

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2041618	<b>(X3) Date Survey Completed</b> 05/07/2024
<b>Name of Provider or Supplier</b> Pennsylvania Dermatology Group, Pc	<b>Street Address, City, State</b> 2301 Huntingdon Pike, Huntingdon Valley, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Histotechnician, the laboratory failed to establish and follow a written policy to assess the competency of 2 of 3 Clinical Consultants (CC), 2 of 3 General Supervisors (GS) and 2 of 3 testing personnel (TP) for their responsibilities performed in the Histopathology laboratory in 2022 and 2023. Findings Include: 1. On the day of the survey, 05/07/2024 at 1:00 pm, the laboratory could not provide a competency assessment policy to assess the competency of the 2 of 3 CC and GS (CMS 209 personnel #2 and #3) for their supervisory responsibilities, and the 2 of 3 TP (CMS 209 personnel #2 and #3) who performed microscopic examinations in the Histopathology laboratory in 2022 and 2023. 2. The laboratory could not provide competency assessment records for the following personnel: - CC #2, GS #2, TP #2 (CMS 209 personnel #2) for 2022 and 2023 - CC #3, GS #3, TP #3 (CMS 209 personnel #3) for 2023 3. The Histotechnician confirmed the findings above on 05/07/2024 at 02:00 pm.</p>
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) log, Mohs procedure manual and interview with the Histotechnician, the laboratory failed to establish criteria for intended reactivity to ensure acceptable staining characteristics of Hematoxylin & Eosin (H&E) stains used in Histopathology from 09/06/2022 to the date of survey. Findings include: 1. On the day of survey, 05/07/2024 at 1:30 pm, a review of the laboratory's Quality Control Log for Slide Preparation and the Mohs procedure manual revealed the laboratory did not establish or document criteria for intended reactivity to ensure acceptable H&E staining characteristics when Histopathology slides were examined from 09/06/22 to 05/07/24. 2. The Histotechnician confirmed the findings above on 05/07/24 at 2:00 pm.