

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2126667	(X3) Date Survey Completed 10/03/2024
Name of Provider or Supplier Metrolina Dermatology And Skin	Street Address, City, State 10502 Park Road, Suite 100, Charlotte, NC	
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 review of manufacture's instruction manual, review of 2022, 2023, and 2024 laboratory maintenance logs, and interview with laboratory clinical supervisor 10/03 /2024, the laboratory failed to ensure that the established relative humidity (RH) ranges for the cryostat were within manufacturer's specifications. Findings: Review of "Instruction Manual The Avantik QS12 Cryostat" Chapter 1, Environmental Specifications page 14, revealed "...Relative Humidity Max. 60% RH up to 35C...". Review of "Metrolina Dermatology Cryostat Daily Temperature, Cleaning & Maintenance Logs" revealed humidity range "(40% to 70%)". The laboratory's established humidity range 40% - 70% does not meet the manufactures specifications RH max 60%. During interview at approximately 11:00 a.m. laboratory clinical supervisor stated she was not aware of the humidity max of 60%, and the logs were probably not updated before her arrival.</p>