

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 08D2212358	<b>(X3) Date Survey Completed</b> 08/01/2025
<b>Name of Provider or Supplier</b> Dermatology Partners - N Wilmington	<b>Street Address, City, State</b> 2000 Foulk Road, Suite A, Wilmington, DE	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	D0000 A Recertification Survey was conducted on August 1, 2025 at approximately 1:00 PM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory document review and interview, the laboratory failed to retain records for peer-review proficiency testing (PT). This was noted for 3 out of 5 events reviewed. Findings included: Review of the records for the peer-review PT conducted to satisfy the requirement for twice-yearly accuracy verification revealed that results for the first event of 2023 and both events of 2024 were not available for review. Review of the "Proficiency Testing" section of the "Policies and Procedures" manual, approved by Laboratory Director (LD) #1 on 08/01/2025, revealed the following statement: "Results of each Proficiency Test will be entered in a log and kept in the laboratory management manual, as part of its permanent records." During an interview on 08/01/2025 at 1:30 PM, Senior Director of Clinical Development (SDCD #8) stated that the laboratory moved the previous month, and the records could not be located; they may have been inadvertently discarded.</p>
<b>D3039</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(5)</p> <p>(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p>

This STANDARD is not met as evidenced by:

Based on laboratory record review and interview, the laboratory failed to maintain copies of the monthly Quality Assurance (QA) checklists for two years. This was noted for 21 out of 24 months reviewed. Findings included: Review of the QA monthly checklists revealed completed checklists for 01/2023, 05/2025 and 06/2025. However, the QA monthly checklists for the remainder of 2023 and all of 2024 were not available for review. Review of the "Quality Assurance Policy" section of the "Policies and Procedures" manual, approved by Laboratory Director (LD) #1 on 08/01/2025, revealed the following statement: "Any discrepancies found in the checklist for the month will be documented on a lab error form and kept in the manual for 2 years." During an interview on 08/01/2025 at 2:05 PM, Senior Director of Clinical Development (SDCD) #8 stated that the laboratory moved the previous month, and the missing QA checklists could not be located; they may have been inadvertently discarded.