

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520986	(X3) Date Survey Completed 06/08/2021
Name of Provider or Supplier Madison Womens Clinic	Street Address, City, State 15 Madison Professional Park, Rexburg, ID	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a record review of proficiency testing (PT) from American Association of Bioanalytics (AAB) and an interview with the laboratory lead on 6/8/2021, the laboratory failed to ensure that the individual(s) testing PT samples and the laboratory director sign a statement attesting that PT samples were tested in the same manner as patient specimens. The findings include: 1. A review of PT records from AAB for event one of 2021 identified that the laboratory failed to ensure that the testing personnel and laboratory director signed the attestation statement for Clinical Microscopy and that the laboratory director signed the attestation for Hematology with differential. 2. A review of PT records from AAB for event two of 2021 identified that the laboratory failed to ensure that the testing personnel and laboratory director signed the attestation statement for Clinical Microscopy and Hematology with differential. 3. The laboratory reports performing 2,100 moderate complexity tests annually.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a record review of proficiency testing (PT) from American Association of Bioanalytics (AAB) and an interview with the laboratory lead on 6/8/2021, the laboratory failed to review PT and evaluate results that were less than 100% but greater than or equal to 80%. The findings include: 1. A review of PT records from AAB for event one of 2020 identified that the laboratory failed to evaluate the results for the following analytes; Lymphocyte % with a score of 80%, and Monocyte % with a score of 80%. 2. A review of PT records from AAB for event one of 2021 identified that the laboratory failed to evaluate the results for the following analytes; Neutrophil /granulocyte % with a score of 80%. 3. An interview with the laboratory lead on 6/8 /2021 at 10:20 am confirmed that the laboratory failed to evaluate PT results that were less than 100% but greater than or equal to 80%. 4. The laboratory reports performing 2,100 moderate complexity tests annually.