

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0678764	<b>(X3) Date Survey Completed</b> 10/01/2025
<b>Name of Provider or Supplier</b> Schweiger Dermatology, Pllc - Rochester	<b>Street Address, City, State</b> 2150a South Clinton Avenue, Rochester, NY	
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>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory systems Quality Assessment (QA) procedures, QA records, as well as interview with the General Manager (GM) and Regional Manager (RM), the laboratory failed to perform and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements. FINDINGS: 1. There was no documentation of "Monthly Quality Assurance Checklist" records for February 2025 and August 2025. 2. The "Laboratory Quality Assurance" form was not completed from July 29, 2024, through October 1, 2025. 3. These are contrary to instructions indicated in the current, approved Quality Management Program procedure. 4. The GM and RM confirmed the findings on October 1, 2025, at approximately 4:30 P.M.</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>(b)(1)(i) 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. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.</p>

This STANDARD is not met as evidenced by:  
Based on review of Standard Operating Procedures (SOPs), maintenance records, as well as interviews with the GM and RM, the laboratory failed to perform and document maintenance activities. FINDINGS: 1. The "Maintenance of Lab" and "Hematoxylin & Eosin Quality Control and Maintenance" forms were not completed for November 4, 2024, and November 5, 2024. 2. This is contrary to instructions indicated in the current, approved SOPs. 3. Twenty-one total Mohs surgery specimens were processed, analyzed, and results released for November 4, 2024, and November 5, 2024. 4. The GM and RM assured the surveyor on October 1, 2025, at approximately 4:30 P.M. that the required maintenance was performed and the Testing Personnel (TP) failed to complete the respective forms. 5. The GM and RM confirmed the findings on October 1, 2025, at approximately 4:30 P.M.

**D5781**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of temperature and humidity records, SOPs, lack of corrective action records, as well as interviews with the GM and RM, the laboratory failed to perform and document corrective action for test systems that did not meet the laboratory's established performance specifications. FINDINGS: 1. The documented ambient room temperature, 66.7F, and humidity, 19%, on the "Room Temperature and Humidity Maintenance Log" deviated from the specified range of 68F - 86F and 20% - 60%, respectively, on January 22, 2025. 2. There was no documentation of corrective action performance for the respective out-of-range ambient room temperature and humidity. 3. This is contrary to instructions included in the current, approved SOPs. 4. The GM and RM confirmed the findings on October 1, 2025, at approximately 4:30 P.M.