

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2182365	<b>(X3) Date Survey Completed</b>  12/22/2020
<b>Name of Provider or Supplier</b>  Lifesensors, Inc	<b>Street Address, City, State</b>  271 Great Valley Parkway, Malvern, PA	
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 lack of documentation and interview with the General Supervisor (GS) the laboratory failed to record daily temperatures for 1 of 1 Mr Winter walk-in refrigerator where the testing reagents are store and the room temperature where the test are being perform from 7/10/2020 to the date of survey. Findings Include: 1. On the date of survey 12/22/2020, the laboratory could not provided temperature records for 1 of 1 Mr. Winter walk in refrigerator. 2. The laboratory could not provide room temperature records for the room where test were being perform. 3. The GS confirmed the findings above on 12/22/2020 at 11:22 a.m.</p>