

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2088704	(X3) Date Survey Completed 09/07/2023
Name of Provider or Supplier Ogden Clinic - Bountiful	Street Address, City, State 1560 Renaissance Town Dr Ste 210, Bountiful, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<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. The laboratory performs approximately 650 MOHS procedures annually using the Avantik QS12 Cryostat. Findings include: 1. Document review revealed there was no written policy that included the monitoring and documentation of laboratory temperature and humidity. 2. 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%. 3. Direct observation of the laboratory's flammable storage cabinet on September 7, 2023 at 10:05 AM revealed 10% Neutral Buffered Formalin was to be stored between temperatures of 15C to 30C. 4. In an interview on September 7, 2023 at 9:50 AM, HT1 confirmed room temperature and humidity was not monitored and documented for MOHS equipment and chemicals.</p>