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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>39D2179899           | <b>(X3) Date Survey Completed</b><br><br>01/30/2026 |
| <b>Name of Provider or Supplier</b><br><br>St Luke's Mohsmicrographicsurgery   | <b>Street Address, City, State</b><br><br>1600 St Luke'S Blvd, Suite 102, Easton, 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>(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 lack of documentation and interview with the Medical Technologist (MT), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Olympus BX46 microscope used to perform histopathology microscopic slide examinations from 11/01/2025 to 01/30/2026. Findings include: 1. The manufacturers operating environment specifications stated, " Olympus BX46 microscope: 5-40 degrees Celsius (ambient temperature); maximum 80 % relative humidity." 2. On the day of the survey, 01/30/2026 at 10:45 am, the laboratory failed to provide documentation for the monitoring of room temperature and humidity to ensure operating conditions were met for the following instruments used to perform histopathology microscopic examinations from 11/01/25 to 01/30/2026: - 1 of 1 Olympus BX46 microscope 3. The laboratory performed 2,414 histopathology slide examinations in 2025 (CMS 116, estimated annual volume, dated 12/22/2025). 4. The MT confirmed the findings above on 1/30/2026 at 10:45 am.</p> |