

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 24D2254382	<b>(X3) Date Survey Completed</b> 01/24/2024
<b>Name of Provider or Supplier</b> Dermatology Duluth, Llc	<b>Street Address, City, State</b> 4316 Rice Lake Rd Ste 101, Duluth, MN	
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>D5217</b>	<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 document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of two of two Microbiology microscopic examinations at least twice annually in 2022 and 2023. Findings are as follows: 1. The laboratory performed microscopic examinations for fungus and parasites under the specialty of Microbiology as confirmed by the Mohs technician (MT) during a tour of the laboratory at 1:00 p.m. on 01/24/24. 2. Microscopic examination accuracy verification via AAD, ACMS, ASMS, or other was required annually as established in the KOH examination procedure found in the Mohs Procedure Manual. 3. Documentation of microscopic accuracy verification was not found during review of 2022 and 2023 laboratory records. 4. The laboratory was unable to provide 2022 and 2023 microscopic examination accuracy verification documentation upon request. 5. The laboratory performed the following microscopic examinations as indicated on the KOH testing log: Year Examination type 2022 14 fungal examinations 2023 16 fungal examinations 1 parasitic examination 6. In an interview at 3:05 p.m. on 01/24/24, the MT confirmed the above finding. .</p>
<b>D5313</b>	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)</p> <p>The laboratory must document the date and time it receives a specimen.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on document review and interview with laboratory personnel, the laboratory failed to document the time Histopathology patient specimens were received into the laboratory in 2023 and 2024. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery with microscopic examination under the subspecialty Histopathology as confirmed by the Mohs Technician (MT) during a tour of the laboratory on at 1:00 p.m. on 01/24/24 2. Patient specimen receipt time documentation on the Mohs map was required as established in the Mohs Procedure found in the Mohs Procedure Manual. 3. The time of tissue receipt into the laboratory was not documented in testing records for three of four cases reviewed on date of survey. See below Case Date DD23-356 05/09/23 DD23-517 10/05/23 DD24-679 01/09/24 4. In an interview at 3:35 p.m. on 01/24/24, the MT confirmed the above finding. .

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(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.

This STANDARD is not met as evidenced by:

. Based on observation and interview with laboratory personnel, the laboratory failed to ensure two of four bottles of Histopathology dyeing materials were not used after the expiration date had been exceeded in 2023 and 2024. Findings are as follows: 1. The laboratory performed Mohs Micrographic surgery with microscopic examination under the subspecialty of Histopathology as confirmed by the Mohs technician (MT) during a tour of the laboratory at 1:00 p.m. on 01/24/24. 2. Two of four bottles of tissue marking dye observed as present and available for use during the tour of the laboratory were in use beyond the expiration date. See below. Avantik Tissue Marking Dye Color Lot Expiration Green 129795 09/30/23 Black 138381 12/31/23 3. Monthly quality assurance activities were established in the Quality Assurance procedure found in the Mohs Log Book. Reagents were to be discarded upon expiration as indicated on the Monthly Quality Assurance Checklist also found in the Mohs Log Book. 4. Completed Monthly Quality Assurance Checklists from November 2023, December 2023 and January 2024 indicated reagents were checked for expiration dates. The checklist was not found for October 2023. 5. The laboratory performed 174 Mohs procedures between 10/01/23 through 01/24/24 using the expired dyes as indicated in the Mohs Log found in the Mohs Log Book. See below. Month Patients tested October 2023 27 November 2023 62 December 2023 42 January 2024\* 43 6. In an interview at 1:05 p.m. on 01/24/24, the MT confirmed the above finding. \* 01/01/24 - 01/24/24 .

**D5609**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(e)(f)

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the laboratory

failed to retain lot number and expiration date records for two of two stains used for Histopathology testing in 2022, 2023, and 2024. Findings include: 1. The laboratory performed Mohs micrographic surgery with microscopic examination under the specialty of Histopathology as confirmed by the Mohs technician (MT) during a tour of the laboratory at 1:00 p.m. on 01/24/24. 2. Documentation of reagent lot number and expiration date was required as established in the Quality Assurance for Routine Stains procedure found in the Mohs Log Book. 3. Documentation of stain lot numbers and expiration dates was not found from 05/21/22 through 01/24/24 during review of the Chemical Log Sheet found in the Mohs Log Book. 4. The laboratory was unable to provide the missing documentation upon request. 5. In an interview at 2:50 p.m. on 01/24/24, MT confirmed the above finding. .