

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0047289	(X3) Date Survey Completed 03/24/2026
Name of Provider or Supplier Trego Lemke Memorial Hospital	Street Address, City, State 320 N 13th St, Wakeeney, KS	
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 review of instrument type, manufacturer's instructions, an unaccepted geometric mean (GM), patient testing volumes and interview with general supervisor #1 (GS#1) and the technical consultant (TC), the laboratory failed to enter the correct International Sensitivity Index (ISI) in the Sysmex 600 series for reagent lot changes for Dade Innovin reagent for prothrombin time (PT) prior to use for patient testing. Findings: 1. Prothrombin time (PT) testing are performed on the 600 series coagulation analyzer from Sysmex. 2. The Sysmex 600 series instrument setting for PT testing showed Dade Innovin reagent lot #564680, expiration 1/30/28 and an ISI of 1.06. 3. Dade Innovin package instructions states the ISI to be entered in the Sysmex 600 series instrument should be 1.01 4. The GM study for the new Dade Innovin reagent is 10.1. The GM entered into the Sysmex 600 series was 10.2. 5. The incorrect ISI of 1.6 was entered incorrectly on 5/31/25. 6. Dade Innovin reagent lot #564680 was placed into use for patient testing on 5/31/25 with 95 patient results reported from 5/31/25 to 3/24/26. 7. Interview with GS #1 and the TC on 3/24/26 at 11:30 a.m. confirmed, the laboratory failed to follow manufacturer's package insert instruction on reagent lot changes for the ISI on the Sysmex 600 series, Dade Innovin reagent for prothrombin time (PT) prior to use for patient testing.</p>