Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520986	06/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Madison Womens Clinic	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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the laboratory manager, the laboratory failed to document the evaluations and corrective actions for unsatisfactory hematocrit and platelet scores from the American Proficiency Institute (API) since the last survey on October 26, 2017. This is a repeat deficiency from the last survey. Findings: 1. A review of PT results from API and laboratory documents revealed the laboratory failed to evaluate and document corrective actions for a score of 40% for hematocrit on the 2018 event 2 and an 80% for platelets on both the 2018 event 1 and 2019 event 1. 2. A review of PT results from API and laboratory documents revealed the laboratory failed to evaluate and document corrective actions for potassium hydroxide (KOH) scores of 0% for both the 2018 event 1 and 2019 event 1. 3. The laboratory performed approximately 2000 complete blood counts and 100 KOHs in 2018. 4. An interview with the laboratory manager on June 4, 2019 at 12:45 PM, confirmed there was no evaluation or corrective actions documented for the hematocrit, platelet, and KOH analytes.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to monitor the accuracy and precision of the complete blood count (CBC) controls over time to detect changes or variance in the test performance since the last survey on October 26, 2017. Findings: 1. A record review of quality control records for the Emerald CBC instrument revealed the laboratory failed to monitor or record the control procedures over time to detect errors and problems with the test system. 2. The laboratory performed approximately 2000 complete blood counts in 2018. 3. An interview with the laboratory manager on June 4, 2019 at 12:45 PM, confirmed the laboratory did not monitor or record control procedures over time to detect errors with the test system.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on patient record reviews, quality control records, and an interview with the laboratory manager, the laboratory failed to have a system in place to identify the testing personnel who performed patient complete blood counts (CBCs) on the Emerald analyzer from the test report dates reviewed between January through May 2019. This is a repeat deficiency from the last survey on October 26, 2017. Findings: 1. A review of the Emerald CBC patient test reports and quality control reports revealed the CBC instrument reports failed to identify the testing personnel who performed the tests. 2. An interview with the laboratory manager on June 4, 2019 at 1: 45 PM, confirmed the laboratory failed to identify the testing personnel who performed the CBCs.