| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>52D0991033 | (X3) Date Survey Completed<br><br>06/26/2024 |
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| **Name of Provider or Supplier**<br><br>Madison Medical Urology | **Street Address, City, State**<br><br>13133 N Port Washington Rd, Mequon, 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 |
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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the regional director, staff A, the laboratory director and testing personnel did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods for five of six urine microscopy events reviewed from event 2 in 2022 through event 1 in 2024. Findings include: 1. Review of API PT records showed no signatures on the attestation forms for the following events: 2022 Hematology/Coagulation-2nd Event and 3rd Event 2023 Hematology/Coagulation- 2nd Event and 3rd Event. 2023 Hematology /Coagulation-1st Event not submitted. 2024 Hematology/Coagulation-1st Event 2. Interview with staff A on June 26, 2024, at 9:50 AM confirmed the laboratory director and testing personnel did not attest to the routine integration of PT samples into the patient workload using the laboratory's routine methods from event 2 in 2022 through event 1 in 2024. |
| **D3029** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(2)<br><br>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory procedures and interview with the regional director, staff A, the laboratory did not retain one of one discontinued procedure with the date the procedure was discontinued. Findings include: 1. Review of laboratory procedures showed the "Quality Assurance Program" procedure had been updated in July 2022. Further review showed no evidence of the previous procedure with a discontinued date. 2. Interview with staff A on June 26, 2024, at 9:58 AM confirmed the laboratory did not retain a copy of the previous quality assurance procedure with date of discontinuance. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of laboratory procedures and competency assessments, and interview with the regional director, staff A, the laboratory did not follow their written policies for training and competency evaluation for two of two current testing personnel. Findings include: 1. Review of the "Quality Assurance Program" procedure stated "Personnel performing non-waived testing must have an initial, six month and annual competency check". Further reviewed stated: "v. Compete assessment will include but is not limited to the following elements: 1. Direct observation of routine patient test performance, including patient preparation (if applicable), specimen handling, processing, and testing. 2. Monitoring the recording and reporting of test results. 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. 4. Direct observation of performance of instrument maintenance and function checks. 5. Assessment of test performance through testing previously analyzed specimens, internal blinc testing samples or external proficiency testing samples. 6. Assessment of problem solving skills." 2. Review of competency assessment records showed no documentation of annual competency assessment for staff B and staff C in 2023 to include all six elements. 3. Interview with staff A on June 26, 2024, at 9:50 AM confirmed the laboratory did not follow their written policies for competency assessment. |
| **D5221** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(d)<br><br>All proficiency testing evaluation and verification activities must be documented.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the regional director, staff A, the laboratory failed to document evaluation and verification activities related to corrective action for one of one submission failure in 2023. Findings include: 1. Review of API PT records showed scores of 0% for 2023 Hematology/Coagulation-1st Event. Further review showed a corrective action statement "Testing was not completed prior to due date. Specimen packet was transferred to alternative refrigerator and not found until several |

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| | months later. For remediation, Lab Director reviewed several consecutive patient specimens, requiring all staff to read and result to confirm accuracy." No documentation of the laboratory director review of patient testing and testing personnel accuracy check was available. 2. Interview with staff A on June 26, 2024, at 10:05 AM confirmed the laboratory failed to document evaluation and verification activities related to corrective action. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on survey review of laboratory procedures and patient urinalysis test reports and interview with the regional director, staff A, the reference ranges were not available to authorized personnel who ordered the test for one of one patient reviewed. Findings include: 1. Review of the "PPM-Microscopic Urinalysis Examination (POC)" procedure showed the approved reference ranges to include: "A. Red Blood Cell (RBC): 0-2/high powered field (hpf) B. White Blood Cell (WBC): 0.5/hpf C. Bacteria: None Seen D. Epithelial Cells: None-Few E. Mucus: None-Present F. Amorphous Crystals: None-Present G. Hyaline Cast: 0.1/low power field (lpf) H. Other elements: None seen." 2. Review of patient 1 in the Electronic Health Record (EHR) showed no reference ranges listed on the report. 3. Interview with staff A on June 26, 2024, at 10:35 AM confirmed the reference ranges for urine microscopic results were not available to authorized personnel in the EHR. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of competency assessment records and interview with the regional director, staff A, the technical consultant did not document competency assessment for two of two testing personnel responsible for urine microscopy testing in the laboratory in 2023. Findings include: 1. Review of competency assessments for testing personnel, staff B and staff C, showed no documentation of competency assessment for urine microscopy testing in the laboratory for 2023. 2. Interview with staff A on June 26, 2024, at 9:50 AM, confirmed the technical consultant did not document competency assessment for testing personnel performing urine microscopy testing in 2023. This is a repeat deficiency from July 6, 2022. |