

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2196720	(X3) Date Survey Completed 07/31/2026
Name of Provider or Supplier Pennsylvania Dermatology Specialists	Street Address, City, State 1122 Street Road, Suite 204, Southampton, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Clinical Administrator (CA), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Olympus BX41 Microscope used to perform dermatopathology slide examinations from 02/19/2025 to date of survey. Findings Include: 1. The operating environment listed in the manual for Olympus BX41 model microscopes stated: "ambient temperature 5 to 40 degree Celsius and Maximum relative humidity is 80% for temperature to 31 degrees Celsius." 2. On the date of the survey, 07/31/2026 at 08:40 am, the laboratory failed to provide documentation for monitoring room temperatures (acceptable range: 5-40 degrees Celsius) and humidity (acceptable ranges up to 80%) to ensure operating conditions were met for 1 of 1 Olympus BX41 microscope used for dermatopathology slide examinations from 02/19/2025 to 07/31/2026. 3. The laboratory performed 1500 dermtopathology examinations in 2025 (CMS 116, estimated annual volume dated 06 /26/2026). 4. The CA confirmed the findings above on 07/31/2026 at 08:50 am.