

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D2133385	<b>(X3) Date Survey Completed</b> 07/07/2022
<b>Name of Provider or Supplier</b> Wasatch Dermatology	<b>Street Address, City, State</b> 5734 S 1475 E, Ste 300, South Ogden, 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 record review, direct observation, and interview with testing personnel #1 (TP1), room temperature and humidity of the laboratory was not monitored. The laboratory performs approximately 3,500 tests annually. Findings include: 1. Record review of maintenance logs did not include recorded room temperature and humidity. There was no written policy for the monitoring room temperature or room humidity. 2. No thermometer or hygrometer was present in the laboratory during observation on 07/07/2022 at approximately 13:30. 3. The Leica CM1510 Cryostat requires an operating environment of less than 22C and relative humidity must not exceed 60%. 4. In an interview on 07/07/2022 at approximately 14:15, the testing personnel #1 confirmed room temperature and humidity was not monitored or recorded.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper</p>

use.

This STANDARD is not met as evidenced by:

Based on direct observation, record review, and staff interview with testing personnel #1, the laboratory failed to write open and expiration dates on 7 of 7 bottles of dye used for inking tissue for Mohs histopathology slides. The laboratory performs approximately 500 Mohs histopathology slides per year. Findings include: 1. During laboratory tour on 07/07/2022, laboratory failed to have open and expiration dates written on 7 of 7 tissue marking dyes. 2. In an interview on 07/07/2022 at approximately 14:15, testing personnel #1 stated that they do not write open and expiration dates on reagents when they are being put into use. 3. During record review of the laboratory's standard operating procedure (SOP) manual on 07/07/2022, the laboratory failed to include instructions to document preparation and expiration dates on dye when it is put into use.