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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>34D2043305                   | <b>(X3) Date Survey Completed</b><br><br>12/10/2024 |
| <b>Name of Provider or Supplier</b><br><br>Summit Plastic Surgery And Dermatology  | <b>Street Address, City, State</b><br><br>1717 Shipyard Boulevard, Suite 100, Wilmington, NC |   |
| 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 review of manufacturer's instruction manual, review of 2023 and 2024 laboratory maintenance logs, and interview with the Laboratory Director (LD) 12/10/2024, the laboratory failed to ensure that the established humidity ranges for the cryostat were within the manufacturer's requirements. Findings: Review of "Leica CM1850 Cryostat Instruction Manual," page 14 section 4.1 Site Requirements revealed, "...- Air humidity must not exceed 60%...". Review of "Hematoxylin and Eosin Staining Maintenance Logs," revealed humidity range "Humidity no greater than 63% ". The laboratory's established humidity range, no greater than 63%, does not meet the manufacturer's instruction manual requirements not to exceed 60%. During interview at approximately 1:50 p.m., the LD confirmed that the humidity range does not match the cryostat instruction manual requirements.</p> |