

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1019850	<b>(X3) Date Survey Completed</b>  01/28/2021
<b>Name of Provider or Supplier</b>  Metabolic Disease Laboratory	<b>Street Address, City, State</b>  720 20th Street South Kaul Bldg Rm 648, Birmingham, 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 LS 6500 Scintillation System Operating Manual and an interview with Testing Personnel #1, the laboratory failed to monitor and document room temperature and humidity each day of patient testing. The surveyor noted this on 32 of 32 months. The findings include: 1. A review of LS 6500 Scintillation System Operating Manual Appendix A revealed "...A.8 Temperature Control Accessory - Maximum Relative Humidity: 85% - Ambient Temperature Range: 15 degrees to 30 degrees Celsius...". The LS 6500 Scintillation System is used to provide automated counting of the level of radioactivity in radioactively-tagged samples. 2. During an interview conducted on 01/28/2021 at 11:05 AM, Testing Personnel #1 confirmed the laboratory had not monitored room temperature and humidity in the laboratory.</p>