Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2302186	01/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Partners - Lancaster	150 Farmington Lane, Suite 4, Lancaster, 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
D0000	A recertification survey was conducted by the Pennsylvania State Agency at Dermatology Partners - Lancaster on 01/09/2026. The laboratory was found out of compliance with the following conditions: 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. 493.1290 Condition: Postanalytic Systems.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. 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 have safety data sheets (SDS) accessible to ensure protection from chemical reagents and stains for 2 of 2 reagents stored in the laboratory from 08/14/2024 to 01/09/2026. Findings Include: 1. On the day of survey, 01/09/2026, at 11:39 am, the laboratory could not provide SDS to ensure protection from the following chemical reagents and stains stored in the laboratory from 08/14/2024 to 01/09/2026: - Avantik Tissue Marking Dye Kit, lot #'s 229809, 230858, 190249. - Avantik Embedding Matrix, EM0199. 2. The SDCD confirmed the above findings on 1/09/2026 at 11:56 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 observation in the laboratory, review of laboratory temperature records, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to monitor temperatures to ensure acceptable reagent storage conditions were maintained when the laboratory was closed for 452 of 513 days from 08/14/2024 to 01/09/2026. Findings include: 1. On the day of survey, 01/09/2026, at 10:08 am, during the tour of the laboratory, the surveyor observed the following reagents stored in the laboratory: - Avantik Embedding Matrix for Frozen Sections, storage requirements 39 to 86 F. 2. Review of the laboratory's temperature records revealed the laboratory failed to monitor and document temperatures to ensure acceptable reagent storage conditions were maintained for 452 of 513 days from 08/14/2024 to 01/09/2026 when the laboratory was closed. 3. The laboratory performed 1100 dermatopathology microscopic examinations in 2025 (CMS 116, estimated annual volume, dated 01/07/2026). 4. The SDCD confirmed the above findings on 1/09/2026 at 11:56 am.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient test reports and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to meet applicable postanalytical systems requirements in 493.1291 for 2 of 2 patient test reports reviewed for microscopic dermatopathology examinations performed from 08/14/2024 to the date of the survey. (refer to D5805).
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Based on review of patient test reports (Mohs maps) and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to include the address of the location where dermatopathology microscopic (Mohs) slide examinations were performed on 2 of 2 patient test reports reviewed from 08/14/2024 to the day of survey. Findings Include: 1. On the day of survey, 01/09/2026, at 10:12 am, review of 2 of 2 patient test reports (Mohs maps) revealed the laboratory failed to include the address of the laboratory where dermatopathology microscopic (Mohs) slide examinations were examined from 08/14/2024 to 01/09/2026. 2. The laboratory performed 1100 dermatopathology microscopic examinations in 2025 (CMS 116, estimated annual volume, dated 01/07/2026). 3. The SDCD confirmed the above findings on 1/09/2026 at 11:56 am. Repeat deficiency*
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the Senior Director of Clinical Development (SDCD), the Laboratory Director (LD) failed to provide overall management and direction of the laboratory in accordance with 493.1445 from 08/14 /2024 to 01/09/2026. Refer to D6086 and D6093.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory failed to ensure established procedures for the twice annual verification of accuracy for dermatopathology microscopic examination testing were followed for 4 of 4 peer review evaluations performed from 8/14/2024 to 01/09/2026. Findings include: 1. The laboratory's Proficiency Testing policy stated "Upon receipt of the pathology report from the Dermatopathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician. Stain quality, visibility of epidermis, and next step required will also be compared against records." 2. On the day of survey, 01/09/2026 at 9:38 am, the laboratory failed to provide documentation for the review performed upon receipt of pathology reports from the Dermatopathologist for the following 4 of 4 peer review evaluations completed from 08/14/2024 to 01/09/2026: - Dermatology Partners - Semiannual Proficiency Testing Year: 2024 Testing Period: January 1,2024 - June 30, 2024 - Dermatology Partners - Semiannual Proficiency Testing Year: 2024 Testing Period: July 1 - December 31 - Dermatology Partners - Semiannual Proficiency Testing Year: 2025 Testing Period: January 1 - June 30 - Dermatology Partners - Semiannual Proficiency Testing Year: 2025 Testing Period: July 1 - December 31 3. The SDCD confirmed the above findings on 1/09/2026 at 11:56 am.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview with the Senior Director of Clinical Development (SDCD), the laboratory director (LD) failed to ensure a Quality Assurance (QA) program was maintained and documented to ensure the quality of services provided for 5 of 17 months from 08/14/2024 to 01/09/2026. Findings include: 1. The Laboratory's Quality Assurance Procedure stated, "Monthly the nurse or Mohs histotech, along with the laboratory director or testing personnel, will check off the line items on the Monthly Quality Assurance Checklist." 2. On the date of the survey, 01/09/2026 at 9:49 am, the laboratory failed to provide monthly documentation for the QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes for the following 5 of 17 months from 08/14/2024 to 01/09/2026: - 8/2024, 9/2024, 10/2024, 11/2024, 12/2024. 3. The SDCD confirmed the above findings on 1/09/2026 at 11:56 am. Repeat deficiency*
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel competency assessment records and interview with the Senior Director of Clinical Development (SDCD), the Technical Supervisor (TS) failed to ensure that annual competency evaluations were documented to ensure 1 of 1 testing personnel (TP) who conduct preanalytical, analytical, and postanalytical phases of testing maintained their competency from 08/14/2024 to 01/09/2026. Findings Include: 1. On the day of the survey, 01/09/2026 at 9:20 am, review of the laboratory's personnel competency assessment records revealed the TS failed to ensure annual competency was documented to ensure 1 of 1 TP (CMS 209, personnel #2, dated 01/07/2026) that performed the following testing maintained their competency from 08/14/2024 to 01/09/2026: - Mohs Dermatopathology microscopic examination 2. The laboratory performed 1100 dermatopathology microscopic examinations in 2025 (CMS 116, estimated annual volume, dated 01/07/2026). 3. The SDCD confirmed the above findings on 1/09/2026 at 11:56 am.