

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2148953	<b>(X3) Date Survey Completed</b>  01/30/2019
<b>Name of Provider or Supplier</b>  Aurora Fertility Services	<b>Street Address, City, State</b>  6815 118th Ave, Fertility Clinic, Kenosha, 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>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the AAB (American Association of Bioanalysts) proficiency testing report and interview with the laboratory director, the laboratory did not review one of one ungraded Sperm Cell ID result from the S2 event in 2018. Findings include: 1. Review of the 2018 AAB proficiency testing report for event S2 showed one (sample 3) of five samples was ungraded by the proficiency testing provider. The laboratory reported result for sample three was 'normal'; the expected result was 'abnormal head'. The report shows no evidence of review. 2. Interview with the laboratory director on January 30, 2019 at 1:00 PM confirmed the laboratory did not review the ungraded result to verify accuracy of the test system.</p>