

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D2074807	(X3) Date Survey Completed 03/18/2026
Name of Provider or Supplier Beaufort County Memorial Island Imaging Center	Street Address, City, State 40 Palmetto Parkway, Hilton Head Island, 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 onsite recertification survey was conducted at the Beaufort County Memorial Island Imaging on March 18, 2026, by the South Carolina Department of Public Health (SC DPH), Bureau of Nursing Homes and Medical Services. The facility was found to be out of compliance with Medicare Condition 42 CFR Part 493, CLIA laboratory requirements. The following CONDITION and STANDARD LEVEL DEFICINCIES were found to be out of compliance: D2000-ENROLLMENT AND TESTING OF SAMPLES CFR(S): 493.801 D6000-MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(S): 493.1403
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory failed to enroll in a proficiency testing (PT) program for one or more tests that it performs for 2 out of 2 years (2024 and 2025). Findings included: 1. A review of CMS 116 application reveals creatinine and blood urea nitrogen (BUN) moderately complex testing are performed. 2. Surveyor requested and the laboratory failed to provide PT testing scores for creatinine and BUN as required in subpart I 493.801. No</p>

scores were available on the day of inspection. 3. In an interview on March 18, 2026, at 1:45 pm in the office with Quest consultant and hospital quality management representative, the above findings were confirmed.

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 on direct observation, lack of documentation, and staff interview, the laboratory failed to define and monitor the room/storage temperature to be consistent with the manufacturer's instructions for 2 out of 2 years reviewed (2024 and 2025). Findings included: 1. During a tour of the laboratory, the surveyor directly observed the package label for epoc Blood Analysis, 45 BGEM Test Cards, Lot #02-25325-50, expiration 2026-05-08, 15 degrees C to 30 degrees C (59 F to 86F). 2. A review of epoc CLSI Procedure Manual reveals the epoc Test Cards are to be stored at room temperature (15 degrees C -30 degrees C). 3. Surveyor requested and the laboratory failed to provide documentation of set criteria for room temperature within acceptable limits in accordance with manufacturer's storage instructions. 4. In an interview on March 18, 2026, at 1:45 pm in the office with Quest consultant and hospital quality management representative, the above findings were confirmed. Celsius= C Fahrenheit= F

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and staff interview, the laboratory failed to provide a developed and/or approved by current laboratory director Individualized Quality Control Plan (IQCP) for moderately complex testing for 2 out of 2 (creatinine and BUN) analytes performed by the imaging center. Findings included: 1. A review of quality control (QC) records reveals two levels of QC are run monthly. 2. Surveyor requested but the laboratory failed to provide an approved IQCP

	<p>plan and/or documentation of data for epoc Blood Analysis System as required 493.1256(c). 3. In an interview on March 18, 2026, at 1:45 pm in the office with Quest consultant and hospital quality management representative, the above findings were confirmed.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283.</p> <p>This STANDARD is not met as evidenced by: Based on policies and procedures reviewed, lack of documentation, and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems as specified 493.1251 through 493.1283 for the 2 out of 2 moderately complex analytes reviewed (creatinine and BUN). Findings included: 1. A review of QC reveals a partial mechanism to monitor the analytic system of moderate complex testing of epoc Blood Analysis System. 2. Surveyor requested and the laboratory failed to provide an established written policy to assess an ongoing review process that encompasses all facets of the quality of moderate complex testing performed in the imaging center. The laboratory failed to provide an evaluation of its effectiveness. 3. In an interview on March 18, 2026, at 1:45 pm in the office with Quest consultant and hospital quality management representative, the above findings were confirmed.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review, lack of documentation, and staff interview, the laboratory director failed to provide overall management and direction in accordance with 493.1407 of this subpart for 2 out of 2 years reviewed (2024 and 2025). Refer to D2000, and D6005</p>
<p>D6005</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p> <p>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.</p>

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and staff interview, the laboratory director failed to visit onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits per year for 2 out of 2 years reviewed (2024 and 2025). Findings included: 1. A review of policies and procedures, job descriptions, and quality control records reveals lack of documentation demonstrating laboratory director's on-site visits to monitor continuous compliance with current laws and regulations. 2. In an interview on March 18, 2026, at 1:45 pm in the office with Quest consultant and hospital quality management representative, the above findings were confirmed.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and staff interview, the technical consultant failed to establish and/or document in-service training and education for the moderately complex epoc Blood Analysis System for 2 out of 2 employees. Findings included: 1. A review of CMS 209 Laboratory Personnel Report (CLIA) reveals 1 TC and 2 testing personnel (TP) for moderate complex testing. 2. A review of personnel files reveals the laboratory lacks documentation of epoc instrument and Blood Analysis Test System training for creatinine and BUN. a. Documentation of what materials are needed to perform the test and where are they stored. b. Documentation of what process and/or procedure are used to perform the test. c. Documentation of what, how, and when to run QC on the instrument. d. Documentation on how to retrieve patient's test and interpret results. e. Documentation of what maintenance to perform and how often. f. Documentation of how to troubleshoot the Point of Care analyzer. No documentation of what TP were trained on was available on the day of inspection. 3. In an interview on March 18, 2026, at 1:45 pm in the office with Quest consultant and hospital quality management representative, the above findings were confirmed.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and staff interview, the technical consultant failed to complete documentation of competency for all personnel performing moderately complex epoc Blood Analysis System for 2 out of 2 employees. Finding included: 1. A review of personnel records, initial Training Quiz (2pages), Lab Competency Worksheet Point of Care (initial, 6 months, and Annual) reveals incomplete records for 2 out of 2 employees: i. TP1 ii. TP2 2. A review of

"Epoc System Training Quiz" and Lab Competency Worksheet Point of Care Testing both lack the following documentation: 1. Trainer and/or evaluator's name 2. Signature of trainer and/or evaluator 3. Date training and/or evaluation performed 3. In an interview on March 18, 2026, at 1:45 pm in the office with Quest consultant and hospital quality management representative, the above findings were confirmed.

D6068

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and staff interview, the laboratory failed to establish written responsibilities for testing personnel and what corrective actions should be taken when test system deviates from the laboratory's established performance specifications for 2 out of 2 moderately complex tests. Findings included: 1. A review of CMS 209 laboratory personnel report (CLIA) reveals 2 TPs. 2. A review of CT Scan Tech job responsibilities lacks documentation of TP responsibilities for performing and reporting moderately complex tests. 3. In an interview on March 18, 2026, at 1:45 pm in the office with Quest consultant and hospital quality management representative, the above findings were confirmed.