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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>23D1056150 | <b>(X3) Date Survey Completed</b><br><br>03/11/2026 |
| <b>Name of Provider or Supplier</b><br><br>Holland Dermatology   | <b>Street Address, City, State</b><br><br>441 N 120th Ave, Holland, MI     |   |
| 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>(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:<br/>. Based on observation, record review, and interview with the Registered Nurse (RN), the laboratory failed to monitor room temperature and humidity for specimen processing and histopathology tissue examination for 23 (May 2024 through March 2026) of 23 months reviewed. Findings include: 1. On 03/11/2026 at 9:18 am, during a tour of the laboratory, the surveyor observed that there was no thermo-hygrometer in use to monitor room temperature and humidity in areas where specimen processing and slide examination were performed. 2. On 03/11/2026 at 9:21 am, an interview with the RN confirmed that a thermo-hygrometer was not present in the laboratory and that room temperature and humidity were not monitored in areas where specimen processing and histopathology tissue slide examination were performed since the last survey (May 2024 through March 2026). 3. On 03/11/2026 at 9:22 am, the surveyor requested the manufacturer's instructions for the microscope used for histopathology tissue slide examination; however, no documentation was provided. 4. A review of manufacturer's instructions for the Seiler Clinical Microscope, Model Microlux III, obtained from the manufacturer's website, revealed the following environmental operating requirements: a. Operating Temperature: 50F - 70F (10C - 25C) b. Operating Relative Humidity: 30% - 75%</p> |