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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D2126488 | (X3) Date Survey Completed 06/16/2025 |
| Name of Provider or Supplier The Dermatology Group Pa | Street Address, City, State 300 E Hazel St, Orlando, FL | |
| 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 |
|---------------------------|---|
| D0000 | An announced CLIA recertification survey was conducted at The Dermatology Group PA on June 16, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies: |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) 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 observation, review of the procedure manual and the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, and interview, the laboratory failed to use non-expired reagents (dyes) for orienting and mapping surgical tissue according to the yellow stickers from 03/15/2025 to 06/16/2025. Findings: 1. Observations during a tour of the laboratory on 06/16/2025 at 9:30 AM, revealed the dyes used for orientation and mapping of the patients' surgical tissues were expired. No other dyes were located in the laboratory. 2. Observation of the Red Tissue Marking Dye lot #154023 listed the manufacturer's expiration date was 07/31/2024. Review of the red dye bottle showed two labels were attached to the bottle. The white label showed the red dye was received on 10/22/2022 (as I see it) and the expiration date was 07/2024. The yellow sticker covering the manufacturer's expiration date showed the received date was 07/2024, the date opened was 5/15/2025, and the expiration date was 07/31/25. 3. Observation of the Green Tissue Marking Dye lot #164883 listed the manufacturer's expiration date was 03/31/2025. Review of the bottle of green dye, with a yellow sticker covering the manufacturer's expiration date, showed the received date was 07/2024, the date opened was 05/15/2025, and the expiration date was 08/31/2025. 4. Observation of the Blue Tissue</p> |

Marking Dye lot #152500 listed the manufacturer's expiration dates was 06/30/2024. Review of the bottle of blue dye, with a yellow sticker covering the manufacturer's expiration date, showed the received date was 10/2024, the date opened was 3/15/2025, and the expiration date was 07/31/25. 5. Comparison of the expirations date on the manufacturer's label and the open date on the yellow stickers showed all three dyes were expired before they were used according to the yellow stickers. 6. Review of the procedure titled Histopathology - Mohs Surgery noted "Do not use reagents after expiration date. 7. Review of the CLIA application listed the laboratory had an annual test volume of 300. 8. During an interview on 06/16/2025 at 9:40 AM, the Site Manager confirmed the dyes were expired, 9. During an interview on 06/16/2025 at 10:02 AM, the Site Manager stated the Mohs Technician did not give her an explanation as to why she covered up the expiration dates on the dyes and wrote in new expiration dates.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel record, and interview, the Technical Supervisor failed to document the competency evaluation of one of one high complexity Testing Personnel (A) from April 15, 2023 to June 16, 2025. Findings: 1. Review of the personnel records for Testing Personnel A (Mohs Surgeon) showed there was no documentation of annual competency evaluations on the Mohs Surgeon. 2. During an interview on 04/29/2025 at 11:35 AM, the Site Manager stated did not have any documentation of competency evaluation on the Mohs Surgeon.