

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2042078	(X3) Date Survey Completed 05/05/2021
Name of Provider or Supplier Cunningham Pathology	Street Address, City, State 2010 Brookwood Medical Center Drive, 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 Procedure Manual, a review of the Microm HM525 Operator's Manual, and an interview with the Laboratory Manager, the laboratory failed to monitor and document room temperature and humidity. This was noted for room temperature from January 2021 to March 2021 for the Frozen Room and for humidity all of 2020 (except from December 24th to December 31st) and January 2021 to March 2021. The findings include: 1. A review of the "Cold Storage and Equipment Temperature Documentation" in the Procedure Manual revealed "Temperature-dependent equipment containing reagents and/or patient/client specimens and environments are monitored to ensure the accuracy of patient/client test results..." 2. A review of the Microm HM525 Operator's Manual page 15 revealed "Temperature (Operating Limits) +5 degree C to + 35 (+41 degree F to +95 degree F) (at a max. Relative humidity of 60%)" 3. During an interview on 05/05/2021 at 12:05 PM, the Laboratory Manager confirmed the room temperature for the Frozen Room had not been reported from January 2021 to March 2021. The Laboratory Manager also confirmed the humidity was not documented in 2020 (except from December 24 to December 31) and 2021 (January to March).</p>