

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2270340	<b>(X3) Date Survey Completed</b> 08/27/2024
<b>Name of Provider or Supplier</b> Dermatology Of Philadelphia	<b>Street Address, City, State</b> 2301 E Evesham Rd, Voorhees, NJ	
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 surveyor review of the Procedure Manual (PM), Mercedes Scientific Dyes package inserts (PI), Olympus BX40 Microscope Instructions Manual (IM) and Tanner Scientific TN50 Cryostat Operating Instructions Manual (OIM), the room temperature and humidity log (LOG) and interview with the Laboratory Director (LD), the laboratory failed to provide the correct acceptable ranges for room temperature and humidity consistent with the manufacturer's instructions from 10/13/22 to 8/27/24. The findings include: 1. The surveyor observed the strictest requirements for room temperature, 20-25C and humidity, 30-60%, based on the PI, IM and OIM. 2. The PM and LOG stated the acceptable ranges were room temperature, 12-32C and humidity, 25-65%. 3. The LD confirmed on 8/27/24 at 12:30 pm that the laboratory failed to provide the correct room temperature and humidity acceptable ranges in the PM and on the LOG.</p>
<b>D5435</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check</p>

protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Therm Pro thermohygrometer used for room temperature and humidity in the laboratory and interview with the Laboratory Director (LD), the laboratory failed to provide documentation of calibration for the Therm Pro thermohygrometer used in the laboratory from 10/13/22 to 8/27/24. The findings include: 1. The laboratory could not provide documentation of calibration for the Therm Pro thermohygrometer used for room temperature and humidity. 2. The LD confirmed on 8/27/24 at 10:00 am that they could not provide documentation of calibration for the Therm Pro thermohygrometer.