Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2005771	(X3) Date Survey Completed 07/16/2024
Name of Provider or Supplier Dermatology & Skin Cancer Specialists, Psc	**Street Address, City, State** 3213 Summit Square Suite 200, Lexington, KY	

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
D0000	A recertification survey was conducted on 07/16/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, and confirmed in staff interview; the laboratory failed to monitor and document room temperature for 2 of 2 storage areas. Findings included: 1. Observed on 07/16/2024 at 10:20 a.m. the following two areas in the facility where bottles of Fresenius Kabl Xylocaine, bottles of Hospira Lidocaine Hydrochloric Acid (HCL) Injection, and a bottle of Cancer Diagnostic Inc Tissue Marking Dyes were stored: a. Hallway closet; 1 package of 25 bottles of Fresenius Kabl Xylocaine, Lot Number HN4761 and 15 bottles of Hospira Lidocaine Hydrochloric Acid (HCL) Injection, Lot Number 6131790 b. Laboratory; 1 bottle of Cancer Diagnostic Inc Tissue Marking Dyes, Lot Number 9344 No temperature monitoring devices were observed in the two areas. 2. The manufacturer's instructions on the labels of each bottle stated storage requirements as follows: a.) Fresenius Kabl Xylocaine, 20 degrees to 25 degrees Celsius (68 degrees to 77 degrees Fahrenheit), b.) Hospira Lidocaine Hydrochloric Acid (HCL) Injection, 20 degrees to 25 degrees Celsius (68 degrees to 77 degrees Fahrenheit), c.) Cancer Diagnostic Inc

	Tissue Marking Dyes, 15 degrees to 30 degrees Celsius (59 degrees to 86 degrees Fahrenheit) 3. In an interview on 07/16/2024 at 12:15pm, the Laboratory Director stated that the temperature was not monitored in these two storage areas. This confirmed the findings.