Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D2121074	**(X3) Date Survey Completed** 12/23/2024
Name of Provider or Supplier Pennsylvania Dermatology Partners Laurys Station	**Street Address, City, State** 5646 Wynnewood Drive, Suite 202, Laurys Station, 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 Director of Training and Compliance (DTC), the laboratory failed to ensure that the verification of accuracy for histopathology slide examinations stained using hematoxylin and eosin (H&E) were performed at least twice annually in 2023. Findings Include: 1. On the day of the survey, 12/23/2024 at 10:00 am, the laboratory failed to provide documentation for the verification of accuracy for histopathology slide examinations stained using H&E, were performed at least twice annually in 2023. 2. The laboratory performed 530 histopathology examinations in 2023 (estimated annual volume CMS-116). 3. The DTC confirmed the findings above on 12 /23/2024 at 10:00 am.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 lack of documentation, review of the Quality Assurance (QA) procedure, and interview with Director of Training and Compliance (DTC), the Laboratory

	Director (LD) failed to ensure a QA program was established and maintained to ensure the quality of services provided by the laboratory for 12 out of 12 months in 2023. Findings include: 1. The laboratories QA procedure states the following: - " Monthly the nurse or tech will check off the monthly quality assurance checklist." - " This check list is used to evaluate General Laboratory systems, pre-analytic systems, analytic systems, and post-analytic Systems." - " The Laboratory Director will also review and sign off the check list monthly." 2. On the day of survey 12/23/2024 at 09: 30 am, the laboratory could not provide QA documentation that reviews the pre-analytical, analytical, and post-analytical phases of the laboratory for 12 out of 12 months in 2023. 3. The DTC confirmed there were no QA records on 12/23/2023 at 09:45am. *Repeat Deficiency
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Director of Training and Comliance (DTC), the laboratory failed to have the required records accessible during the laboratory survey performed on 12/23/2024. Findings Include: 1. On the day of the survey, 12/23/2024 at 09:30 am, the laboratory could not provide the following records upon request: - Current Board Certifications for Laboratory Director. 2. The DTC confirmed the finding above on 12/23/2024 at 09:30 am.