

|                                                                                                                            |                                                                                       |                                                     |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------------------|
| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>39D2082546            | <b>(X3) Date Survey Completed</b><br><br>06/18/2026 |
| <b>Name of Provider or Supplier</b><br><br>Nj Cd DbA Dedicated Dermatology                                                 | <b>Street Address, City, State</b><br><br>2895 Hamilton Blvd Suite 202, Allentown, 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| D5028              | <p>HISTOPATHOLOGY<br/>CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of the laboratory's Mohs procedure manual, quality control (QC) log and interview with the Regional Supervisor (RS), the laboratory failed to establish and document the laboratory's criteria for intended reactivity (493.1273(a)) to ensure acceptable staining characteristics of Hematoxylin &amp; Eosin (H&amp;E) stains used for histopathology examinations performed from 11/12/2024 to the date of survey. Refer to D5601</p>                                                                         |
| D5209              | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES<br/>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:<br/>Based on procedure review, lack of documentation and interview with the Regional Supervisor (RS), the laboratory failed to follow the established competency assessment (CA) procedure to assess the competency of 1 of 2 Technical Supervisors (TS), and 1 of 2 General Supervisor (GS) for their supervisory responsibilities and 5 of 6 Testing personnel (TP) who performed histology examinations from 11/12/2024 to 06/18/2026. Findings Include: 1. On the day of survey, 06/18/2026 at 10:30 am,</p> |

|              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              | <p>review of the SOP Manual stated, "23. Personnel Training and Competency - Initial training documented-Competency assessed at 6 months, 12 months, then annually - Records maintained - Competency includes: Direct observation of testing-Review of QC documentation-Blind slide review- Documentation of results. Competency is assessed and documented by the LD or qualified designee. 2. On the day of survey, 06/18/2026 at 10:30 am, the laboratory failed to provide CA records for 1 of 2 TS and 1 of 2 GS (CMS 209 TS/GS #2, dated 6/16/2026) for their supervisory responsibilities performed from 11/12/2024 to 06/18/2026. 3. The laboratory failed to provide CA records for 5 of 6 TP (CMS 209, TP #2, 3, 4, 5, and 6) that performed macroscopic histopathology (grossing and inking) examinations from 11/12/2024 to 06/18/2026. 4. The laboratory performed 160 Mohs examinations in 2025 (CMS 116 estimated annual volume, dated 06/16/2026). 5. The RS confirmed the findings above on 06/18/2026 at 10:45 am.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>D5429</b> | <p><b>MAINTENANCE AND FUNCTION CHECKS</b><br/>CFR(s): 493.1254(a)(1)</p> <p>(a)(1) 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> <p>A. Based on observation of the laboratory, lack of documentation, and interview with the Regional Supervisor (RS), the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 1 of 1 timer used for staining histopathology slides in the laboratory from 11/12/2024 to the day of the survey. Findings include: 1. On the day of the survey, 06/18/2026 at 10:00 am, observation of the laboratory revealed the following timer used to aid in the staining of histopathology slides was past due for calibration: - McKesson Timer S/N 51631, due 09/19/2025 2. The laboratory failed to provide maintenance/functions checks records for 1 of 1 McKesson timer from 9/19/2025 to 06/18/2026. 3. The laboratory performed 160 Mohs histopathology slide examinations in 2025 (CMS 116, estimated annual volume, dated 06/16/2026). 4. The RS confirmed the above findings on 06/18/2026 at 10:10 am. B. Based on review of maintenance logs, lack of documentation, and interview with the Regional Supervisor (RS), the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 1 of 1 Avantix QS12 cryostat used for histopathology slides in the laboratory from 11/12/2024 to the day of the survey. Findings include: 1. On the day of the survey, 06/18/2026 at 9:30 am, the laboratory failed to provide the maintenance logs for 1 of 1 Avantix QS12 cryostat for the following months: - 2024-December - 2025-June, October, November, December - 2026-January, February 2. The laboratory performed 160 Mohs histopathology slide examinations in 2025 (CMS 116, estimated annual volume, dated 06/16/2026). 3. The RS confirmed the above findings on 06/18/2026 at 10:10 am.</p> |
| <b>D5601</b> | <p><b>HISTOPATHOLOGY</b><br/>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Mohs procedure manual, quality control (QC) log and interview with the Regional Supervisor (RS), 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 for 2 of 2 years from 11/12/2024 to the date of survey.

Findings include: 1. The laboratory's "Mohs CLIA Laboratory Standard Operating Procedure Manual states, "12. Quality Control (QC) Daily stain control slide performed and reviewed. Qc result documented as Acceptable -Unacceptable. If QC fails: 1. Testing is halted; 2. Root cause identified (reagent, equipment, technique); 3. Corrective action documented; 4. QC repeated before patients' results released.

Trouble shooting: Poor staining-check reagent expiration and rotation; Thick section-recalibrate cryostat; Artifact- repeat sectioning." 2. On the day of survey, 06/18/2026, 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 for 2 of 2 years from 11/12/2024 to 06/18/2026. 3. The laboratory could not provide QC logs for the following months: - 2025 - October, November, December - 2026 - January, March 4. The laboratory performed an annual volume of 160 histopathology examinations in 2025 (CMS 116, estimated annual volume, dated 06/16/2026). 5. The RS confirmed the findings above on 06/18/2026 at 10:45 am. \*\* Repeat Deficiency\*\*