Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2073703	05/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pennsylvania Dermatology Partners - Douglassville	258-260 E Ben Franklin Highway, Birdsboro, 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	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's peer review records, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to ensure that the verification of accuracy for MOHS microscopic slide examinations was performed at least twice annually, as required for tests not included in subpart I for 1 of 1 year in 2025. Findings Include: 1. On the day of the survey, 5/19/2026 at 10:47 am, the laboratory failed to provide documentation for the verification of accuracy of MOHS microscopic slide examinations stained using hematoxylin and eosin (H&E) performed at least twice annually in 2025. 2. The laboratory performed 1,900 microscopic slide examinations (histopathology) in 2025 (CMS-116, estimated annual volume, dated 5/19/2026). 3. The SDCD confirmed the findings above on 5/19/2026 at 11:30 am.
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 lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to monitor room temperature to ensure proper storage of reagents, on weekends and holidays for 188 of 575 days from 6/4 /2024 to 12/31/2025. Findings include: 1. On the day of survey, 5/19/2026 at 10:30 am, review of the laboratory's temperature records revealed the laboratory failed to monitor and document room temperature to ensure proper storage of the following reagent was maintained for 188 of 575 days from 6/4/2024 to 12/31/2025: Avantik OCT Embedding Matrix, manufacturers recommended storage is 39 to 86 degrees Fahrenheit. 2. The laboratory performed 1900 total histopathology tests/examinations in 2025 (CMS 116, estimated annual volume, dated 5/19/2026). 3. The SDCD confirmed the findings above on 5/19/2026 at 12:00 pm.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control (QC) logs, lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to document a control slide of known reactivity to ensure acceptable staining characteristics of Hematoxylin & Eosin (H&E) stains for 142 of 142 days when dermatopathology microscopic slides were examined from 6/4 /2024 to 12/31/2025. Findings include: 1. On the day of survey, 5/19/2026 at 11:30 am, a review of the laboratory's H&E Stain - Autostainer procedure stated, "Have the surgeon initial off that the stain quality is acceptable before any additinal patient testing is performed". 2. The laboratory failed to provide documentation of acceptable staining characteristics of H&E stains used in Histopathology for 142 of 142 days from 6/4/2024 to 12/31/2025. 2. The laboratory performed 1900 total tests /examinations in 2025 (CMS 116, estimated annual volume, dated 5/19/2026). 3. The SDCD confirmed the findings above on 5/19/2026 at 12:00 pm.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature log records and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to document all corrective actions taken when room temperatures exceeded the laboratory's acceptable range for 5 of 92 days from January to December 2025. Findings include: 1. On the day of the survey, 5/19/2026 at 11:15 am, review of the laboratory's Room Temperature Log revealed the temperature documentation exceeded the laboratories acceptable range of 68 to 76 degrees Fahrenheit for the following 5 of 92 days from January 2025 to December 2025: -4/21/2025, 4/22/2025, 5/20/2025, 9/16/2025, and 12 /29/2025. 2. The laboratory failed to provide documentation for the corrective actions taken when room temperatures exceeded the laboratory's acceptable range from January 2025 to December 2025. 3. The SDCD confirmed the finding above on 5/19 /2026 at 12:30 pm.