

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0385982	(X3) Date Survey Completed 09/11/2024
Name of Provider or Supplier George C Grape Community Hospital	Street Address, City, State 2959 Us Highway 275, Hamburg, IA	
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>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 Sysmex CA-660 coagulation reagent verification records, observation of the coagulation instrument, and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at 11:03 am on 09/11/2024, the laboratory failed to program the correct normal patient mean into the coagulation instrument for one out of one lot number of prothrombin time reagent (lot number 564624, expiration 06/02/2025). The findings include: 1. The laboratory began using prothrombin time reagent lot number 564624 (expiration 06/02/2025) for patient testing on 04/29/2023. 2. Review of the coagulation reagent verification records for prothrombin time reagent lot number 564624 indicated that the laboratory established a normal patient mean of 10.1 seconds. 3. Observation of the coagulation instrument showed that the laboratory programmed a normal patient mean of 9.8 seconds in the CA-600 instrument for prothrombin time reagent lot number 564624. 4. At the time of the survey, personnel identifier #5 confirmed that the laboratory programmed the incorrect normal patient mean into the coagulation instrument for prothrombin time reagent lot number 564624 (expiration 06/02/2025).</p>