

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0453281	(X3) Date Survey Completed 03/12/2025
Name of Provider or Supplier Greeley County Hospital / Long Term Care	Street Address, City, State 506 Third Street, Tribune, 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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for Dade Innovin, quality control and quality assessment records for coagulation, observation of the laboratory's Sysmex CA-600 series and interview, revealed that the laboratory did not follow manufacturer's instructions for International Safety Index (ISI) upon utilizing a new lot number from 1/1/2025 to time of survey. Findings: 1. Quality control and quality assessment records for the Sysmex CA-600 Series coagulation analyzer on 3/12/2025 determined the Prothrombin Time (PT) and International Normalized Ratio (INR) for 42 patients could be affected with the current lot of Dade Innovin in use. 2. The laboratory failed to update the ISI in the Sysmex CA-600 series upon the new Lot to Lot completion on 1/1/2025. 3. The manufacturer's current lot of Dade Innovin (564665 Exp: 6/13/2027) listed the ISI for the CA-500/CA-600 series 1.08 is currently being used. 4. The Sysmex CA-600 series operated in the laboratory for PTs and International Normalized Ratio (INR)s utilizing the information of Dade Innovin (564615 3/3/2024) had the ISI listed as 1.04 with a Geometric Mean of 10.8, but using Dade Innovin Lot # 564665. 5. From 1/1/2025 through 3/12/2025 there were 42 PTs /INRs reported on patients with the incorrect ISI on the Sysmex CA-600 series for the current lot number of Dade Innovin. 6. Interview with Technical Consultant and the Laboratory Director on 3/12/2025 at 11:30 a.m. confirmed, the laboratory failed follow manufacturer's instructions for the International Safety Index (ISI) upon utilizing a new lot number of Dade Innovin for the Sysmex CA-600 series from 1/1/2025 to 3/12/2025.</p>