

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D0250081	<b>(X3) Date Survey Completed</b> 06/12/2025
<b>Name of Provider or Supplier</b> Spartanburg Dermatology & Skin Surgery	<b>Street Address, City, State</b> 2020 North Church Place, Spartanburg, SC	
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>D0000</b>	An announced onsite CLIA recertification survey was conducted on June 12, 2025, at the laboratory of Spartanburg Dermatology and Skin Surgery Clinic by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a list of Standard Level deficiencies cited as a result of the CLIA recertification survey on June 12, 2025:
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 records review, manufacturer's instructions, direct observation, and staff interview, the laboratory failed to ensure materials were being stored as required in 30 out of 30 months reviewed (2023, 2024, 2025). Findings included: 1. Review of laboratory records reveals a lack of documentation of monitoring the temperature and humidity where materials were stored. 2. During a tour of the laboratory on June 12, 2025 at 12:30pm, the surveyor noted the lack of any device to monitor the temperature and humidity. The following supplies were being stored in the room: a. 1 flat of Becton Dickinson K2 EDTA lavender top collection tubes (lot #5048308) expiration date 06/30/2026, storage temperature 4-25 degrees C. b. 2 flats of Becton Dickinson</p>

Tiger top collection tubes (lot #5118790) expiration date 03/31/2026, storage temperature 4-25 degrees C. 3. In an interview with the Practice Manager (PM) on June 12, 2025 at 12:30pm, the PM agreed the laboratory was not monitoring the temperature and humidity of the laboratory.

**D6083**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(2)

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

This STANDARD is not met as evidenced by:  
Based on records review, manufacturer's instructions, direct observation, and staff interview, the laboratory director (LD) failed to ensure that the physical plant and environmental conditions of the laboratory are appropriate for materials used in patient testing. Findings included: 1. Review of laboratory records reveals a lack of documentation of monitoring the temperature and humidity where materials were stored. 2. Review of the procedure manual reveals a lack of documentation as to the acceptable temperature and humidity ranges in the laboratory. 3. Review of the procedure manual reveals documentation of the LD's review and approval of the procedure manual. 4. During a tour of the laboratory on June 12, 2025 at 12:30pm, the surveyor noted the lack of any device to monitor the temperature and humidity. The following supplies were being stored in the room: a. 1 flat of Becton Dickinson K2 EDTA lavender top collection tubes (lot #5048308) expiration date 06/30/2026, storage temperature 4-25 degrees C. b. 2 flats of Becton Dickinson Tiger top collection tubes (lot #5118790) expiration date 03/31/2026, storage temperature 4-25 degrees C. 5. In an interview with the PM on June 12, 2025 at 12:30pm in the laboratory office, the above findings were confirmed.