Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2198195	05/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Beaufort County Memorial Hospital	122 Okatie Center Boulevard North Suite 160, Okatie, SC	

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	An announced CLIA initial survey was conducted at Beaufort Memorial Okatie Medical Pavilion on 05/16/2024 by the South Carolina Department of Environmental Control (SCDHEC). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following STANDARD LEVEL DEFICIENCES were found to be out of compliance:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observations, review of Piccolo Xpress chemistry operator's manual, and staff interview, the laboratory failed to follow manufacturer's instructions for reagent handling and ensure that disc was not used past the expiration date and time for the one test day reviewed (05/16/2024). 10 out of 10 reagent pouches for Piccolo Xpress chemistry analyzer were at room temperature. Findings included: 1. The surveyor observed one box of Picclo Xpress pouches in a box at room temperature with no date or time of when the box was placed at room temperature. Pouches were unopened in box. 2. A review of operator's manual for Picclo Xpress for chemistry analyzer states on page (pg.)2-8 "a disc can remain in its sealed pouch at room temperature for a cumulative period of 48 hours. Longer time at room temperature can cause suppression of chemistries and disc cancellations." "Disc can be used directly from the refrigerator (stored at 2-8 degrees C) without warming". 3. In an interview on 05/16/2024 at 12:30 pm with testing personnel (TP1) in the laboratory, the above finds were confirmed. Key C=Celsius

D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on records review (form CMS 209 testing personnel list, and proficiency testing records) and testing personnel interview, it was determined that the laboratory failed to ensure that proficiency testing (PT) samples were rotated among all testing personnel who routinely performed hematology complete blood count (CBC) for 2023 Events 3 out of 3. Findings included: 1. The laboratory listed 2 testing personnel (TP) on the CMS-209 personnel form on the day of the survey. 2. A review of the American Proficiency Institute (API) records showed that only the technical consultant (TC) performed all the CBC proficiency testing events 1, 2, and 3 for 2023. 3. In an interview on 05/16/2024 at 12:30 pm with TC confirmed that the laboratory failed to ensure all testing personnel participated in proficiency testing.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on lack of documentation and staff interview the laboratory failed to retain attestation sheet for Hematology/Coagulation proficiency testing from API for 2021. No documentation of review for 3 of 3 events for 2021. Findings included: 1. On 05/16 /2024 surveyor reviewed Hematology/Coagulation proficiency test reports. 2. A review of API 2021 Hematology/Coagulation revealed no attestation sheet, lack of documented laboratory director and analyst signatures for 2021. Lack documentation of laboratory director's review. 3. An interview on 05/16/2024 at 12:30 pm in the laboratory with the Technical Consultant (TC) confirmed the above findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	This STANDARD is not met as evidenced by: Based on document review, and staff interviewed the laboratory failed to have the analyst and laboratory director to sign attestation statement for 1 of 3 2024 PT events. Findings included: 1. All API surveys reviewed for 2024 (1 of 3) were not signed by the analyst and not signed by the laboratory director. 2. In an interview on 05/16/2024 at 12:30 pm in the laboratory with the TC and TP1 confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on records review (CMS 209 testing personnel, and employee competency evaluation forms), and staff interview, the laboratory failed to assess the competency of one of one TC and two of two testing personnel for 2022 through 2024. Findings included: 1. The laboratory listed 1 (TC) and 2 (TP) on the CMS-209 form on the day of the survey. 2. A review of competency files revealed a lack of documentation for TC. Surveyor requested competency forms for technical consultant. No documents were provided on the day of the survey. 3. A review of testing personnel's files revealed: a) TP 1 lacked competency documentation for 2024. b) TP 2 lacked competency documentation for 2022 and 2023. 4. In an interview on 05/16/2024 at 12: 30 pm with TC in the laboratory the above findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of policies and procedures, records reviewed and staff interview, the laboratory failed to establish written policies (i.e. quality management plan) and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Reference D2007, D2009, D2015, D5209, D5411 Findings included: 1. The surveyor requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor and assess the quality of the general laboratory system. 2. In an interview on 05/16/2024 at 2:45 pm with TC confirmed these findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of the "Instructions for use" DXH 520, laboratory maintenance records, confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for instrument maintenance. For 9 out of 23 months lacked documentation of monthly maintenance. 2 years out of 2 years, lacked documentation for yearly maintenance. Findings included: 1. A review of Beckman Coulter "Instruction for Use" DXH 520 published version: v2 revealed in Chapter 12 Cleaning Procedures, performing a bleach cycle "every 1,000 cycles or monthly, whichever comes first." 2. Cleaning the WBC bath filter monthly noted on pg. 12-1 and on maintenance checklist, Chapter 12 Cleaning Procedures. 3. A review of Beaufort Memorial Hospital (BMH) Okatie DXH520 maintenance checklist records revealed 9 months out of 23 lacked documentations of monthly maintenance performed from January 2022 through December 2023. No maintenance documented for the following months: a. March 2022 b. April 2022 c. June 2022 d. August 2022 e. September 2022 f. November 2022 g. October 2022 missing h. December 2022 i. January 2023 j. April 2023 4. A review of BMH Okatie DXH520 maintenance checklist records from January 2022 through December 2023 revealed the lack of documentation for 2 of 2 years for yearly maintenance. No yearly maintenance documented for the following years: a. Year 2022 b. Year 2023 5. In a staff interview on 05/16/2024 at 12:30 pm with TP1 and TC, the above findings confirmed.