

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2250375	(X3) Date Survey Completed 03/27/2025
Name of Provider or Supplier Alabama Dermatology And Skin Specialists, Llc	Street Address, City, State 2045 Cecil Ashburn Dr, Se Suite 201, Huntsville, AL	
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 a review of the temperature records, the Avantik QS12 cryostat user manual, and an interview with the Laboratory Director, the Laboratory failed to document humidity for the Avantik cryostat. This was noted for 10 months of 14 months reviewed from 2024 through 2025. The findings include: 1. A review of the temperature records revealed the laboratory failed to document humidity for the Avantik cryostat from May 2024 through February 2025. 2. A further review of the Avantik QS12 user manual page 14 revealed, "Relative Humidity: Max 60% RH..." 3. During an interview on March 28th, 2023, at 7:37 AM, the Laboratory Director did not realize that humidity was not documented with the room temperature.</p>