

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2172817	<b>(X3) Date Survey Completed</b> 10/14/2025
<b>Name of Provider or Supplier</b> Schweiger Dermatology Group	<b>Street Address, City, State</b> 501 Gordon Drive, Exton, PA	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the General Manager (GM), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Leica DM1000 microscope and 1 of 1 Avantik cryostat (QS12) for histopathology (Mohs) microscopic slides from 11/01/2023 to 04/30/2025. Findings include: 1. The manufacturers operating environment specifications stated the following: -Leica DM 1000 microscope: 5-35 degrees Celsius (ambient temperature); maximum 80 % relative humidity - Advantik Cryostat: 5-35 degrees Celsius (ambient temperature); maximum 60% relative humidity. 2. On the day of the survey, 10/14/2025, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following instruments used to perform histopathology (Mohs) microscopic examinations from 11 /01/2023 to 04/30/2025: - 1 of 1 Lecia DM1000 microscope - 1 of 1 Avantik cryostat (QS12) 3. The laboratory performed 2991 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 09/24/2025). 4. The GM confirmed the above findings on 10/14/2025 at 09:30am.</p>