

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0305030	<b>(X3) Date Survey Completed</b>  03/16/2023
<b>Name of Provider or Supplier</b>  Evergreen Medical Center	<b>Street Address, City, State</b>  101 Crestview Ave, Evergreen, AL	
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>D2089</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records and an interview with the Technical Consultant, the laboratory failed to participate in Proficiency Testing for Routine Chemistry. This was noted for one out of four Chemistry events reviewed from November 2021 to the date of the current survey, 3/16/2023. The findings include: 1. A review of American Proficiency Institute PT records revealed the laboratory scored 0% on all analytes for 2023 Chemistry 1st due to failure to submit results within the time frame established by the PT provider. 2. During an interview on 3/15/2023 at 3:00 PM, the Technical Consultant confirmed the laboratory failed to submit their results under previous laboratory management.</p>
<b>D5439</b>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions;</p>

(b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of Calibration Verification (C/V) records, a review of Policies and Procedures, and an interview with the Technical Consultant, the laboratory failed to perform Calibration Verifications on the Beckman Coulter DxC 700 AU at least every six month as per CLIA regulations. The findings include: 1. A review of Calibration Verification records revealed the following: a) Uric Acid, Cholesterol, Blood Urea Nitrogen (BUN), Triglyceride, Phosphorus, Magnesium, Glucose, Creatinine, Calcium, Total Iron, Ammonia - C/V performed 5/22/22. No documentation of a C/V for the second half of 2022 was found for these analytes b) Total Iron, Ammonia, Sodium, Potassium, Chloride, Ethanol, Total Protein, Albumin, Direct Bilirubin, Total Bilirubin, Alkaline Phosphatase (ALP), Aspartate Transaminase (AST), Lipase, Lactate Dehydrogenase (LDH), Gamma-glutamyl Transferase (GGT), Creatinine Kinase (CK), Amylase, Alanine Transaminase (ALT) - C/V performed 12/13/22. No documentation of a C/V for the first half of 2022 was found for these analytes. 2. A review of Policies and Procedures revealed under section "Calibration Verification", "...Calibration Verification is performed every six months.." 3. During an interview on 3/16/2023 at 9:45 AM, the Technical Consultant confirmed the above findings.

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of Quality Control records, patient log records, and an interview with the Technical Consultant, the laboratory failed to ensure two levels of quality controls were run each day of patient testing. This was noted for seven total days in

April 2022 and August 2022. The findings include: 1. A review of Quality Controls records and patient log reports revealed the following: a) 4/5/22 - Level 1 out for Alkaline Phosphatase (ALP). 11 patients were run. b) 4/22/22 - Both levels out for Triglycerides. 6 patients were run. c) 4/23/22 - Level 2 out for Total Protein. 8 patients were run. d) 4/25/22 - Level 1 out for Alkaline Phosphatase. 8 patients were run. e) 4/26/22 - Level 1 out for Gentamycin. 6 patients were run. f) 8/13/22 - Level 2 out for Sodium, Calcium, Glucose, Blood Urea Nitrogen (BUN), Alkaline Phosphatase (ALP), Alanine Transaminase (ALT), Aspartate Transaminase (AST), Total Protein, Total Cholesterol, Low-Density Lipoprotein (LDL), Iron, and Creatinine Kinase (CK). 34 patients were run. g) 8/26/22 i) Level 1 out for Sodium. 11 patients were run. ii) Level 2 out for Total Cholesterol, Triglyceride, Low-Density Lipoprotein (LDL), Amylase, and Lipase. 13 patients were run. iii) Both levels out for Glucose, Alanine Transaminase (ALT), Aspartate Transaminase (AST), and Creatinine Kinase. 26 patients were run. 2. During an interview on 3/16/2023 at 10:15 AM, the Technical Consultant confirmed the above findings.

**D6046**

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

(b) The technical consultant is responsible for-- (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.

This STANDARD is not met as evidenced by:  
Based on a review of Testing Personnel records and an interview with the Technical Consultant, the Technical Consultant failed to implement and document evaluations that included the six minimal regulatory requirements for assessment of competency for all non-waived testing in the Laboratory. This was noted for nine out of nine Testing Personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of Testing Personnel records revealed forms used for Competency Assessment entitled "Age Specific Competency Evaluation". The form failed to include the six minimal regulatory requirements for assessment of competency, as follows: a) Direct observation of routine patient testing b) Monitoring the recording and reporting of patient test results c) Review of quality control records, proficiency testing results, and preventive maintenance records d) Direct observations of performance of instrument maintenance and function checks e) Assessment of problem solving skills 2. During an interview on 3/16/2023 at 10:00 AM, the Technical Consultant confirmed the above findings.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:  
Based on a review of personnel evaluation records and an interview with the Technical Consultant, the Technical Consultant failed to evaluate the performance of Testing Personnel annually. This was noted for two of nine Testing Personnel listed on the Laboratory Personnel Report (Form CMS-209). The findings include: 1. A

review of personnel evaluation records revealed the following: a) An annual competency dated 2/27/2023 for all non waived testing was reviewed for Testing Personnel #2. No evidence of an annual competency performed in 2022 was found for Testing Personnel #2 despite being previously qualified as of the date of the last survey (11/3/2021). b) An annual competency dated 3/6/2023 for the Instrumentation Laboratory GEM Premier 3500 Arterial Blood Gas Analyzer was reviewed for Testing Personnel #8. No evidence of an annual competency performed in 2022 was found for Testing Personnel #8 despite being previously qualified as of the date of the last survey (11/3/2021). 2. During an interview on 3/15/2023 at 2:00 PM, the Technical Consultant confirmed the above findings.