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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>39D2172816                    | <b>(X3) Date Survey Completed</b><br>12/19/2023 |
| <b>Name of Provider or Supplier</b><br>Schweiger Dermatology Group   | <b>Street Address, City, State</b><br>701 East Baltimore Pike, Ste #B, Kennett Square, 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>  |
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| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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:<br/>Based on a lack of documentation and interview with the general manager (GM), the laboratory failed to monitor and document the room humidity to ensure operating conditions were met for the histopathology testing from 01/11/2022 to the day of the survey. Findings Include: 1. On the day of the survey, 12/19/2023 at 11:21 am, a review of the Leica CM 1510 cryostat manufacturer's instructions revealed that all specifications related to temperature are valid only for an ambient temperature up to 22 C and for an air humidity lower than 60%. 2. The laboratory failed to provide documentation of humidity for the Leica CM 1510 cryostat for histopathology testing in 2022 and 2023. 3. The GM confirmed the findings above on 12/19/2023 at 12:30 pm.</p> |
| <b>D5429</b>              | <p>MAINTENANCE AND FUNCTION CHECKS<br/>CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>  |

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the general manager (GM), the laboratory failed to perform and document maintenance on 1 of 1 thermometer for the histopathology testing from 09/29/2023 to the day of the survey. Findings Include:

1. On 12/19/2023, at 12:15 pm, an observation of the laboratory revealed that Digi Sense (S/N 210833680) thermometer used to monitor room temperature (RT) for grossing, inking, and mapping expired on 29 September 2023. 2. The laboratory could not provide maintenance procedure and documentation for the thermometer. 3. The GM confirmed the findings above on 12/19/2023 at 12:30 pm.