Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0389360	02/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Aurora Health Center-22nd Avenue	7540 22nd Ave, Kenosha, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, observation of test equipment, and interview with the technical consultant, the laboratory did not verify the ISI (International Sensitivity Index) provided by the manufacturer was accurately entered into the coagulation analyzer. Findings include: 1. Review of laboratory records showed the laboratory started using Innovin lot 549704 in November 2017. Further review shows the ISI value provided by the manufacturer for the laboratory's instrument is 1.03. 2. Observation of the coagulation instrument at 11:45 AM on February 7, 2018 showed the ISI was set at 1.00. 3. Interview with the technical consultant, staff A, on February 7, 2018 at 11:45 AM confirmed the ISI entered in the analyzer and used to calculate the International Normalized Ratio (INR) was not the ISI provided by the manufacturer.