Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2089517	07/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology & Skin Surgery Specialists Of Arizona	8415 N Pima Rd Ste 212, Scottsdale, 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
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 temperature records for review and interview with the facility personnel, the laboratory failed to monitor and document the room temperature where dermatopathology reagents are utilized and stored and failed to monitor and document the temperature of the cryostat used in conjunction with Mohs testing during 2021. Findings include: 1. The laboratory processes and interprets dermatopathology slides in conjunction with Mohs surgery, with an approximate annual test volume of 2,000. 2. No room temperature documentation was presented for review from 2021 to indicate the laboratory monitored and documented the temperature of the room each day of patient testing, where dermatopathology reagents are utilized and stored. 3. No documentation was presented for review to indicate the laboratory monitored and documented the cryostat temperature each day of patient testing during 2021. 4. The facility personnel confirmed that the laboratory failed to monitor and document the cryostat temperature and the room temperature of the laboratory where reagents are stored and used for patient testing during 2021.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must 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. The laboratory must 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 established microscope maintenance policy and interview with the facility personnel, the laboratory failed to perform and document the microscope maintenance as defined by policy during 2020 and 2021. Findings include: 1. The laboratory's policy titled, "Microscope Use Protocol Quality Control" indicates that the microscope stage and ocular eyepieces are to be cleaned every 6 months or sooner if needed, grounding check is monitored when service is completed and the ocular micrometer is calibrated as needed. 2. No documentation was presented for review to indicate the laboratory performed the microscope maintenance as indicated above during 2020 and 2021. The microscope was used for patient testing regularly during that time period. 3. The facility personnel confirmed that the laboratory failed to perform maintenance on the microscope as indicated in policy during the timeframe indicated above.