Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0520986	05/07/2025
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) and an interview with the laboratory lead on 5/7/2025, the laboratory failed to have testing personnel attest to the integration of PT samples with routine testing of patient samples in 2024 and 2025. The findings include: 1. A review of PT results from AAB-MLE for 2024 identified that the laboratory failed to have the performing testing personnel attest that the PT samples were tested with patient samples for three of three events for non-chemistry and three of three events for chemistry. 2. A review of PT results from AAB-MLE for 2025 identified that the laboratory failed to have the performing testing personnel attest that the PT samples were tested with patient samples for 2025 event one. 3. An interview with the laboratory lead on 5/7/2025 at 9: 00 am confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the laboratory lead on 5/7/2025, the laboratory failed to establish and follow written policies and procedures to assess technical consultant (TC) competency in 2023 and 2024. The findings include: 1. The CMS 209 identified six (6) testing personnel (TP) performing moderate complexity testing and one (1) technical consultant. 2. A review of laboratory procedures identified that the laboratory failed established policies and procedures to assess TC competency. 3. A review of training and competency assessment records identified that the laboratory director failed to perform a competency assessment for the TC in 2023 and 2024. 4. An interview with the laboratory lead on 5/7/2025 at 9:20 am confirmed the above findings. 5. The laboratory reports performing 2,050 moderate complexity tests annually.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation from American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE), a lack of laboratory documentation and an interview with the laboratory lead on 5/7/2025, the laboratory failed to evaluate inaccurate PT results in 2024 and 2025. The findings include: 1. A review of PT documents for 2024 from AAB-MLE identified that the laboratory failed to evaluate inaccurate results for the following: chemistry event 2 vaginal wet mount sample 1, non-chemistry event 3 neutrophil/granulocyte sample 11. 2. A review of PT documents for 2025 from AAB-MLE identified that the laboratory failed to evaluate inaccurate results for the following: hemoglobin sample 4, neutrophil /granulocyte sample 4 and vaginal wet mount sample 1 for event one. 3. An interview with the laboratory lead on 5/7/2025 at 8:55 am confirmed the above findings. 4. The laboratory reports performing 2,050 tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and an interview with the laboratory lead on 5/7/2025, the Laboratory Director failed to approve, sign and date the laboratory policies and procedures. The findings include: 1 A record review of laboratory policies and procedures identified that the Laboratory Director failed to review, approve, sign and date the laboratory policies and procedures after becoming the Laboratory Director in November 2023. 2. An interview with the laboratory lead on 5/7/2025 at 9:30 am confirmed that the Laboratory Director has not approved, signed or dated the laboratory policies and procedures. 3. The laboratory reports performing 2,050 tests annually.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a direct observation and an interview with the laboratory lead on 5/7/2025, the laboratory failed to discontinue the use of expired influenza A/B tests. The findings include: 1. A direct observation of the laboratory's waived test kits on 5/7 /2025 identified that the laboratory failed to discontinue the use of four (4) Consult Diagnostic Influenza A/B test cassettes, lot 442K21A, expiration 10/31/2024 prior to the expiration dates. 2. An interview with the laboratory lead on 5/7/2025 at 10:00 am confirmed the above finding. 3. The laboratory reports performing 2,100 waived tests annually.