

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0390513	(X3) Date Survey Completed 07/06/2022
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and the Centers for Medicare and Medicaid Services (CMS) Form CMS-116 submitted by the laboratory and interview with testing personnel, the laboratory retained none of the urine microscopic intermediate test records for the 1,204 microscopic examinations testing personnel performed in 2021. Findings include: 1. Review of laboratory records showed no evidence of patient test records other than the test report in the electronic medical record (EMR). 2. Review of Form CMS-116 "Clinical Laboratory Improvement Amendments (CLIA) Application for Certification", Section VIII, Non-Waived Testing, showed the laboratory performed 1,204 non-waived urinalysis tests in 2021. 3. Interview with testing personnel (staff A) on July 6, 2022 at 10:35 AM revealed testing personnel recorded microscopic test results on the printout from the CLINITEK Status analyzer and confirmed testing personnel discarded the printouts with patient test records after entering the results into the EMR.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step</p>

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the "Urinalysis Policy and Procedure" in the laboratory procedure manual and patient test results and interview with testing personnel, the procedure does not meet eight of the fourteen required elements in this standard. Findings include: 1. Review of the "Urinalysis Policy and Procedure" showed the procedure did not include the following eight required elements: a) Requirements for labeling: there were no instructions for labeling the specimen container or the tube used for centrifuging urine for microscopic evaluation. b) Criteria for specimen acceptability or rejection: the procedure did not address reasons for rejection of a specimen and did not include a minimum acceptable volume of urine. c) Step by step performance: The procedure did not include instructions to mix the sediment with the remaining urine after decanting and before microscopic examination. The procedure did not include instructions to evaluate the specimen with low (10x) magnification for counting epithelial cells and casts. The procedure directed testing personnel to check the specimen for Red Blood Cells (RBC), White Blood Cells (WBC), epithelial cells, bacteria, calcium oxalate, amorphous phosphate, and sperm. Additional elements - hyaline casts and mucus - were reported in the electronic medical record (EMR) but were not included in the procedure (see finding 2). The procedure did not include descriptions of the elements or provide instructions for referring a sample with unidentified elements. d) Control procedures e) Reference intervals (normal ranges) f) Pertinent literature references: the procedure did not include descriptions of the microscopic elements and did not provide references to aid in the identification of elements. g) The method for entering results in the patient record: the procedure provided instructions to enter results on a "Laboratory Sheet labeled Urine", no instructions are available for result entry in the EMR. h) Description of steps to take if the test system becomes inoperable: the procedure did not include instructions for referral of a specimen if elements were unidentified by testing personnel or if the system was otherwise inoperable. 2. Review of reported patient test results in the EMR showed the report included RBC, WBC, Bacteria, Epithelial Cells, Mucus, Amorphous, Hyaline casts and 'other'. The procedure did not provide instructions for identifying mucus or hyaline casts. (See finding 1c). 3. Interview with testing personnel (staff A) on July 6, 2022 at 9:55 AM confirmed the urinalysis procedure did not include all the required elements. This is a repeat deficiency previously cited on February 18, 2014.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(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 surveyor review of the laboratory procedure manual and interview with testing personnel, the laboratory director had not approved, signed, and dated one of two reviewed procedures. Findings include: 1. Review of two procedures in the laboratory procedure manual showed no evidence the laboratory director approved the "Urinalysis Policy and Procedure". 2. Interview with testing personnel (staff A) on July 6, 2022 at 9:55 AM confirmed there was no documented evidence the director had approved the "Urinalysis Policy and Procedure".

