Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D0967660	**(X3) Date Survey Completed** 10/30/2024
Name of Provider or Supplier Penn State Hershey Dermatopathology	**Street Address, City, State** 500 University Dr, Room C7714, Hershey, 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) 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. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 6 of 6 Olympus Microscopes used to perform dermatopathology slide examinations from 09/10/2020 to date of survey. Findings Include: 1. The operating environment listed in the manual for Olympus BX model microscopes states: "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, 10/30/2024 at 10:00 am, the laboratory failed to provide documentation for monitoring room temperatures (acceptable range: 5-40 degrees Celsius) and humidity (acceptable ranges 40 to 80%) to ensure operating conditions were met for the following 6 of 6 Olympus BX model microscopes used for dermatopathology slide examinations from 09/10/2020 to 10/30/2024. -BX51 -BX40 (2) -BX50 -BX43 -BX41 3. The LD confirmed the findings above on 10/30/2024 at 10:00 am.