

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0918686	(X3) Date Survey Completed 02/18/2020
Name of Provider or Supplier Aurora Medical Group	Street Address, City, State 9200 W Loomis Rd, Franklin, WI	
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	<p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Siemens CA-660 coagulation analyzer printouts and interview with the technical consultant, the laboratory did not perform quality control (QC) each eight hours of operation on the coagulation analyzer on two days from December 19 through December 27, 2019. Findings include: 1. Review of Siemens CA-660 printout revealed: On December 19, 2019, QC was performed at 9:57 AM, Patient 1 and Patient 2 testing performed at 6:12 PM and Patient 3 testing performed at 6:13 PM. No additional QC was performed between the two times. On December 26, 2019, QC was performed at 10:24 AM, Patient 4 testing performed at 7:02 PM. No additional QC was performed between the two times. 2. Interview with the technical consultant on February 18, 2020 at 11:15 AM confirmed the laboratory did not perform quality control each eight hours of operation prior to patient testing on the Siemens CA-660 coagulation analyzer.</p>