

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0272561	(X3) Date Survey Completed 07/14/2022
Name of Provider or Supplier Suncoast Skin Solutions Inc	Street Address, City, State 525 North Dacie Point, Lecanto, 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	<p>An announced CLIA recertification survey was conducted at Suncoast Dermatology and Skin Surgery Center PA on 07/14/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:</p>
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 record review and interview with the MOHS Technician , the laboratory failed to record the room humidity every day that testing was performed (475 days) from 4/20/2020 to the day of survey, 07/14/2022. Findings Included: Review of the Leica cryostat instrument manual revealed that the maximum room humidity should be 60%. Review of the laboratory's Reagent Filtering/Disposal?Quality & Temperature Logs from April 2020 to July 2022 revealed no column to record humidity. On 7/15/22 at 12:30 PM., the MOHS Technician stated she did not know the laboratory was supposed to be documenting room humidity.</p>