Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2279695	04/15/2025
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Institute Of Dermatology Payson	127 E Main St Ste A, Payson, 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
D0000	An initial survey was performed on April 15, 2025. The facility was found to be NOT in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1230 - General Laboratory Systems
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of Histopathology records and staff interviews, the laboratory failed to ensure positive identification and optimum integrity of 7 out of 9 dermatopathology specimens from the time of collection through completion of testing and reporting of test results (refer to D5203); and failed to monitor, identify and correct errors found with positive identification and optimum integrity of dermatopathology specimens (refer to D5291). The number and severity of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
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 7 out of 9 Mohs test records on April 15, 2025, lack of established policies and procedures and interview with the facility personnel, the laboratory failed to ensure positive identification and optimum integrity of 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 a reported annual test volume of 456. It is the practice of the laboratory to assign a unique accession number to each Mohs specimen which is documented on the laboratory's Mohs log, Mohs map and patient's slides. The final pathology report is maintained in the patient's EHR (Electronic Health Record). 2. The laboratory failed to ensure positive identification and optimum integrity of 7 out of 9 patient's specimens from the time of collection or receipt of the specimen through completion of testing and reporting of results, as evidenced below: - One of one Mohs map reviewed from 1/20/25 failed to include the accession number of the Mohs specimen. - One of one Mohs map reviewed from 2/03/25 failed to include the accession number of the Mohs specimen. - Mohs case# P017-2025 (as documented in the log book) failed to include the accession number of the Mohs map. - Mohs case# P004-2025 (as documented in the log book) failed to include the accession number of the Mohs map. - Mohs case# P139-2023 failed to include an accurate test result in the EHR. The Mohs map stated, "Stage 1: Positive in Deep Margin." The test result documented in the patient's EHR stated, "Stage 1: Frozen section analysis showed: No residual tumor seen. Histology: There were no malignant cells seen in the sections examined." - The Mohs map for case# P010-2025 (as documented on the laboratory's Mohs log and patient's slides) contained an incorrect accession number (P004-2025). - Two out of four slides for Mohs case# P255-2024 were labeled with an incorrect testing date (4-14-24). The correct testing date for case# P255-2024 was 4-15-24 as verified by laboratory personnel. 3. No documentation was presented for review to indicate the laboratory established 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. 4. The facility personnel interviewed on 4/15/25 at 12:22 PM acknowledged the errors indicated above and confirmed that no policies and procedures were established by the laboratory 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.
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 review of established quality assessment (QA) policies and procedures on April 15, 2025, review of the laboratory's Mohs log and interview with the facility personnel, the laboratory failed to monitor, assess and correct problems identified in

	the general laboratory systems requirements specified at 493.1231 through 493.1236, including but not limited to, problems identified with specimen identification and integrity. Findings include: 1. It is the practice of the laboratory to perform a monthly audit of one patient's Mohs record to ensure the case was performed and documented correctly throughout the preanalytic, analytic and postanalytic systems. 2. The laboratory's Mohs log reviewed from January 2025 revealed the laboratory staff wrote over and assigned different accession numbers to cases P007-2025 through P017-2025. 3. Review of the monthly QA audit from 1-31-2025 indicated only one case was reviewed (P006-2025). 4. The laboratory failed to take action to identify errors or potential errors with the reassigned accession numbers for cases P007-2025 through P017-2025. 5. The laboratory's established QA procedures were not effective at monitoring, assessing and correcting errors found in the general laboratory systems, including but not limited to, ensuring the positive identification and optimum integrity of patient's specimens throughout the entire test process. 6. The facility personnel interviewed on 4/15/25 at 12:50 PM acknowledged that the laboratory failed to investigate errors or potential errors with the reassigned accession numbers from January 2025, and acknowledged that the laboratory's QA processes at the time of the survey were not effective at monitoring, assessing and correcting problems identified in the general laboratory system.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 review of the laboratory's Mohs procedure manual on April 15, 2025 and interview with the facility personnel, the procedure manual failed to include the laboratory's system for entering results in the patient record and reporting patient results. Findings include: 1. The laboratory performs the microscopic interpretation of patients' slides in conjunction with the Mohs procedure under the subspecialty of Histopathology. Patient testing began on June 9, 2023, with a reported annual test volume of 456. It is the practice of the laboratory to enter the Mohs test results into the patient's Electronic Health Record (EHR). 2. The Mohs procedure manual reviewed during the survey failed to include the laboratory's system for entering and

