

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2149326	<b>(X3) Date Survey Completed</b>  02/03/2025
<b>Name of Provider or Supplier</b>  Blue Ocean Dermatology Llc	<b>Street Address, City, State</b>  1840 Greenwich Ave, Winter Park, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Blue Ocean Dermatology LLC on February 3, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 define cryostat temperature ranges for tissues processing in MOHS dermatology testing. Findings: Review of 2023 Cryostat maintenance log revealed there were no temperature ranges for the Cryostat to determine if the temperatures noted were appropriate for use. Review of Cryostat or microtome function test signed by the Laboratory Director on 5/01/2020 read, " to ensure all equipment needed for the performance of Mohs and frozen tissue cutting is clean and in working order perform patient tissue arrives Procedure: one hour before each 'Mohs or frozen procedure the histologist will conduct an inspection of the microtome to assure: 1. The cryostat is at the desired temperature and record temperature in the cryostat maintenance log ." On/2/3/2025 at 1:09 PM, the Office manager confirmed temperature ranges were not written in cryostat logs to determine when cryostat was at desirable temperature for use.</p>