

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D0877753	<b>(X3) Date Survey Completed</b> 02/14/2025
<b>Name of Provider or Supplier</b> Upstate Public Health Region	<b>Street Address, City, State</b> 220 Mcgee Road, Anderson, 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>	Multiple site survey was performed at two sites on two different days with the following results: An announced onsite recertification survey was conducted on January 16, 2025, at Upstate Public Health Spartanburg County Laboratory Department by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirement for Laboratories. An announced onsite recertification survey was conducted on February 14, 2025, at Upstate Public Health Seneca Health Department Laboratory by the South Carolina Department of Public Health's Bureau of Nursing Homes and Medical Services. The laboratory was found to be in compliance with 42 CFR Part 493, CLIA Requirements for Laboratories.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on records review for Spartanburg County Health Laboratory CMS -209, lack of documentation, and an interview with laboratory director on January 16, 2025, the laboratory failed to establish and follow written policies and procedures to assessment of one of one clinical consultant. Findings include: 1. A review of CMS 209 Laboratory Personnel Report reveals one clinical consultant (CC) for Spartanburg County Health Department. 2. The surveyor requested and the laboratory failed to provide a written policy and procedure to describe the laboratory's competency assessment of clinical consultant for moderately complex testing on January 16, 2025, day of survey. 3. During an interview with laboratory director on 01/16/2025 at 3:45 pm in the conference room, the laboratory director confirmed there was no written policy or procedure for competency assessment.</p>

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

(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.

This STANDARD is not met as evidenced by:

Based direct observations at Spartanburg County Health Laboratory, records review, and staff interview, the laboratory failed to maintain acceptable room temperature range. Findings include: 1. During a tour of the laboratory on 01/16/2025, the surveyor directly observed blood collection tubes: a. In Public Health Lab, BD vacutainer Red Tiger Top tubes, Lot 4046200, expired(exp.) 01/31/2025, twenty tubes. b. In TB Lab, Lavender, Lot #4045163, exp 06/30/2025, 100 tubes c. In TB Lab, BD vacutainer Red Tiger Top tubes, Lot #4046200 d. In TB Lab, QTF Tubes, QuantiFERON Nil, Lot # A240434A, exp. 07/31/2025 Manufacturer instruction label states to store tubes 4 to 25oC Celsius = C 2. A review of environmental room temperature logs reveal, the public health laboratory, room #139 range was outside manufacturer's instructions. a. On 01/03/2023 and 01/04/2023 the maximum temperature was 26.9oC 3. A review of environmental room temperature logs for room #125, reveal a. On 01/04/2023 maximum temperature was 29.7oC b. 01/30/2023 maximum temperature was 27.4oC c. 04/02/2023 maximum temperature was 28.4oC d. 04/12/2023 maximum temperature was 28.4oC 4. During an interview with laboratory director on 01/16/2025 at 3:45 pm in the conference room, the laboratory director confirmed the temperature ranges on the log.

**D6056**

**CLINICAL CONSULTANT**

CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

This CONDITION is not met as evidenced by:

Based on record review of Spartanburg County Health Laboratory CMS209, lack of documentation, and staff interview the laboratory failed to establish written responsibilities for clinical consultant. Findings included: 1. Review of CMS 209 personnel form revealed the one clinical consultant. 2. Review of policy and procedures revealed the laboratory failed to document responsibilities for clinical consultant. 3. A review of personnel competency forms revealed the laboratory lack documentation for clinical consultant competency. 4. In an interview on 01/16/2025 at 3:45 pm in the conference room with the laboratory director confirmed there was no competency for clinical consultant (CC).