

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2213205	(X3) Date Survey Completed 08/16/2021
Name of Provider or Supplier Luminary Dermatology Pa	Street Address, City, State 2032 Hawthorne St, Sarasota, FL	
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
D0000	An announced CLIA initial survey was conducted at Luminary Dermatology PA on 08/16/21. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 review of maintenance records, review of the laboratory's procedure manual, review of the cryostat instrument manual, and interview with the Administrator, the laboratory failed to document humidity for 5 of 5 days of testing (3/29/21, 4/26/21, 5/24/21, 7/12/21, and 8/9/21). Findings Included: Review of maintenance records revealed the humidity percentage was not documented on the 5 days that testing was performed, 3/29/21, 4/26/21, 5/24/21, 7/12/21, and 8/9/21. Review of the Microm cryostat instrument manual revealed that operating conditions require a humidity of less than 60%. Review of the laboratory's procedure "Thermometers/Temperature Controls" dated 4/12/21 revealed that "Temperature and humidity must be taken daily and recorded in the lab." Interview on 08/16/21 at 10:30 AM, the Administrator stated the percent humidity was not recorded because they did not have a device to record humidity.</p>