	reporting results in the patient's EHR. 3. Interview with the facility personnel on 4/15 /2025 at 12:08 PM confirmed the Mohs procedure manual lacked information regarding the laboratory's system for entering and reporting patient test results in the EHR.
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 lack of humidity records for review from June 9, 2023 through April 15, 2025, review of the manufacturer's specifications for the Leica CM 1850 Cryostat and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity of the room where the cryostat is utilized. Findings include: 1. The laboratory utilizes the Leica CM 1850 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with an annual test volume of 456. 2. The manufacturer's specifications for the Leica CM 1850 Cryostat reviewed during the survey listed an operating relative humidity range of 0%-60%. 3. The laboratory failed to provide documentation demonstrating the ambient humidity of the room where the cryostat is utilized was monitored and recorded on each day of patient testing from June 9, 2023 through April 15, 2025 4. The facility personnel interviewed on 4/15/25 at 12:30 PM confirmed the laboratory failed to monitor and document the ambient humidity on each day of patient testing as indicated above.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance policy for the microscope used for patient testing, lack of annual maintenance records and interview with the facility personnel, the laboratory failed to perform and document annual maintenance of the microscope during 2024. Findings include: 1. The laboratory's microscope maintenance policy states, "Preventative maintenance needs to be completed and documented yearly." 2. The laboratory failed to provide records of annual preventative maintenance from 2024 for the microscope that is used for patient testing in the subspecialty of Histopathology. 3. The facility personnel interviewed on 4/15 /25 at 12:45 PM confirmed the laboratory failed to provide documentation of annual maintenance from 2023 and 2024 for the microscope used by the laboratory to read

	patient slides. 4. The laboratory began patient testing on 6/09/23 in the subspecialty of Histopathology, with a reported annual test volume of 456.
D5801	TEST REPORT CFR(s): 493.1291(a) (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 review of final test results maintained in the Electronic Health Record (EHR) and interview with the facility personnel, the laboratory failed to have a system in place to ensure test results and other patient-specific data are accurately and reliably transcribed into the patient's EHR for one out of one patients. Findings include: 1. Patient-specific data and the final test result information for Mohs is manually transcribed by laboratory personnel into the patient's EHR. 2. One out of one Mohs cases reviewed (# P139-2023) failed to include the correct test result in the patient's EHR. The Mohs map stated, "Stage 1: Positive in Deep Margin." The final test result documented in the patient's EHR stated, "Stage 1: Frozen section analysis showed: No residual tumor seen. Histology: There were no malignant cells seen in the sections examined". 3. No documentation was presented for review during the survey conducted on 4/15/25 to indicate the laboratory has a system in place to ensure the accuracy of patient-specific data and patient test results that are manually entered by laboratory staff into the patient's EHR. 4. The facility personnel interviewed on 4/15 /25 at 11:20 AM acknowledged the test result error for case# P139-2023 and confirmed the laboratory failed to have a system in place to verify the accuracy of patient-specific data and patient test results that are manually entered into the EHR.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 personnel record review and the laboratory's policies and procedures on April 15, 2025, the laboratory director failed to establish policies and procedures for monitoring the competency of 3 out of 3 individuals who conduct preanalytic, analytic, and postanalytic phases of testing in the subspecialty of histopathology. Findings include: 1. The laboratory has three Mohs technicians who are responsible for logging, labeling, processing, and staining Mohs specimens and entering test

	results into the patient's Electronic Health Record (EHR). 2. The laboratory director failed to establish policies and procedures to monitor individuals who conduct preanalytic, analytic, and postanalytic 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. 3. The facility personnel interviewed on 4/15/25 at 12:40 PM acknowledged that laboratory director failed to establish policies and procedures as indicated above, and failed to assure the competency of 3 out of 3 histotechnicians who conduct preanalytic, analytic, and postanalytic phases of testing. 4. The laboratory performs 456 tests annually in the specialty of Histopathology.