

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2073703	(X3) Date Survey Completed 09/14/2022
Name of Provider or Supplier Pennsylvania Dermatology Partners - Douglassville	Street Address, City, State 258-260 E Ben Franklin Highway, Birdsboro, 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 lack of peer review records and interview with the Center Manager (CM), the laboratory failed to verify twice annually the accuracy of Moh's micrographic examination for 1 of 2 verifications in 2021. Findings Include: 1. On the day of survey, 09/14/2022 at 11:32 AM, a review of the laboratory's peer review policy revealed that verification of Moh's microscopic examination is required twice a year. 2. A review of peer review records revealed, the laboratory performed Moh's microscopic examination in 2021. The verification of Moh's microscopic examination was performed once, not twice as required. 3. The CM confirmed the findings above on 09/14/2022 at 12:48 PM.</p>
D5429	<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: Based on observation of microtome analyzers during the laboratory tour, lack of documents, and interview with the Laboratory Manager (LM), the laboratory failed to provide documentation for Annual maintenance on 1 of 1 Micron HM 310 microtome analyzer from 8/2020 to 9/2022. Findings include: 1. On the day of survey, 09/14</p>

/2022 at 12:28 PM, a laboratory tour revealed that the laboratory failed to perform yearly maintenance on 1 of 1 Micron SM 310 analyzer from 2021 to the day of the survey. 2. The maintenance sticker observed at the time of survey on the analyzer indicated that the last maintenance was performed on 8/2020 and was due on 8/2021. 3. The LM confirmed the above findings on 09/14/2022 at 1:48 PM.

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 lack of Immunohistochemistry staining negative quality control (QC) records and interview with the Laboratory Manager (LM), the laboratory failed to perform negative reactivity check for the Histopathology slides examined from 2021 through 2022. Findings include: 1. On the day of survey 09/14/2022 at 11:48 AM, a review of the laboratory's Immunohistochemistry procedure revealed that only positive control slides are required with each test slide. 2. The laboratory could not provide negative reactivity check readings for the Immunohistochemical stain slides from 2120 through the date of survey. 3. The LM confirmed the findings above on 09/14/2022 at 12:48 PM.