

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0686356	(X3) Date Survey Completed 05/03/2022
Name of Provider or Supplier Grisell Memorial Hospital District #1	Street Address, City, State 210 South Vermont Avenue, Ransom, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the procedure manual, hematology quality control (QC), patient test records, subspecialty information, 2020, 2021 and 2022 proficiency testing (PT) records, and interview with the Laboratory Director (LD), the laboratory failed to enroll in PT for prothrombin time and international normalized ratio (PT/INR) at time of survey. Findings: 1. Review of the Abbott i-STAT 300G policy showed a procedure for PT/INR testing signed by the LD. 2. The laboratory established an Individualized Quality Control Plan (IQCP) for PT/INR to perform QC monthly on the i-STAT system. 3. Interview with testing personnel #1 disclosed that there were no PT enrollments for the hematology subspecialty of PT/INR testing due lack of availability with current PT provider American Association of Bioanalysts (AAB) and did not pursue a different PT provider approved under the rules of the Clinical Laboratory Improvement Amendments. 4. PT/INR was designated as a subspecialty hematology test, performed at this lab, on the Form CMS-116, dated March 24, 2022. 5. Review of PT hematology records for 2020 Events 1, 2, 3; 2021 Events 1, 2, 3 and 2022 Event 1 showed no enrollment records for the subspecialty PT/INR. 6. Interview with the LD on 5/03/2022 at 9:45 a.m. confirmed the laboratory failed to enroll in PT for the hematology subspecialty PT/INR.</p>