

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2181294	(X3) Date Survey Completed 05/06/2025
Name of Provider or Supplier Thomas Dermatology	Street Address, City, State 2350 Miracle Mile Ste 600, Bullhead City, 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>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of room temperature, cryostat temperature and laboratory humidity records from 2/02/2023 through the survey date of 5/06/2025 and interview with the facility personnel, the laboratory failed to 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. Findings include: 1. The laboratory performs testing in the subspecialty of Histopathology with a reported annual test volume of 450. 2. No documentation was presented for review to indicate the laboratory defined acceptable ranges for the room temperature, the cryostat and the ambient humidity of the room where test reagents are utilized and patient specimens are tested. 3. The facility personnel interviewed on 5/06/2025 at 2:15 PM confirmed the laboratory failed to define acceptable ranges for the room temperature, cryostat temperature and ambient humidity of the room where patient testing occurs.</p>