

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2087783	(X3) Date Survey Completed 05/02/2023
Name of Provider or Supplier Pa Dermatology Partners Ne Phlly	Street Address, City, State 9501 Roosevelt Blvd Suite 508, Philadelphia, 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	<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 review of the peer review records and interview with the Laboratory Manager (LM), the laboratory failed to perform at least twice annually the accuracy of Mohs micrographic examinations for 1 of 1 testing personnel (TP) in 2021, 2022 and 2023. Finding Include: 1. On the day of survey, 05/02/2023 at 10:38 am, review of Mohs micrographic examinations peer review records revealed that the evaluation and verification activity was performed once in 2022. 2. Further review of Mohs micrographic examinations peer review records showed that the laboratory did not clearly record who was the assessed pathologist and who was the reviewer for the Mohs micrographic examinations in July 2021, January 2022 and January 2023. 3. The laboratory's annual volume for histopathology is 600 patient examinations (CMS 116 form). 4. The LM confirmed the findings above on 05/02/2023 around 11:00 am.</p>
D5417	<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 the observation of the laboratory and interview with the laboratory manager (LM), the laboratory failed to ensure that 3 of 5 bottles of Avantik tissue marking dyes</p>

were not used beyond their expiration date from 05/2020 to the day of survey. Finding include: 1. On the day of survey, 05/02/2023 at 11:12 am, observation of the laboratory revealed that the following 3 of 5 bottles of Avantik tissue marking dyes were expired: - Blue Avantik tissue marking dye bottle, Lot# 0066596 - Expired: 05/2020. - Yellow Avantik tissue marking dye bottle, Lot# 066896 - Expired: 05/2020. - Black Avantik tissue marking dye bottle, Lot# 067444 - Expired: 06/2020. 2. The LM confirmed the finding above on 05/02/2023 around 11:10 am

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 laboratory manager (LM), the laboratory failed to perform maintenance on 1 of 1 microscope from 07/2021 to 05/02/2023. Findings Include: 1. On the day of survey, 05/02/2023 at 11:18 am, observation of the microscope revealed that 1 of 1 microscope was due for maintenance on 07/2021. 2. The last calibration for the microscope was on 04/03/2020. 3. The laboratory did not provide maintenance records for the microscope for 2021 and 2022. 4. The LM confirmed the findings above on 05/02/2023 around 11:10 am