Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2184889	02/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Mohs Surgery, Pllc	7530 N Oracle Rd, Suite 102, Tucson, AZ	

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 review of Mohs test records and interview with the facility personnel, the laboratory failed to ensure positive identification for 1 out of 5 dermatopathology specimens from the time of collection through completion of testing and reporting of test results. Findings include: 1. The laboratory performs testing in conjunction with the Mohs procedure under the subspecialty of histopathology, with an approximate annual test volume of 3,000. It is the practice of the laboratory to assign a unique accession number to each Mohs specimen. The unique accession number is documented on the laboratory's Mohs log, Mohs map, patient's slides and final test report maintained in the patient's Electronic Medical Record (EMR). 2. The laboratory failed to ensure positive identification of a patient's specimen throughout the entire test process for 1 out of 5 Mohs cases reviewed during the survey, MR# MM0000000348 from testing performed on 4/05/23. Direct observation of the test records indicated the following: the patient's slides and Mohs log were labeled with accession# 5636, the original test report maintained in the EMR and the original Mohs map indicated accession# 5654, and the amended test report maintained in the EMR and corrected Mohs map indicated accession# 5436. 3. The corrected Mohs map and final (amended) test report maintained in the EMR for the patient referenced above failed to include the correct accession number at the time of the survey conducted on February 11, 2025. The correct accession number as verified with laboratory personnel during the survey should have been documented as #5636. 4. The facility personnel interviewed on 2/11/25 at 12:50 PM confirmed that the correct case# is

	5636 as written on the Mohs log and on the slide labels, and also confirmed that the laboratory identified the error, corrected the Mohs map and issued an amended test report on 4/10/23, however an incorrect accession number, #5436, was documented on the corrected map and amended test report.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for the microscopic interpretation of Frozen Biopsy specimens and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2024. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of the microscopic interpretation of Frozen Biopsy specimens at least twice annually during 2024. 2. The facility personnel interviewed on 2/11/25 at 2:05 PM confirmed the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2024, as indicated above. 3. The laboratory performs approximately 5 frozen biopsies annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of humidity records from 2023 through the survey date of 2/11/2025, review of the manufacturer's specifications for the Leica CM1520 Cryostat and interview with the facility personnel, the laboratory failed to define an operating humidity range which is consistent with the manufacturer's instructions for two of two cryostats. Findings include: 1. The laboratory utilizes two Leica CM1520 cryostats in conjunction with patient testing under the subspecialty of Histopathology. The laboratory reports an annual test volume of 3,000. 2. The manufacturer's specifications for the Leica CM1520 cryostat listed an operating relative humidity range of 20% -60%. 3. Review of the laboratory's humidity records from 2023 through 2/11/2025 indicated the humidity range as 0-100%. 4. The facility personnel interviewed on 2/11 /2025 at 1:55 PM confirmed the laboratory failed to define a humidity range for the two cryostats which is consistent with the manufacturer's requirements.
D5787	TEST RECORDS CFR(s): 493.1283(a)

	(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of Frozen Biopsy pathology reports and interview with the facility personnel, one out of two frozen biopsy reports failed to include the correct identity of the individual who performed the gross description. Findings include: 1. The laboratory performs the gross description on Frozen Section tissue specimens under the subspecialty of histopathology, with an approximate annual test volume of 5. 2. One out of two Frozen Biopsy pathology reports (MR# MM0000004213 from 9/21 /23) reviewed during the survey listed the individual who performed the gross description as "Gross Description: K.W., MA". 3. The facility personnel interviewed on 2/11/2025 at 1:20 PM stated that only the laboratory director performs the gross description of pathology specimens and confirmed the frozen biopsy test report indicated above listed an employee who did not perform the gross description.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 review of frozen biopsy pathology reports and interview with the facility personnel, the laboratory failed to include the gross description on 2 out of 2 frozen biopsy test reports reviewed during the survey. Findings include: 1. The laboratory performs the microscopic interpretation of frozen biopsy specimens in the subspecialty of histopathology, with an approximate annual test volume of 5. 2. Two out of two frozen biopsy pathology reports (MR# MM0000004213 from 9/21/23 and MM0000005229 from 9/09/24) failed to include the gross description. The gross description (including weighing, measuring, describing color, specific orientation for diagnostic interpretation, and other characteristics of the tissue) must be included on the pathology test report. 3. The facility personnel interviewed on 2/11/2025 at 1:20 PM acknowledged that the gross description was missing from the pathology test reports referenced above.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of a documented lab error form from 4/05/23, review of the amended pathology test report for the error identified on 4/05/23 and interview with the facility personnel, the laboratory failed to ensure resolution of a problem that was identified in the test reporting process for 1 out of 5 Mohs cases reviewed during the survey. Findings include: 1. The laboratory produced documentation of a completed "Lab Error" form from 4/05/23, patient H.E. The form indicated the following information: Accession#: 5436, Date: 4/5/23, Specimen Site: Right Inferior Central Malar Cheek, Error: Wrong accession # in chart, Correction: Corrected to site right #, Future Prevention: Double Check. 2. The facility personnel interviewed on 2/11/25 at 12:50 PM stated that the laboratory identified a reporting/accessioning error for the Mohs case referenced above and documented the error on the Lab Error form. The facility personnel stated that the Mohs log and Mohs slides indicated the correct accession number (#5636). The accession number, which was manually transcribed on the test report (operative note) maintained in the patient's Electronic Medical Record (EMR) and handwritten on the Mohs map, was incorrect and listed as #5654. The laboratory identified the error and amended the test report with the statement, "This amendment changes the case# from 5654 to 5436." The laboratory also corrected the Mohs map to show accession# 5436. The facility personnel acknowledged that the case# was still incorrect on the amended test report and on the Mohs map at the time of the survey, and confirmed that the correct case# should have been entered as #5636. 3. The laboratory failed to monitor and document that the corrective action taken for the Mohs case indicated above resolved the error and prevented recurrence of the problem. 4. The laboratory failed to establish and/or revise written policies and procedures to ensure that corrective actions are taken by the laboratory to resolve problems and prevent recurrence of problems identified in the postanalytic systems specified specified in 493.1291. 5. The laboratory performs 3,000 tests annually in the subspecialty of histopathology.