

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0628373	(X3) Date Survey Completed 05/22/2025
Name of Provider or Supplier Harney District Hospital Lab	Street Address, City, State 557 W Washington St, Burns, OR	
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: This STANDARD is not met as evidenced by: Based on the Coagulation instrument data review, Dade Innovin reagent package insert review and testing personnel interview on 05/21/2025 at 1300, the laboratory failed to verify the Dade Innovin reagent lot number in use was current in the instrument. Findings include: a. Upon review of the Sysmex CA-600 coagulation analyzer, the Dade Innovin reagent lot number in the analyzer was Lot 564615A expiration 03/03/2025, with an International Sensitivity Index (ISI) of 1.04. b. Upon review of the Dade Innovin reagent package insert currently in use on the analyzer, the lot number is 564640 expiration 12/01/2025, with an International Sensitivity Index (ISI) of 1.09. c. Interview with testing personnel (TP3) confirmed the laboratory was using Dade Innovin reagent lot number 564640 expiration 12/01/2025. d. The laboratory performs approximately 489 prothrombin time tests annually.</p>