

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D2090204	<b>(X3) Date Survey Completed</b>  03/10/2020
<b>Name of Provider or Supplier</b>  Biomat Usa Inc	<b>Street Address, City, State</b>  771 N College Rd, Twin Falls, ID	
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 it was revealed that the laboratory failed to document the humidity in the area where the Reichert refractometers were in use. Findings: 1. A review of environmental records from 2018 and 2019 revealed no documentation of the humidity in the area where the Reichert refractometers were used for testing client specimens. 2. A review of the Reichert Analytical Instruments TS Meter - DSP User's Guide Revision 13970000-100 on page 4 revealed a required operating relative humidity as follows: 80% for temperatures to 31 degrees Celsius decreasing linearly to 50% (relative humidity at 40 degrees Celsius. 3. An interview on 03/10/2020 at 11:00 AM with the center manager confirmed that no documentation of humidity was available.</p>