

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2159481	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Sunrise Dermatology	Street Address, City, State 8832 Us Hwy 90, Daphne, 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 Thermo Scientific CryoStar NX70 Operator Guide, a review of Environmental Temperature logs, and an interview with Testing Personnel #1, the laboratory failed to monitor and document room temperature and humidity from October 2019 to June 15, 2021. The findings include: 1. A review of Thermo Scientific CryoStar NX70 Operator Guide revealed the following environmental requirements, "Temperature (Recommended Operation): +15 degrees C to +35 degrees C. [Celsius] ... Relative Humidity: Max 80% RH.". 2. A review of Environmental Temperature logs revealed the laboratory did not monitor and document room temperature and humidity until June 15, 2021. 3. During an interview conducted on 05/25/2022 at 10:45 AM, Testing Personnel #1 confirmed the above findings. SURVEYOR ID #32558 Licensure and Certification Surveyor</p>