

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0692297	(X3) Date Survey Completed 08/15/2023
Name of Provider or Supplier Advocare Olivo Dermatology Center	Street Address, City, State 201 Haddon Ave, Westmont, NJ	
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 surveyor review of the Leica DM 750 Microscope and Leica CM1510S Cryostat Instruction Manuals (IM) and interview with the Laboratory Director (LD) and Testing Personnel #2 (TP #2) provided on the CMS-209, the laboratory failed to provide the correct room temperature and humidity per the IM's requirements in the laboratory from 4/8/21 to the date of the survey. The findings include: 1. The surveyor observed that the strictest requirements for room temperature was 18-40C and humidity was 20-60% based on the IM's specifications. 2. The LD and TP #2 confirmed on 8/15/23 at 1:00 pm that the acceptable laboratory room temperature and humidity provided on the daily log was not strict enough.</p>