

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 42D0950004	<b>(X3) Date Survey Completed</b> 08/23/2024
<b>Name of Provider or Supplier</b> Beaufort County Memorial Hospital	<b>Street Address, City, State</b> 989 Ribaut Road, Beaufort, 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 August 23, 2024 by the South Carolina Department of Public Health's (SC DPH) Bureau of Nursing Homes and Medical Services at the clinical laboratory of Beaufort Memorial Oncology. The laboratory was found to be out of compliance 42 CFR Part 493, CLIA Requirements for Laboratories The following is a description of the Stanard Level Deficiencies cited:
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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 the lack of documentation, direct observation, and staff interview, the laboratory failed to monitor the temperature and humidity of the laboratory environment. Findings included: 1. Review of laboratory documentation reveals temperature measurements for the laboratory area. 2. No documentation for environmental monitoring was available for the two (2) phlebotomy drawing rooms. Blood collection tubes were stored in these 2 rooms. 3. During a tour of the laboratory and phlebotomy drawing rooms, the surveyor noted the lack of environmental monitoring devices in the phlebotomy drawing rooms. 4. In a staff interview on August 23, 2024, at 1:30pm in the laboratory with technical consultant (TC), the findings were confirmed.</p>

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on the lack of documentation, direct observation and staff interview, The laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. Findings included: 1. Review of laboratory documentation reveals the lack written policy and procedures for the following: a. Performance and documentation of Quality Controls. b. Performance and documentation of Quality Assurance monitors. c. Performance and documentation of Proficiency Testing. 2. By document review, the surveyor recognized that the laboratory was using the manufacturer's instructions on how to perform testing on the DxH 520 hematology analyzer and the Abbott Piccolo chemistry instrument. 3. Document review reveals no evidence review or sign off by the laboratory director for the above mentioned procedures. 4 In a staff interview with the TC on August 23, 2024 at 1;30pm in the laboratory, the findings were confirmed.