

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  42D2102939	<b>(X3) Date Survey Completed</b>  01/24/2025
<b>Name of Provider or Supplier</b>  Brio Primary Care	<b>Street Address, City, State</b>  2 Bella Grove Drive, Greenville, 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 onsite CLIA recertification survey was conducted on January 24, 2025, at the clinical laboratory of Brio Primary Care - Greenville by the South Carolina Department of Public Health's (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with 42 CFR Part 493, CLIA Requirements for Laboratories. The following is a list of deficiencies identified during the CLIA survey:
<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 laboratory policy and procedure, direct observation, and staff interview, the laboratory failed to ensure materials were being stored as required. Findings included: 1. Review of the laboratory's Quality Assessment Plan reveals that the storage of materials and specimens must follow manufacturer's recommendations. 2. During a tour of the laboratory on January 24, 2025 at 1:00pm, the surveyor observed collection tubes in the phlebotomy drawing room without a device to monitor the temperature and humidity. 3. Review of laboratory records reveals a lack of documentation for temperature and humidity of the phlebotomy drawing room. 4. In an interview with laboratory testing personnel (TP) on January 24, 2025, at 1:00pm in the laboratory, the findings were confirmed.</p>

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on laboratory policy and procedure, direct observation, and staff interview, the laboratory failed to ensure expired testing supplies were not available for use.

Findings included: 1. Review of laboratory's Quality Assessment Plan reveals that the laboratory must follow manufacturer's recommendations for storage of supplies. 2.

During a tour of the laboratory on January 24, 2025 at 1:00pm, the surveyor observed a temperature and humidity measuring device in use with a manufacturer's expiration date of April 19, 2019. 3. In an interview with laboratory TP on January 24, 2025, at 1:00pm in the laboratory, the findings were confirmed.