

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0995867	(X3) Date Survey Completed 05/21/2019
Name of Provider or Supplier Sunnycoast Dermatology Inc	Street Address, City, State 3900 20th Street, Vero Beach, 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
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, the laboratory failed to record the temperature and humidity of the room where testing was performed from 5/21/17 to 5/21/19. Findings: The laboratory has one Avantik QS11 cryostat. The manual for the cryostats noted that the operating conditions of the laboratory should be 5 degrees Celsius up to 35 degrees Celsius at a maximum relative humidity of 60%. A review of the laboratory's logs showed that the laboratory failed to record the temperature and humidity of the room where testing was performed. On 5/21/19 at 10:50 AM, the Mohs Technician A stated that they did not record the room temperature or the humidity of the laboratory.</p>