT of 10.4 seconds for the new lot of prothrombin reagents put into use on March 01, 2024. 2. A review of coagulation records lacked studies to determine the MNPT per the manufacturer's instructions for use, which stated that it should be determined for each lot using the method and coagulation analyzer used to analyze patient samples. 3. A review of the test volume sheet revealed 271 prothrombin time patient tests were performed in the last 12 months, from March 04, 2024, to March 04, 2025. 4. An interview with TS #1 on March 04, 2025, at 2:00 PM stated the MNPT value was determined by another laboratory with a different coagulation analyzer and used from March 01, 2024, to March 04, 2025. The MNPT was evaluated and corrected at the time of the interview.</p>