

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D2194863	<b>(X3) Date Survey Completed</b>  11/01/2023
<b>Name of Provider or Supplier</b>  Central Utah Dermatology	<b>Street Address, City, State</b>  861 N Main, Richfield, UT	
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>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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: Based on document review, direct observation, and interview with Histotechnician 1 (HT1), room temperature and humidity of the laboratory was not monitored and documented since the last survey conducted on 02/08/2021. The laboratory performs approximately 220 MOHS procedures annually using the Avantik QS12 Cryostat. Findings include: 1. Document review of the Avantik QS12 Cryostat Instruction Manual revealed the cryostat requires an operating environment of 5C to 35C and relative humidity of up to 60%. 2. Direct observation of the laboratory on 11/01/2023 at 1:50 PM failed to locate a thermometer or hygrometer in the laboratory. 3. In an interview on 11/01/2023 at 1:55 PM, HT1 confirmed room temperature and humidity was not monitored and documented for the Avantik QS12 Cryostat.</p>