

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D2256514	<b>(X3) Date Survey Completed</b> 11/28/2023
<b>Name of Provider or Supplier</b> Duly Health And Care - Oak Lawn Derm	<b>Street Address, City, State</b> 4061 W 95th St - Ste 4a, Oak Lawn, IL	
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>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the practice supervisor (PS), the laboratory: a) failed to evaluate and document the biannual method accuracy for Mohs histopathology testing at least twice a year in 2022 and 2023. Affecting a total of 24 Mohs surgeries (refer to D5217).</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 review of laboratory records, lack of documentation, and interview with the practice supervisor (PS), the laboratory failed to evaluate the biannual method accuracy for Mohs histopathology testing at least twice a year in 2022 and 2023. Affecting a total of 24 Mohs surgeries. Findings include: 1. Review of the "duly Health and Care Derm Lab Proficiency Testing Policy" revealed the following: "1. MOHS PROFICIENCY TESTING (SLIDE REVIEW) Biannually representative</p>

Mohs cases will be reviewed with a dermatopathologist or another Mohs micrographic surgeon for correlation of histologic diagnoses." 2. Review of laboratory records and lack of documentation revealed the laboratory failed to evaluate and document the biannual method accuracy for Mohs testing at least twice a year in 2022 and 2023. Affecting a total of 24 Mohs surgeries. 3. On 11/28/2023, at 8:40 a.m., the PS confirmed the above findings.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on the surveyor's review of the manufacturer's maintenance schedule, laboratory records, lack of documentation, and interview with the practice supervisor (PS), the laboratory failed to perform and document the maintenance for one of one cryostat machine (Avantik Serial # S21040395) for two of two testing years (2022 and 2023). Affecting a total of 24 Mohs surgeries. 1. Review of the manufacturer's "Avantik Technical Service & Support Maintenance" record for one of one cryostat machine (Avantik Serial # S21040395) revealed maintenance was due to be performed in June, 2022. a. "Maintenance: Completed on 6/21 Due 6/2022" "Make /Model # AVANTIK QS12" "Serial # S21040395" "Avantik Specialist Initials L.SZ" 2. Review of laboratory records and lack of documentation revealed the laboratory failed to perform and document the maintenance for the cryostat machine (Avantik Serial # S21040395) for two of two testing years (2022 and 2023). Affecting a total of 24 Mohs surgeries. 3. On 11/28/2023, at 9:18 a.m., the PS confirmed the above findings.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of laboratory records, lack of documentation, and interview with the practice supervisor (PS), the technical supervisor (TS) failed to evaluate and document the competency of two of two testing personnel at least semiannually during the first year of Mohs histopathology testing in 2022 and 2023. Affecting a total of 24 Mohs surgeries. Findings Include: 1. Review of the "duly Health and Care Derm Lab Quality Assurance Policy" revealed the following: "5. The competency of Testing Personnel will be evaluated, according to the Competency Assessment Policy and documented every year (twice for the first year of new technicians) by the Laboratory Director or an appropriate, designated staff member (e.g., Technical

Consultant or Technical Supervisor) to ensure that all Testing Providers maintain their competency in testing and laboratory management functions. Evaluations will be recorded using the appropriate Competency Assessment Form." 2. Review of the "duly Health and Care MOHS TECHNICIAN COMPETENCY ASSESSMENT" forms for two of two (TP 2 and TP 3) testing personnel revealed the "Initial Date of Observation/Assessment: 5/29/22"; a second assessment due to be completed by 05/29/23. 3. Review of laboratory records and lack of documentation revealed the TS failed to evaluate and document the competency of TP 2 and TP 3 at least semiannually during the first year of Mohs testing in 2022 and 2023. Affecting a total of 24 Mohs surgeries. 4. On 11/28/2023, at 8:35 a.m., the PS confirmed the above findings.