

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2091155	(X3) Date Survey Completed 04/03/2025
Name of Provider or Supplier Dermatology Ltd, Chadds Ford	Street Address, City, State 1788 Wilmington West Chester Pike, Glen Mills, PA	
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>(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 lack of documentation and interview with Testing Personnel (TP)#8, the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Leica DM 1000 LED microscope used for microbiology slide examinations performed from 05/18/2023 to the day of survey. Findings include: 1. The Leica DM 1000 LED microscope manufacturer's technical specifications for ambient operating temperatures are 15-35 degrees Celsius and maximum 80% relative humidity. 2. On the day of the survey, 04/03/2025, the laboratory failed to provide documentation of the monitoring of room temperature and humidity to ensure operating conditions were met for the 1 of 1 Leica DM 1000 LED microscope (s/n 377172) used when potassium hydroxide (KOH) microscopic examinations were performed from 05/18/2023 to 04/03/2025. 3. The laboratory performed 7 KOH microscopic examinations from 05/18/2023 to 04/03/2025. 4. TP #8 confirmed the above findings on 04/03/2025 at 2:02 pm.</p>