

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0724226	<b>(X3) Date Survey Completed</b>  02/22/2024
<b>Name of Provider or Supplier</b>  Azalea Skin Treatment Center	<b>Street Address, City, State</b>  501 Health Park Drive, Suite 150, Garner, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<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 the Avantik Q12 Cryostat instruction manual, review of 2022, 2023, and 2024 laboratory records, and interviews with the clinical supervisor and office manager on 2/22/2024, the laboratory failed to define an appropriate humidity range consistent with the manufacturer's instructions and monitor the humidity to ensure reliable test system operation. Findings: Review of the Avantik Q12 Cryostat instruction manual revealed in "Chapter 2: Environmental Specifications" that relative humidity cannot exceed 60%. Review of laboratory records revealed no documentation of humidity readings for 2022, 2023, and 2024. In interview at approximately 11:47 a.m., the clinical supervisor and office manager stated the following: 1. The clinical supervisor confirmed that humidity levels are not monitored or recorded in the laboratory. 2. The office manager stated that the laboratory was not aware of this requirement.</p>