

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 27D2141070	<b>(X3) Date Survey Completed</b> 12/10/2020
<b>Name of Provider or Supplier</b> Highline Dermatology & Skin Cancer	<b>Street Address, City, State</b> 505 Cascade Loop, Kalispell, MT	
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 and interview, the laboratory failed to record temperature and humidity at the frequency described in their Quality Assurance Program. Findings: 1. Review of Quality Assurance Program, General Laboratory Cleaning and Safety, Equipment Quality control for Cryostats procedure revealed "1) Room temperature and humidity is checked and recorded daily." 2. Review of Room Temperature &amp; Humidity Log documents for August through December of 2020, revealed temperature and humidity values recorded only on days of Cryostat use. 3. Confirmed during interview with Laboratory Director (LD) on 12/10/2020 at 11:50 am, the Room Temperature &amp; Humidity Logs lacked daily record of temperature and humidity as described in the Quality Assurance Program.</p>