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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>03D0528759        | <b>(X3) Date Survey Completed</b><br><br>08/07/2024 |
| <b>Name of Provider or Supplier</b><br><br>Skin Cancer Specialists Ltd   | <b>Street Address, City, State</b><br><br>2250 W Southern Ave Suite 102, Mesa, AZ |   |
| 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 lack of humidity records for review from 2023 and 2024, review of the manufacturer's specifications for the Leica CM1520 Cryostat and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity of the room where the cryostat is utilized. Findings include: 1. The laboratory began utilizing the Leica CM1520 Cryostat in conjunction with Mohs testing in August 2023. 2. The manufacturer's specifications for the Leica CM1520 Cryostat reviewed during the survey listed an operating relative humidity range of 0% -60%. 3. On the survey date of 8/7/2024, the laboratory failed to provide documentation demonstrating the ambient humidity of the room where the cryostat is utilized was monitored and recorded on each day of patient testing from August 2023 through the survey date of 8/7/2024. 4. The facility personnel interviewed on 8/7/2024 at 1:30 PM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above. 5. The laboratory has a reported annual test volume of 5,032 under the subspecialty of Histopathology.</p> |