

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2101446	(X3) Date Survey Completed 07/24/2024
Name of Provider or Supplier Omni Dermatology, Inc	Street Address, City, State 4515 S Mcclintock Dr Ste 101, Tempe, 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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>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 CM1510 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 CM1510 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology, with a reported annual test volume of 540. 2. The manufacturer's specifications for the Leica CM1510 Cryostat reviewed during the survey listed an operating relative humidity range of 0%-60%. 3. On the survey date of 7/24/2024, 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 during 2022, 2023 and 2024 (through the date of the survey). 4. The facility personnel interviewed on 7/24/2024 at 9:00 AM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.</p>