

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0390513	(X3) Date Survey Completed 06/22/2026
Name of Provider or Supplier Madison Medical Urology	Street Address, City, State 2350 N Lake Dr Suite 306, Milwaukee, WI	
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
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 surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the Regional Director of Clinic Operations (Staff A), the laboratory did not review and evaluate the results obtained on proficiency testing performed for two of the last six proficiency testing events. Findings include: 1. Review of API PT records showed the laboratory received PT reports for the following events: 2026 Hematology/Coagulation-1st Event 2025 Hematology/Coagulation-3rd Event 2025 Hematology/Coagulation-2nd Event 2025 Hematology/Coagulation-1st Event 2024 Hematology/Coagulation-3rd Event 2024 Hematology/Coagulation-2nd Event Review of the reports for the 2025 Hematology/Coagulation-3rd Event and 2025 Hematology/Coagulation-2nd Events showed no evidence the laboratory reviewed and evaluated results for the two events. 2. Interview with Staff A on June 22, 2024 at 1:50 confirmed the laboratory did not document review and evaluation of PT results for the two events. This is a repeat deficiency previously cited on June 26, 2024.
D5787	TEST RECORDS CFR(s): 493.1283(a) (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 surveyor review of laboratory records and interview with the Regional Director of Clinic Operations (Staff A), the laboratory did not maintain a record system that included the date and time of sample receipt into the laboratory and date and time of sample testing for one of one record reviewed for a patient's urine microscopy test that was reflexed based on the urine macroscopic results. Findings include: 1a. Review of the instrument printout from the Siemens Clinitek Status analyzer for Patient 1 showed the test time for the urine macroscopic test was 12:00 PM. The printout contained handwritten results for the urine microscopic test. Further review of records showed no indication of the date and time of specimen receipt into the laboratory. Further review showed no indication the time the microscopic test was performed. 1b. Review of the patient test report in the electronic medical record, EPIC, showed the clinic collected the urine at 11:25 AM. Further review showed the laboratory resulted the urine macroscopic and microscopic result at 11:25 AM. 2. Interview with Staff A on June 22, 2026, at 3:10 PM confirmed the time on the instrument printout was different from the electronic medical record for the urine macroscopic test and the laboratory did not maintain record of the time of the urine microscopic test. Further interview confirmed the laboratory failed to maintain record systems to document date and time of specimen receipt into the laboratory and records to identify the date and time the laboratory performed the urine microscopic test.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of one of one urine microscopic patient test reports in the electronic medical record (EMR) and interview with the Regional Director of Clinic Operations (Staff A), the test report did not indicate the correct name and address of the laboratory location where the test was performed. Findings include: 1a. A urine microscopic test report for Patient 1 showed the Resulting Agency was listed as: "A TEST CLINIC". 2. Interview with Staff A on June 22, 2026, at 3:10 PM confirmed the testing was performed at the surveyed laboratory and that the test report did not indicate the name and address of the laboratory. This is a repeat deficiency previously cited on June 26, 2024 and July 6, 2022.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify

failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory procedures and records, and interview with the Regional Director of Clinic Operations (Staff A), the laboratory director did not ensure that the one of one quality assessment program was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings include: 1. Review of the laboratory's 'Quality Assurance Program' approved by the laboratory director on July 29, 2022, revealed, in part, the laboratory performed a post analytical review of the result report, and a chart review. Further review indicated the laboratory monitored specific quality assurance markers. The program document stated, "The records of our quality assurance activities are filed with this plan and are available for review." 2. Review of the laboratory's records revealed no evidence of documentation of the elements described in the quality assurance program. 3. Interview with Staff A on June 22, 2026, at 1:55 PM confirmed the quality assurance program records were not available, confirming the laboratory director did not ensure maintenance of the quality assessment program to assure the quality of laboratory services provided.

D6071

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(2)

(b)(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

This STANDARD is not met as evidenced by:
Based on surveyor review of proficiency testing (PT) records and interview with the Regional Director of Clinic Operations (Staff A), testing personnel did not maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples for two of two PT events reviewed in 2025. Findings include: 1. Review of the PT records for 2025 Hematology/Coagulation - first event and third event revealed form, 'American Proficiency Institute Attestation Statement,' stating, "The undersigned certify that, as closely as possible, these proficiency testing samples were tested in the same manner as patient specimens." The laboratory director and two testing personnel signed and dated each of the forms. The form included a line "Sample Set(s) Tested" for testing personnel to record the samples tested. This line was blank. Further review of the records showed no indication of which testing personnel performed the urine microscopic portion of the proficiency testing for the two events. 2. Interview with Staff A on June 22, 2026, at 1:50 PM confirmed the personnel performing the urine microscopic testing could not be determined from the PT records.