

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2107253	<b>(X3) Date Survey Completed</b> 04/16/2024
<b>Name of Provider or Supplier</b> Pennsylvania Dermatology Partners-Pottstown	<b>Street Address, City, State</b> 2093 E High Street, Pottstown, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, laboratory's Proficiency Testing manual review, and interview with the director of training and compliance (DOTC), the laboratory failed to verify twice annually the accuracy of dermatopathology microscopic examinations performed in 2022. Findings include: 1. The laboratory's Proficiency Testing manual stated, "Semi-annually, the tech or risk manager will send five cases containing the original slides, label it with only the surgical case number, and send it for a microscopic examination by a Board Certified Dermatopathologist. No differential diagnosis will be offered with the specimen. The slide may be labeled "Proficiency Test" by the sending laboratory for the records of the reference laboratory." 2. On the day of survey, 04/16/2024 at 11:00 am, the laboratory could not provide documentation of the semiannual verification of accuracy of dermatopathology microscopic examinations performed in 2022. 3. The DOTC confirmed the findings above on 04/16/2024 at 12:30 pm.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on observation of the laboratory, procedure review, and interview with the director of training and compliance (DOTC), the laboratory failed to perform and document preventative maintenance (PM) on 1 of 1 cryostat used for dermatopathology macroscopic examinations performed from 07/2023 to the day of the survey. Findings include: 1. The laboratory's cryostat procedure states, "Preventative maintenance and grounding checks are done and documented annually." 2. On the day of survey, 04/16/2024 at 12:08 pm, during observation of the laboratory the surveyor observed on the sticker that PM on 1 of 1 cryostat (AVANTIK QS 11) was due in 07/2023. 3. According to the CMS 116 the laboratory performed 900 dermatopathology macroscopic examinations in 2023. 4. The DOTC confirmed the findings above on 04/16/2024 at 12:30 pm.