

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  44D2073235	<b>(X3) Date Survey Completed</b>  05/08/2023
<b>Name of Provider or Supplier</b>  Curcio Dermatology, Pc	<b>Street Address, City, State</b>  2125 Bandywood Dr, Nashville, TN	
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 observation of the laboratory, manufacturer manual review, and staff interview, the laboratory failed to monitor temperature and humidity environmental conditions where the Avantik QS11 cryostat and Linistat automated stainer were in use for patient tissue processing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 05/08/2023 at 9:05 a.m. revealed the Avantik QS11 cryostat (serial 59500 ) and the Thermo Scientific Linistat automated stainer (serial LS1776A1404 ) in use for processing tissue patient samples removed during Mohs surgical procedures. 2. Review of the manufacturer manuals revealed the following: Avantik QS 11 Cryostat instruction manual environmental operating conditions require 5C-35C and maximum relative humidity of 60%. Linistat automated stainer environmental operating conditions require +5C-40C and maximum relative humidity 80%. 3. Interview on 05/08/2023 at 11:00 a.m. with the laboratory director and testing person two confirmed the laboratory did not monitor room temperature or humidity conditions where the Avantik QS11 and Linistat automated stainer was in use in 2021, 2022, or 2023.</p>