

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0947411	<b>(X3) Date Survey Completed</b>  11/01/2018
<b>Name of Provider or Supplier</b>  Us Dermatology Partners -Dr Bryan Townsend	<b>Street Address, City, State</b>  8044 Shoal Creek Boulevard, Austin, TX	
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 review of the cryostat operator's manual, laboratory environmental records, and interview with facility personnel, the laboratory failed to monitor the humidity of the operating environment for 10 of 10 months between January 1, 2018 and October 31, 2018. The findings included: 1. Based on review of the Thermo Scientific Cryostat Microm HM 525 Technical Data, on page 12 of the operator's manual, the document states the following: "Operating Requirements: 5 degrees Celsius up to 35 degrees Celsius (at a max relative humidity of 60 percent)." 2. Based on a review of environmental laboratory records from 2018, the laboratory had recorded laboratory temperatures but failed to records laboratory humidity levels for 10 of 10 months between January 2018 and October 2018. The laboratory performs testing three days per week. 3. In an interview with the Laboratory Manager at 10:53 hours on 11/01 /2018, the Laboratory Manager stated the laboratory had the necessary equipment needed to monitor humidity levels but had not kept the documentation of humidity levels previously.</p>