

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2039545	<b>(X3) Date Survey Completed</b> 01/18/2018
<b>Name of Provider or Supplier</b> Pennsylvania Dermatology Partners, Inc	<b>Street Address, City, State</b> 2128 Penn Ave, 1st Floor, West Lawn, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, Mohs procedure manual review and interview with the Histology Technologist and Mohs Technician, the laboratory failed to have the current director's signature for the procedures currently in use. Findings include: 1. On the date of survey (01/18/2018), The first page of the Policies and Procedures manual reviewed, stated, the Laboratory Director will review the manual yearly. 2. Review of the procedure manual revealed, the laboratory director last reviewed the procedure in 08/01/2012. 3. The Histology Technologist and Mohs Technician confirmed the finding above on 01/18/2018 around 12:20 PM.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a laboratory tour and interview with the Histology Technologist and Mohs Technician, the laboratory failed to ensure expired reagents were not used beyond the expiration dates. Findings Include: 1. On the date of survey 01/18/2018, the laboratory tour revealed that the following reagents were expired: - 2 of 2 bottles of Avantik Ultra Clear Xylene Sub. Lot#151115V. Expired: 11/2017 - 1 of 1 bottle of Green</p>

Tissue Marking Dye. Lot# H33850. Expire: 09/2016 2. In 2016, 1400 specimen were read. 3. The Histology Technologist and Mohs Technician confirmed the findings above on 01/18/2018 around 12:35 PM.

**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 cryostat and interview with the a Histology Technologist and Mohs Technician, at the time of the survey, the laboratory failed to document maintenance of 1 of 1 Cryostat Microtome. Findings include: 1. The Laboratory Cryostat Maintenance procedure states: Preventative maintenance and grounding checks are done and documented annually. 2. At the time of survey, (01/18/2018 at 12:15) the laboratory could not provide documentation for the yearly maintenance of the Cryostat Microtome. 3. The last service sticker on the instrument revealed: Last serviced on: 4/24/2012 Due for Maintenance: 4/24/2013 4. In 2016, 1400 specimen were read. 5. The Histology Technologist and Mohs Technician confirmed the findings above on 01/18/2018 around 12:45 PM.

**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 the review of Patient Mohs Reports, interview the Histology Technologist and Mohs Technician, the lab failed to include the location of where Mohs slides reading is performed on the Patient reports from 2016 to the date of survey. Finding Include: 1. On the date of survey (01/18/2018), review of 2 of 2 Mohs maps/ reports revealed that the address on the report was not the current location where slide reading is performed. 2. In 12 months 1,400 specimens were read. 3. The Histology Technologist and Mohs Technician confirmed the findings above on 01/18/2018 around 01:00 PM.