Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0519557	(X3) Date Survey Completed 10/15/2024
Name of Provider or Supplier Memorial Regional Health	**Street Address, City, State** 750 Hospital Loop Rd, Craig, CO	

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 an observation, and an interview with the laboratory's general supervisor (GS), the laboratory failed to follow the manufacturer's instructions for calculating the international normalized ratio (INR) from prothrombin time (PT) coagulation specimens on the Sysmex CA600 coagulation analyzer since the last recertification survey on 10/22/2021. The laboratory performs approximately 891 PT/INR tests annually. Findings include: 1. An observation on October 15, 2024, at approximately 12:00 PM, revealed the laboratory failed to input the current lot number of the Innovin reagent (Lot #564652, expiration date: 05/16/2026, ISI = 1.06) into the Sysmex CA600 coagulation analyzer. The previous lot number (Lot # 564628, expiration date: 8/25/2025, ISI = 1.04) was entered in the Sysmex CA600 coagulation analyzer and was being used for INR calculations. 2. Based on an interview with the GS on October 15, 2024, at approximately 12:05 PM, confirmed that that laboratory failed to input the current lot number of Innovin reagent (see above) into the Sysmex CA600 coagulation analyzer, and was using the previous lot of Innovin programming into the analyzer to calculate the INR.