

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>39D2082546</p>	<p><b>(X3) Date Survey Completed</b></p> <p>11/12/2024</p>
<p><b>Name of Provider or Supplier</b></p> <p>Nj Cd DbA Dedicated Dermatology</p>	<p><b>Street Address, City, State</b></p> <p>2895 Hamilton Blvd Suite 202, Allentown, PA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D5217</b></p>	<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 and interview with the medical assistant (MA), the laboratory failed to verify twice annually the accuracy of macroscopic histopathology examinations performed from 11/08/2022 through the date of the survey. Findings include: 1. On the day of survey, 11/12/2024, the laboratory could not provide documentation of the twice annual verification of accuracy for macroscopic histopathology examinations (grossing and inking) performed from 11/08/2022 to 11/12/2024. 2. The laboratory could not provide a procedure for the verification of accuracy for macroscopic histopathology examinations (grossing and inking). 3. The MA confirmed the findings above on 11/12/2024 at 10:45 a.m.</p>
<p><b>D5601</b></p>	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Mohs procedure manual, quality control (QC) log</p>

and interview with the medical assistant (MA), the laboratory failed to establish and document the laboratory's criteria for intended reactivity to ensure acceptable staining characteristics of Hematoxylin & Eosin (H&E) stains used for histopathology examinations performed from 11/08/2022 to the date of survey. Findings include: 1. The laboratory's "Mohs procedures" (SOP S-1) states, "If the control slide is unacceptable, the MOHS tech will make any necessary adjustments and stain another H&E control slide and continue with the process until the surgeon deems the control acceptable." 2. On the day of survey, 11/12/2024, a review of the laboratory's "QC Mohs staining logs" revealed the laboratory failed to establish and document the laboratory's criteria for intended reactivity to ensure acceptable H&E staining characteristics when Histopathology slides were examined from 11/08/22 to 11/12/24. 3. The laboratory performed an annual volume of 150 histopathology examinations in 2023. (CMS 116) 4. The MA confirmed the findings above on 11/12/24 at 10:45 am.