Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2121074	06/27/2018
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
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 Interview with the Histotechnologist and review of the laboratories peer review procedure, the laboratory failed perform at least twice annually the accuracy of Mohs slides read on site from 2017 to the date of survey. Findings Include: 1. On the day of survey, 06/27/2018, the laboratory could not provide documention of peer reviews performed for 2 of 2 testing personnel in 2017 and in 2018 (January 1st, 2018 to June 27th, 2018). 2. The Histotechnologist confirmed the findings above on 06/27 /2018 around 9:10 am.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assurance (QA) Program Policy and interview with the Histotechnologist, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor and assess its Pre-analytical, Analytical and Post-analytical system activities from 2017 to the time of survey. Findings include: 1. On

	the day of survey, 06/27/2018, after review of the laboratories Quality Assurance Program Policy, it was revealed that the laboratory is not following their own procedure to perform QA assessments on a monthly bases in 2017 (12 of 12 months) and from January to May 2018 (5 of 5 months). 2. The Histotechnoologist confirmed the finding above on 06/27/2018 around 09:45 am.
D5805	TEST REPORT CFR(s): 493.1291(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 the laboratories Mohs Maps (Test Reports), and interview with the histotechnologist, the laboratory failed to ensure that all test reports include the address of the laboratories location where the pathology slides are read from January 1st, 2017 to June 27th, 2018. Findings Include: 1. On the day of survey, 06/27/2018, all test reports had one of two of the following address printed on the upper left hand corner of the test report: a). 2913 Windmill Road, Suite 7 Sinking Springs PA, 19608 b). 2588 Ben Franklin Highway Birdsboro PA, 19508 2. The correct address where pathology slides are read is, 5649 Wynnewood Drive, Suite 202 Laurys Station, PA 18059. 3. In 2017, 349 Patients slide were read on site. 4. The Histotechnologist confirmed the findings above on 06/27/2018 around 9:20 am. .
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the Histotechnologist, the laboratory failed to evaluate the competency of all testing personnel (TP) who review Mohs pathology slides in 2017. Findings Include: 1. On the day of survey, 06/27 /2018, the laboratory could not provide 2017 competency assessment documention for TP #2, for review of pathology slides read on site. 2. In 2017, 349 pathology slide were reviewed. 3. The Histotechnologist confirmed the findings above on 06/27/2018 around 9:30 am.