

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2087783	(X3) Date Survey Completed 03/11/2025
Name of Provider or Supplier Pa Dermatology Partners Ne Phlly	Street Address, City, State 9501 Roosevelt Blvd Suite 508, Philadelphia, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Director of training and compliance (DTC), the laboratory failed to ensure that the verification of accuracy for MOHS microscopic examinations were performed at least twice annually, as required for 1 of 1 test not included in subpart I from 01/01/2024 to the date of the survey. Findings include: 1. On the day of survey, 03/11/2025 at 09:12 am, the laboratory the laboratory failed to provide documentation for the verification of accuracy performed for MOHS microscopic examinations at least twice annually from 01/01/2024 to 03/11/2025. 2. The laboratory's proficiency testing policy states "Semi-annually, the tech or risk manager will send five cases containing the original slide and send out for a microscopic examination by a board certified Dermatopathologist". 3. The laboratory reported an annual volume of 1200 microscopic examinations/tests performed in Histopathology (CMS 116 estimated annual volume). 4. The DTC confirmed the above findings on 03/11/2025 at 09:12 am. ***** Repeat Deficiency*****</p>
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</p>

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, lack of documentation, and interview with the Director of Training and Compliance (DTC), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Leica DM 2000 Microscope used to perform histopathology slide examinations from 05/02/2023 to the date of survey. Findings include: 1. The operating environment listed in the instruction manual for the Leica 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, 03/11/2025 at 09:30 am, the laboratory failed to provide documentation for monitoring room temperatures and humidity to ensure operating conditions were met for 1 of 1 Leica DM 2000 microscope used to perform histopathology slide examinations from 05/02/2023 to 03/11/2025. 3. The laboratory performed 1200 (CMS-116 estimated annual volume) histopathology slide examinations in 2024. 4. The DTC confirmed the findings above on 03/11/2025 at 09:30 am.