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 site manager, the test report did not show the name and address of the laboratory where the test was performed and did not include the unit of measure for epithelial cells. Findings include: 1. Review of the urine microscopic test report in the EMR showed no evidence of the location of testing. The only location reference was to 'a test clinic'. Further review of the report showed units of measure for Red Blood Cells, White Blood Cells and Hyaline casts, but no units for epithelial cells. 2. Interview with the site manager (staff D) on July 6, 2022 at 10:40 AM confirmed the test report was missing required elements. This is a repeat deficiency previously cited on September 16, 2009 and October 9, 2007.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of laboratory procedures and records and interview with laboratory staff, the laboratory director had not provided overall management and direction in accordance with 493.1407. Finding include: 1. The director did not ensure a quality assessment program was established and maintained. See D6021. This is a repeat deficiency. 2. The director did not ensure personnel documented training and that staff demonstrated that they perform testing reliably to provide and report accurate results. See D6029. 3. The director did not develop policies and procedures

for the evaluation of testing personnel competency. See D6030. This is a repeat deficiency. D6000 is a repeat deficiency previously cited on November 2, 2005.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory's policies and procedures and interview with testing personnel, the laboratory director had not ensured a quality assessment program was established to assure the quality of laboratory services provided. Findings include: 1. Review of the laboratory procedure manual showed no evidence of a quality assessment policy or procedure that identified mechanisms to monitor, assess and when indicated correct identified problems. 2. Interview with testing personnel (staff A) on July 6, 2022 at 10:10 AM confirmed no other procedures were available and the laboratory had not developed a quality assessment procedure. This is a repeat deficiency previously cited on November 2, 2005.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Item 1: Based on surveyor review of laboratory records and interview with testing personnel, the laboratory had no documented training for one of one new testing person who performed microscopic urinalysis testing. Findings include: 1. Review of laboratory records showed no record of training in microscopic urinalysis for staff C. 2. Interview with staff C on July 6, 2022 at 10:15 AM confirmed there was no documentation of training in interpretation of microscopic urinalysis samples and no documentation showing staff C had demonstrated they could reliably perform microscopic urinalysis testing. Item 2: Based on surveyor review of a patient urinalysis report, proficiency testing records and interview with testing personnel, the director had not ensured testing personnel had received training and could identify all reported microscopic elements. Findings include: 1. Review of a patient urinalysis report shows the report included a determination of the presence of hyaline casts and enumeration of any hyaline casts seen. 2. Review of proficiency testing records for Microscopy/Urine Sediment, event 2 in 2021, image US-03 showed testing personnel

reported "Cell / Element not ID in Lab" and did not identify the element in the image. The expected result for the image was a hyaline cast. 3. Interview with testing personnel (staff A) on July 6, 2022 at 9:45 AM revealed testing personnel were not able to identify the hyaline cast.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and interview with testing personnel, the laboratory director had not established policies and procedures for the evaluation of employee competence in performing non-waived testing. Findings include: 1. Review of laboratory procedures showed no evidence of policies or procedures for the evaluation of employee competence. 2. Interview with testing personnel (staff A) on July 6, 2022 at 10:10 AM confirmed the laboratory director had not established procedures for evaluation of employee competence. This is a repeat deficiency previously cited on November 2, 2005.

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 surveyor review of personnel records and interview with testing personnel, the technical consultant did not evaluate competency of three of three testing personnel to ensure staff maintain competence to perform microscopic urinalysis evaluations. Findings include: 1. Review of personnel records showed no evidence of evaluation of competence for three of three testing personnel (staff A, B, and C) who perform microscopic urinalysis evaluations. 2. Interview with testing personnel (staff A) on July 7, 2022 at 10:10 AM confirmed the technical consultant had not completed competence evaluations for testing personnel that perform microscopic urinalysis.

D6070

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and

maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and proficiency testing (PT) records from 2021 through 2022 and interview with testing personnel, testing personnel did not follow the laboratory's procedures for testing proficiency samples for four of four events reviewed. Findings include: 1. The "Proficiency Testing" procedure included the following statements in the 'Procedure' section: "3. For each survey, a "PROFICIENCY TESTING TRACKING FORM" is completed", and "4. Surveys are to be rotated among staff who normally perform non-waived testing and tested in the same manner as patient samples." 2. Review of PT records from events one, two, and three in 2021 and event one in 2022 showed staff A and B completed all four PT events. No "Proficiency Testing Tracking Forms" are with the PT records. 3. Interview with testing person (staff A) on July 6, 2022 at 9:45 AM confirmed testing personnel did not use tracking forms. Further interview revealed testing personnel independently perform and report patient test results and confirmed staff A and staff B evaluated all proficiency sample images together and reported their agreed upon results to the PT provider.