

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382831	(X3) Date Survey Completed 06/19/2024
Name of Provider or Supplier Greene County Medical Center	Street Address, City, State 1000 W Lincoln Way, Jefferson, 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 #1 (refer to the Laboratory Personnel Report) at 12:44 pm on 06/19/2024, 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 564610, expiration 01/20/2025). The findings include: 1. The laboratory began using prothrombin time reagent lot number 564610 (expiration 01/20/2025) for patient testing on 09/27/2023. 2. Review of the coagulation reagent verification records for prothrombin time reagent lot number 564610 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 10.4 seconds in for prothrombin time reagent lot number 564610. 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory programmed the incorrect normal patient mean into the coagulation instrument for prothrombin time reagent lot number 564610 (expiration 01/20/2025).</p>