Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0305199	(X3) Date Survey Completed 11/10/2021
Name of Provider or Supplier Washington County Hospital	**Street Address, City, State** 14600 St Stephens Avenue, Chatom, AL	

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
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of Prothrombin Time (PT) reagent validation documents for the Stago STA Satellite and an interview with the previous Laboratory Manager, the laboratory failed to include documentation of the manual check of the INR (International Normalized Ratio) calculation on the instrument when new STA Neoplastine (PT) reagent was validated for use for patient testing in November 2020. This was noted on one of one lot numbers of PT reagent in use. The findings include: 1. A review of the Stago STA Satellite Neoplastine (PT) reagent validation records for Lot number 256760 revealed the laboratory established a normal patient mean, and performed parallel patient testing in November 2020, however there was no evidence the studies included a manual check of the INR calculation on the instrument using the new reagent. 2. During an interview on 11/9/2021 at 1:30 PM, the surveyor asked if the laboratory manually checked the INR calculation as a control to ensure numerical data was correctly entered for new lot numbers of PT reagent; the Manager confirmed the lab had not, because they did not realize this was a CLIA requirement. SURVEYOR #32558 Licensure and Certification Surveyor