Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2121074	01/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pennsylvania Dermatology Partners Laurys Station	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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory procedures manuals and interview with the Laboratory Manager (LM), the laboratory failed to have the current director's signature for the procedures currently in use from 11/05/2020 to 01/18/2023. Findings include: 1. On the date of the survey (01/18/2023) at 09:10am, Review of the Policies and Procedures manuals revealed the Laboratory Director did not review and sign the current manual before it was put in use. 2. The LM confirmed the finding above on 01 /18/2023 around 10:05am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation of the microscope and interview with the Laboratory Manager (LM), the laboratory failed to perform maintenance/calibration on 1 of 1 microscope used for Mohs microscopic examinations from 04/2022 to 01/18/2023. Findings include: 1. On the day of the survey, 01/18/2023 at 09:51am, observation of 1 of 1 microscope revealed that the microscope used for Mohs microscopic examinations

	was due for maintenance /calibration on 04/2022. 2. The LM confirmed the finding above on 01/18/2023 around 10:05am.
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. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records and interview with the Laboratory Manager (LM), the laboratory did not document Hematoxylin and Eosin (H & E) stain QC monitoring activities for intended reactivity from 11/05/2020 to the day of the survey. Findings include: 1. On the day of the survey, 01/18/2023 at 09:45 a.m., the laboratory could not provide QC documentation for staining characteristics for the H&E stain performed from 11/05/2020 to 01/18/2023 2. The LM confirmed the finding above on 01/18/2023 at 10:05 a.m.
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 Quality Assurance (QA) documentation, review of the Quality Assurance procedure, and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure a QA program was established and maintained to ensure the quality of services provided by the laboratory in 2021 and 2022. 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 1/18/2023 at 09: 45am, the laboratory could not provide QA documentation that reviews the pre-analytical, analytical, and post-analytical phases of the laboratory in 2021 and 2022. 3. The LM confirmed there were no QA records on 01/18/2023 at 10:05am.