

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0671419	<b>(X3) Date Survey Completed</b>  03/30/2021
<b>Name of Provider or Supplier</b>  Aurora Health Center-Elkhorn	<b>Street Address, City, State</b>  201 E Morrissey Dr, Elkhorn, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the technical consultant did not review the performance specification verification records on the new Sure-Vue serum human chorionic gonadotropin (HCG) test kit prior to reporting patient results. Findings include: 1. Review of "hCG Patient Test Log" showed the laboratory started reporting patients using the Sure-Vue serum HCG test kit on November 18, 2020. 2. Review of the "Method Validation Checklist" form showed the technical consultant reviewed and signed the validation checklist on December 31, 2020. Further review showed the "Date Method Implementation" was January 4, 2021. 3. Interview with the technical consultant on March 30, 2021 at 10:00 AM confirmed the technical consultant did not review and accept the performance specification verification records on the new Sure-Vue serum HCG test kit prior to reporting patient results.</p>