

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0390513	(X3) Date Survey Completed 06/26/2024
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: 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 one of one 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 in 2023 to include all six elements. 3. Interview with staff A on June 26, 2024, at 1:15 PM confirmed the laboratory did not follow their written policies for competency assessment.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p>

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, staff A, the laboratory did not review and evaluate the results obtained on proficiency testing performed for four of six events reviewed. Findings include: 1. Review of API PT records show the no documentation of review and evaluation of PT results for the following events: 2022 Hematology/Coagulation-3rd Event 2023 Hematology/Coagulation-2nd Event and 3rd Event 2024 Hematology/Coagulation-1st Event 2. Interview with staff A on June 26, 2024 at 1:18 PM confirmed the laboratory did not review and evaluate PT results.

D5805

TEST REPORT

CFR(s): 493.1291(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 a urine microscopic patient test report in the electronic medical record (EMR) and interview with the regional director, staff A, the test report did not show the name and address of the laboratory where the test was performed for two of two patients reviewed. Findings include: 1. Review of the urine microscopic test report for patient 1 and patient 2 in the EMR showed no evidence of the location of testing. The only location reference was to "a test clinic". 2. Interview with staff A on June 26, 2024, at 1:20 PM confirmed the test report did not show the name and address of the laboratory. This is a repeat deficiency from July 6, 2022.

D5807

TEST REPORT

CFR(s): 493.1291(d)

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.

This STANDARD is not met as evidenced by:

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 two of two 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 and patient 2 in the Electronic Health Record (EHR) showed no reference ranges listed on the report. 3. Interview with staff A on June 26, 2024, at 1:20 PM confirmed the reference ranges for urine microscopic results were not available to authorized personnel in the EHR.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(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.

This STANDARD is not met as evidenced by:
Based on competency assessment records and interview with the regional director, staff A, the technical consultant did not document competency assessment for one of one testing personnel responsible for urine microscopy testing in the laboratory in 2023. Findings include: 1. Review of competency assessments for the laboratory 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 1:15 PM, 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