

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0912335	(X3) Date Survey Completed 11/20/2024
Name of Provider or Supplier Associated Dermatologists Pc	Street Address, City, State 1055 N La Canada, Ste 125, Green Valley, 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 2023 and 2024, review of the manufacturer's specifications for the Leica CM1850 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 CM1850 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with an annual test volume of 500. 2. The manufacturer's specifications for the Leica CM1850 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 2023 through 2024 (through the survey date of 11/20/2024). 4. The facility personnel interviewed on 11/20/2024 at 8:50 AM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.</p>