

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2126488	(X3) Date Survey Completed 02/22/2019
Name of Provider or Supplier The Dermatology Group Pa	Street Address, City, State 300 E Hazel St, Orlando, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5413	<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, the laboratory failed to record the temperature and humidity of the room where testing was performed from 10/23/17 to 2/22/19. Findings: The manual for the Leica CM1530 cryostat noted that the room temperature of the laboratory should be, "consistently 18 degrees Celsius (C)-35 degrees C." The manual also noted that the relative humidity of the laboratory should be a "relative humidity, maximum 60%." A review of the laboratory's logs showed that the laboratory failed to record the temperature and humidity of the room where testing was performed On 2/22/19 at 10:50 AM, Testing Personnel D stated that they did not record the room temperature or the humidity of the laboratory.</p>