Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0991033	07/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Madison Medical Urology	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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. 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 kept none of the urine microscopic intermediate test records for the 1,613 microscopic examinations testing personnel performed annually. 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 1,613 non-waived urinalysis tests annually. 3. Interview with testing personnel (staff A) on July 6, 2022 at 1:15 PM 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.
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 "Quality Assurance Program" procedure and interview with the clinic manager, the laboratory director did not maintain the quality assurance program since 2010. Findings include: 1. Review of the "Quality Assurance Program" procedure showed the director approved the procedure on March 3, 2010. Further review showed the procedure referenced an accrediting agency (COLA) and identified responsibilities of a Point-of-Care coordinator. Additionally, the procedure included a list of thirteen analyzers and tests. The cover sheet with the procedure showed the procedure was not revised since it was approved. 2. Review of laboratory records showed: COLA, Inc had not accredited the laboratory since December 19, 2019. Competence of testing personnel had not been evaluated as required in the procedure. See D6046. Evidence of review of laboratory records by a POCT Coordinator was not present. The laboratory performed only urine macroscopic & dipstick testing and microscopic analysis. 3. E-mail correspondence with the clinic manager (staff G) on July 21, 2022 at 12:12 PM confirmed the policy did not appear to be current.
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: Based on surveyor review of Form CMS-209 (Centers for Medicare and Medicaid Services) and laboratory records and interview with the clinic manager, the laboratory director did not ensure five of five new testing personnel who performed non-waived testing at this location prior to July 6, 2022 had received appropriate training and had demonstrated they could perform urine microscopic evaluations reliably to provide and report accurate results. Findings include: 1. Review of Form CMS-209 "Laboratory Personnel Report (CLIA)" signed by the laboratory director on June 28, 2022 and submitted for this survey showed six new testing personnel. 2. Review of laboratory records showed no training records or evidence that new testing personnel had demonstrated their ability to perform accurate and reliable testing prior to testing patient samples. 3. Interview with the clinic manager (staff G) on July 6, 2022 at 1:10 PM revealed only five of the six new testing personnel listed on Form CMS-209 independently performed testing as of July 6, 2022. Further interview confirmed there was no documentation of training for the five new testing personnel.
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 laboratory records and interview with the clinic manager, the technical consultant did not evaluate competency of six of six testing personnel to ensure staff maintained competence to perform microscopic urinalysis evaluations. Findings include: 1. Review of personnel records showed completion of a MedTraining Online Urine Sediment module by staff A on October 8, 2020. No other evidence of evaluation of competence in performing urine microscopic analysis during 2021 or 2022 is available for any of the six testing personnel (staff A, B, C, D, E, and F) who perform microscopic urinalysis evaluations. 2. Interview with the clinic manager (staff G) on July 7, 2022 at 1:00 PM confirmed the technical consultant had not completed competence evaluations for testing personnel that performed microscopic urinalysis in 2021 or 2022.
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 and the clinic manager, 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, "For each survey, a "PROFICIENCY TESTING TRACKING FORM" is completed", and the "Proficiency Testing Corrective Action Plan" procedure directed staff to document all remedial action on a Proficiency Testing Corrective Action Form. 2. Review of PT records from events one, two, and three in 2021 and event one in 2022 showed no "Proficiency Testing Tracking Forms" are with the PT records. Additionally, on event one in 2022, the laboratory reported image US-02 as a red blood cell, but the expected result was white blood cell. A Proficiency Testing Corrective Action Form is not included with the PT records. 3. Interview with testing person (staff A) and the clinic manager (staff G) on July 6, 2022 at 1:10 PM confirmed testing personnel did not use tracking forms. Further interview confirmed staff did not use a corrective action form and confirmed staff did not document all corrective actions taken.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and interview with the

	clinic manager, laboratory personnel did not follow laboratory procedures to document the room temperature daily on 127 of 128 days from January to June 2022 and did not document cleaning of the refrigerator semi-annually from February 2021 through June 2022, a period of 17 months. Findings include: 1. Review of the "Laboratory Environment, Specimen/ Reagent Refrigerator, Freezer, Care and Monitoring of" (Point of Care Testing procedure 00.32.034) showed the procedure required recording the temperature of storage areas daily. The procedure also stated, "Refrigerators and freezers should be cleaned on a routine basis, semi-annually at a minimum." 2. Review of maintenance logs from January 2022 through June 2022 showed staff documented the room temperature only once on May 2, 2022. Review of the logs from February 2021 through June 2022 showed staff had not documented the cleaning of laboratory refrigerators. 3. Interview with the clinic manager (staff G) on July 6, 2022 at 1:00 PM confirmed staff had not followed procedures and had not documented daily room temperatures and semi-annual cleaning of laboratory refrigerators.