

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2329842	(X3) Date Survey Completed 09/01/2026
Name of Provider or Supplier California Dermatology Institute	Street Address, City, State 350 W Catalina Dr, Yuma, 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) (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 temperature records and interview with the facility personnel on 9/01/26 at 12:11 PM, the laboratory failed to monitor and document the ambient humidity of the room where the Leica cryostat was utilized for patient testing on 18 out of 18 testing dates between June 2025 through August 2026. Findings include: 1. The laboratory utilizes the Leica Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with an annual test volume of 1,000. 2. The laboratory failed to establish a humidity range consistent with the manufacturer's environmental requirements listed in the Leica operating manual. 3. The laboratory failed to provide documentation demonstrating the ambient humidity of the laboratory was monitored and recorded on each day of patient testing that occurred from June 30, 2025 through August 26, 2026. The laboratory performed patient testing on 18 dates during that timeframe. 4. The facility personnel interviewed on 9/01/26 at 12:11 PM confirmed the laboratory failed to monitor and document the ambient humidity of the room where the cryostat was utilized on each day of patient testing as indicated above.