

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0260979	<b>(X3) Date Survey Completed</b>  10/29/2024
<b>Name of Provider or Supplier</b>  Evans Memorial Hospital	<b>Street Address, City, State</b>  200 North River Street, Claxton, GA	
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>	A recertification survey was performed on , October 30, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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: Observation during the tour of the laboratory and staff interview confirmed there was a bottle of Acetic Acid, a caustic solution, stored in an upper cabinet above the working area. Findings: 1. Observation during the tour of the laboratory confirmed that a bottle of Acetic Acid stored in the upper cabinet, above the working area. Caustic agents should be stored in a metal fire cabinet or metal biohazard cabinet. 2. An interview with the General Supervisor (GS), on 10/29/2024, at approximately 10: 15 am, in the laboratory confirmed the information above.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
A tour of the laboratory, and staff interview, confirmed opened, expired reagents in the laboratory for the Beckman Coulter DxH(BCDxH) 690T hematology analyzer in the refrigerator as well as expired saline solution on the counter in Blood Bank (BB). Findings: 1. Observation during the tour of the laboratory confirmed that the Coulter S Cal reagents, used for the calibration of the BCDxH hematology analyzer, expired on 10/12/2024. 2. Observation during the tour of the laboratory it was confirmed that the open container of Blood Bank (BB) saline, was marked as being open on 08/12/2024. Blood Bank saline has a shelf life of one month (30 days) from the open date. 3. Interview with the Laboratory Supervisor (LS), on 10/29/2024, at approximately 10:20 am, in the laboratory, confirmed the expired Coulter S Cal reagents in the laboratory. Interview with the LS on 10/29/2024 at approximately 10:25 am in the BB area, confirmed the expired BB saline container.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:  
Observation during the laboratory tour, and staff interview, confirmed that the Fisher Scientific IsoTemp Cooler had not been serviced by BioMed since 08/25/2023, the date of installation. Findings: 1. Observation during the laboratory tour confirmed that the IsoTemp Cooler had not been serviced by BioMed since it was installed on 08/25/2023. The date of annual service should have been completed on or before 08/25/2024. 2. Interview with the Laboratory Supervisor, on 10/29/2024, at approximately 10:45 am, in the laboratory, confirmed the statements above.