Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2150315	02/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Madison Medical Affiliates, Inc	12831 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on surveyor review of the submitted Centers for Medicare and Medicaid Services (CMS) Form 116 Application for Certification, laboratory procedures, and interview with the Assistant Director Operations, the procedure for evaluating testing personnel competence does not address competence evaluation for testing personnel performing potassium hydroxide (KOH) testing in one of the two specialty areas of testing. Findings include: 1. Review of the CMS Form 116 submitted for the survey showed the laboratory performed PPM (provider performed microscopy) testing and showed the laboratory performed testing in Microbiology and Pathology. 2. Review of laboratory procedures for competence evaluation showed the procedures addressed testing performed in the Pathology specialty. The procedure did not address evaluation of providers performing KOH testing. 3. Interview with the Assistant Director Operations (staff A) on February 24, 2023 at 3:20 PM confirmed the laboratory had not established procedures to evaluate competence of providers who performed KOH testing.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the Assistant Director Operations, the laboratory did not have a procedure for potassium hydroxide (KOH) testing, one of two test systems performed in the laboratory. Findings include: 1. Review of the laboratory procedure manual showed no evidence of a procedure for KOH testing. 2. Interview with the Assistant Director Operations (staff A) on February 24, 2023 at 3:20 PM confirmed the laboratory did not have a procedure in place for KOH testing.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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 procedures and interview with testing personnel, the laboratory procedures for Mohs testing did not include step by step instructions for processing tissue samples including the inking and mapping procedures for marking tissue specimens. Findings include: 1. Review of procedures in the laboratory manual showed no instructions for inking or chromacoding the tissue. The preferred color patterns used for inking the excised tissue specimen to ensure accurate tissue orientation were not defined in the procedures. 2. Interview with testing personnel (staff B) on February 24, 2023 at 3:10 PM confirmed the procedures did not include instructions for inking the tissue specimens.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically

	transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on surveyor review and comparison of the 'Mohs Surgery Procedure and Repair Note' reports with the Mohs patient log and interview with the Assistant Director Operation showed the number of sections stated in the report was not consistent with the number in the log for one of five patient reports reviewed. Findings include: 1. Review of the patient log showed patient one had a Mohs procedure performed on December 7, 2022 on a basal cell carcinoma from the right parietal scalp. The log showed the tissue was divided into four sections and was clear with one stage. 2. The 'Mohs Surgery Procedure and Repair Note' for patient one on December 7, 2022 included the statement, "A total of none sections were submitted to the Mohs histology laboratory for processing." Other information reported was consistent with the log. 3. Interview with the Assistant Director Operations (staff A) on February 24, 2023 at 3:20 PM confirmed the patient note and the log did not match. Future interview confirmed the laboratory's system did not ensure the 'Mohs Surgery Procedure and Repair Note' was accurate.
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 patient test report including a KOH (potassium hydroxide) test result and interview with the Assistant Director Operations, one of one report reviewed for KOH testing showed the report did not include the address of the testing location and did not specify the source of the specimen that was tested. Findings include: 1. Review of the 'Dermatology Note' for patient two seen on June 28, 2022 showed the report included a positive KOH result. The report did not include the address of the facility and showed the provider (staff D) examined two locations (face and back). The provider did not identify the source of the sample for the KOH test in the report. 2. Interview with the Assistant Director Operations (staff A) on February 24, 2023 at 3:20 PM confirmed the 'Dermatology Note' was the test report for the KOH test and confirmed the sample source and address were not indicated on the report.
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 the Centers for Medicare and Medicaid Services (CMS) Form 209 'Laboratory Personnel Report' and personnel evaluation records and interview with the Assistant Director Operations, the technical consultant did not evaluate the competency of four of five providers that perform KOH testing. Findings include: 1. Review of the CMS Form 209 signed by the laboratory director on February 28, 2023 showed the form identified five physician providers as testing personnel for moderate complexity testing. 2. Review of MTS (Medical Training Solutions) records showed one provider (staff C) had completed the online evaluation for KOH testing in January 2023. No records of competence evaluation from 2022 were available. Review of other personnel evaluation records showed no documented evaluation in 2022 or 2023 of providers that performed KOH tests. 3. Interview with the Assistant Director Operations (staff A) on February 24, 2023 at 3:20 PM confirmed the technical consultant did not evaluate competence of all testing personnel to ensure prompt, accurate, and proficient reporting of KOH results.