

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2052325	(X3) Date Survey Completed 12/15/2021
Name of Provider or Supplier Total Skin And Beauty Dermatology Center	Street Address, City, State 1720 University Boulevard Ste H384, Birmingham, 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>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 Leica CM 1520 Instructions for Use and an interview with the Histotechnician, the laboratory failed to monitor and document room temperature and humidity for the laboratory. This was noted from June 2019 (previous survey) to December 2021(date of survey). The findings include: 1. A review of the Leica CM 1520 Instructions for Use on page 16 revealed "The place of installation must meet the following requirements: ... -Room temperature consistently 18 degrees Celsius to 35 degrees Celsius, -Relative humidity, maximum 60% (non-condensing)..." 2. During an interview on 12/15/2021 at 11:00 AM, the Histotechnician confirmed the laboratory had not recorded room temperature or humidity for the Laboratory since the previous survey in June 2019.</p>