Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0532932	09/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pima Dermatology Pc	5150 East Glenn Street, 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
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 Mohs testing and Frozen Biopsy testing 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 2023. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Mohs testing at least twice annually during 2023. 2. No documentation was presented for review to indicate the laboratory verified the accuracy of Frozen Biopsy testing at least twice annually during 2023. 3. The facility personnel interviewed on 9/17/24 at 2:50 PM confirmed the laboratory failed to verify the accuracy of Mohs testing and Frozen Biopsy testing at least twice annually during 2023. 4. The laboratory performs 1,500 tests annually under the subspecialty of Histopathology.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 2022, 2023 and 2024, review of the manufacturer's specifications for the Leica CM1520 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 CM1520 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with an annual test volume of 1,500. 2. The manufacturer's specifications for the Leica CM1520 Cryostat reviewed during the survey listed an operating relative humidity range of 0%-60%. 3. On the survey date of 9/17/2024, the laboratory failed to provide documention demonstrating the ambient humidity of the room where the cryostat is utilized was monitored and recorded on each day of patient testing from 2022 through 2024 through the survey date of 9/17/2024. 4. The facility personnel interviewed on 9/17/2024 at 2:40 PM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.