

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2042085	(X3) Date Survey Completed 11/23/2022
Name of Provider or Supplier Cunningham Pathology	Street Address, City, State 50 Medical Park East 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 Microm HM 550 Operator's Manual, a review of the environmental records, and an interview with the Laboratory Consultant, the laboratory's criteria for Humidity failed to be consistent with the manufacturer's instructions. This was noted from November 9 2022 to November 23 2022. The findings include: 1. A review of the Microm HM 550 Cryostat Operator's Manual revealed the following: "Operating Conditions...at a maximum relative humidity of 60%...". 2. A review of environmental records revealed the acceptable range for Humidity as 20% - 85%. The records also revealed 11 days in November 2022 which exceeded 60% Humidity. 3. During an interview on 11/23/2022 at 11:30 AM, the Laboratory Consultant explained the laboratory had a new Cryostat, and had failed to update the acceptable ranges for humidity with the operating conditions specified by the manufacturer.</p>