Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1033597	08/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Madison Medical Affiliates Inc	N4 22370 W Bluemound Rd, Suite 200, Waukesha, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records, observation of slides and interview with testing personnel, the laboratory did not follow procedures to ensure positive identification of six of seven retained slides from the Mohs procedure for patient two. Findings include: 1. Review of the Mohs patient test log showed patients one and two had Mohs procedures on the same day. Both patients had the same last name and first initial. 2. Observation of retained stained slides from patient one and two on August 4, 2022 at 10:30 AM revealed the laboratory labeled the slides with computer generated labels that showed the case number and patient's first and last name. The laboratory retained seven slides from the Mohs procedure for patient two. Personnel labeled the first slide with a computer-generated label that showed the name of the patient as identified in the test log. Personnel labeled the remaining slides with computer generated labels showing the case number for patient two and the name of patient one. Evaluation of the labeling under the computer-generated labels showed personnel had written the accession number, last name and first initial on the slides. Personnel hand labeled one of the seven slides with an unrelated, unassigned case number, 22-144. 3. Interview with testing personnel (staff A) on August 4, 2022 at 10:35 AM confirmed personnel did not follow procedures and personnel had mislabeled six of the seven retained slides for patient two.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with testing personnel, the laboratory had not established policies and procedures for an ongoing mechanism to monitor and assess the accuracy of retained patient slides and records. Findings include: 1. Review of laboratory records showed no sign the laboratory assessed the accuracy of slide labeling to ensure correct labeling for retention. 2. Interview with testing personnel (staff A) on August 4, 2022 at 10:35 AM confirmed the laboratory had not established a mechanism to ensure correct labeling of slides and integrity of retained records.