Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0918686	02/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Aurora Medical Group	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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a technical consultant, the laboratory did not retain records showing when each lot number of Innovance D dimer reagent was used for patient testing. Findings include: 1. Review of laboratory records showed no evidence the laboratory retained the lot number and date of use for the Innovance D Dimer reagents. 2. Interview with a technical consultant (staff A) on February 10, 2022 at 12:05 PM confirmed the laboratory did not retain the dates each lot number of Innovance D Dimer reagents was put in use for patient testing.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a technical consultant, the laboratory did not ensure calibrations were performed for the Innovance D dimer assay within six months after the August 17, 2020 calibration as required by the manufacturer. The laboratory tested 37 patients between February 20 and June 9, 2021 using the expired calibration from August 17, 2020. Findings include: 1. Review of calibration records for the Innovance D dimer assay on the Sysmex CA-660 coagulation analyzer showed a calibration was completed on August 17, 2020. The next calibration record was dated June 10, 2021. The calibration record for June 10, 2021 is not complete; the record does not show evaluation of the patient comparison and is not signed or dated by the technologist or approver. 2. Review of patient testing logs from February 20 through June 9, 2021 showed the following patient testing was performed: February 20 - 28, 5 patients March, 15 patients April, 7 patients May, 7 patients June 1 - 9, 3 patients 3. Interview with a technical consultant (staff A) on February 10, 2022 at 12:05 PM confirmed calibration for the Innovance D dimer assay is required every six months and confirmed the calibration was not completed as required after the August 17, 2020 calibration.