

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2011166	<b>(X3) Date Survey Completed</b>  11/18/2021
<b>Name of Provider or Supplier</b>  Dermatology Of North Alabama Inc	<b>Street Address, City, State</b>  2307 Homer Clayton Drive, Guntersville, AL	
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 a review of the Thermo Scientific Cryostat Microm HM 525 Operator's Manual, lack of humidity records, and an interview with the Laboratory Director, the laboratory failed to monitor and document humidity in the laboratory. This was noted from July 2019 to November 2021 (date of survey). The findings include: 1. A review of the Thermo Scientific Cryostat Microm HM 525 Operator's Manual stated "... Operating conditions: +5 degrees Celsius up to +35 degrees Celsius (at a maximum relative humidity of 60%)..." 2. A review of temperature records revealed humidity for the laboratory had not been documented. 3. During an interview on 11/18/2021 at 12:00 PM, the Laboratory Director confirmed that the laboratory had not monitored room humidity, only room temperature.</p>