

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2087795	(X3) Date Survey Completed 02/28/2025
Name of Provider or Supplier Philadelphia Center For Dermatology	Street Address, City, State 361 Highland Ave, Suite 204, Jenkintown, 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 review of laboratory records, lack of documentation, and interview with the Laboratory Director (LD) and the Practice Manager (PM), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Lecia DBLB30T Microscope used to perform histopathology slide examinations from 04/26/2023 to the date of survey. Findings include: 1. The operating environment listed in the instruction manual for the Lecia biological microscope states: "microscope should be kept at temperatures between 0C-40C/32F-104F, with a maximum humidity of 85%." 2. On the date of the survey, 02/28/2025 at 09:40 am, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for 1 of 1 Lecia DBLB30T microscope (s/n 241029) used to perform histopathology slide examinations from 04/26/2023 to 02/28/2025. 3. The laboratory performed 361(CMS-116) histopathology slide examinations from 04/26/2023 to 02/28/2025. 4. The LD confirmed the findings above on 02/28/2025 at 10:15 am.</p>