

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0305030	(X3) Date Survey Completed 04/24/2025
Name of Provider or Supplier Evergreen Medical Center	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on a review of maintenance records, temperature records, Diesse Erythrocyte Sedimentation Rate (ESR) Quality Control (QC) records, Medtox Diagnostics drugs of abuse (DOA) QC records, Quidel Triage QC records, serum Human Chorionic Gonadotropin (HCG) QC records, Beckman Coulter Access 2 immunology QC records, and an interview with the General Supervisor (GS) and Technical Consultant (TC), the laboratory failed to retain documentation for two years. This was noted for eight of twelve months in 2023 and two days of one month reviewed in 2024. The findings include: 1. A review of April through December 2023 documentation revealed no evidence of: a) Maintenance for the Beckman Coulter AU 700 Chemistry analyzer, Beckman Coulter Access 2 Immunology analyzer, ACL Elite Coagulation analyzer, and BactecFX40 Microbiology analyzer. b) Temperature records. c) Diesse ESR QC records. d) Medtox Diagnostics DOA QC records. e) Quidel Triage D-dimer and Cardiac QC records. f) Serum hCG QC records. 2. A review of the Beckman Coulter Access 2 Quality Control (QC) records for June 2024 revealed no QC documentation for 6/6/2024 and 6/12/2024. 3. During an interview on 4-23-2025 at 2:57 PM, the GS and TC confirmed the 2023 documentation was stored by the previous Laboratory Manager and could not be located during the time of the survey; and the Access 2 can only go back to July 2024 QC records.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p>

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on a review of the lack of 2023 documentation, Blood Bank Quality Control (QC) material, maintenance records, calibration records, QC records, and interviews with the General Supervisor (GS) and Technical Consultant (TC), the Laboratory failed to ensure: A) Retention of documentation for 2 years (refer to D 3031). B) QC material was not expired prior to patient testing (refer to D 5417). C) Weekly, bi-weekly, and monthly maintenance was documented (refer to D 5429). D) Calibration verification was performed and documented (refer to D 5439). E) A procedure was in place that monitors the accuracy and precision of test performance over time (refer to D 5441). F) Two control materials of different concentration were within the manufacturer's ranges for each day of patient testing (refer to D 5447). .

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) 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.

This STANDARD is not met as evidenced by:

Based on a review of the Blood Bank Quality Control (QC) records, QC Blood Bank policy, and an interview with the General Supervisor (GS) and Technical Consultant (TC), the laboratory used expired QC material. The surveyor noted the laboratory utilized expired Screening Cells prior to patient testing for three days in 2024. The findings include: 1. A review of the Blood Bank QC records revealed Screening Cells lot # VSS562 expired 7/9/2024 and was utilized on 7/10/24-7/12/24; 6 patients were affected during this time. 2. A further review of the QC Blood Bank policy revealed, "No expired reagent will be used." 3. During an interview on 4-24-2025, at 12:44 PM, the GS was given permission by the Laboratory Director to utilize expired Screening Cells until new material was received.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of the Beckman Coulter (BC) AU 700 maintenance records, BC Access 2 maintenance records, ACL Elite maintenance records, BactecFX40 maintenance records, Blood Bank Refrigerator alarm checks, and an interview with the General Supervisor (GS) and Technical Consultant (TC), the Laboratory failed to

document the following maintenance during 2023, 2024 and/or 2025: 1) BC AU700 Monthly; 4 months in 2024, 2) BC Access 2 Weekly; 1 month in 2024 and 2 months in 2025, 3) ACL Elite Weekly, Bi-weekly, and Monthly; Weekly 2 months in 2024, Bi-weekly and Monthly 8 of 12 months in 2024, 4) BactecFX40 Monthly; 3 months in 2024, 5) Blood Bank Refrigerator alarm checks Monthly; no documentation from the previous survey (3-16-2023) to the current survey (4-24-2025). The findings include: 1. A review of the maintenance records revealed no evidence of documentation for the following: a) BC AU700 Monthly maintenance; April, July, August, and October 2024. b) BC Access 2 Weekly maintenance; December 2024, January and February 2025. c) ACL Elite: 1) Weekly maintenance; May and December 2024. 2) Bi-weekly maintenance; March, May, June, August, September, October, November, and December 2024. 3) Monthly maintenance; January, February, May, June, August, September, November, and December 2024. d) BactecFX40 Monthly maintenance; January, May, and July 2024. e) Blood Bank Refrigerator alarm checks Monthly; no documentation from the previous survey (3-16-2023) to the current survey (4-24-2025). 2. During an interview on 4-23-2025, at 2:57 PM, the GS and TC confirmed the maintenance was performed but not documented.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (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 the Respiratory calibration verification (CV) records, Chemistry CV records, the Laboratory Quality Assurance Plan, and an interview with the GS (General Supervisor) and TC (Technical Consultant), the Laboratory failed to perform CV on the IL GEM Premier 3500 Arterial Blood Gas (ABG) respiratory analyzer and Beckman Coulter (BC) AU 700 chemistry analyzer every six months as per the laboratory policy. This was noted for one of two 2024 CV's missed for respiratory and chemistry since the previous survey (3-16-2023). The findings include: 1. A review of the IL GEM respiratory CV records revealed a CV performed on 10/31/2023 and then almost 12 months later on 10/2/2024. There was no documentation of CV the first half of 2022. 2. A review of the BC 700 AU CV records revealed no evidence of a CV performed and documented since the previous survey on 3-16-2023. 3. A further review of the Laboratory Quality Assurance Plan revealed, "5. Calibrations are done according to the manufacturer's recommendations and at least every six months." 2.

During an interview on 4-24-2025, at 11:01 AM, the GS and TC confirmed CV's are performed every 6 months and the CV due in April 2024 was not performed.

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 a review of Beckman Coulter (BC) DxC 700 AU Chemistry analyzer, BC Access 2 Immunology analyzer, ACL Elite Coagulation analyzer, Sysmex XN 1000 and XN 550 Hematology Quality Control (QC) records and an interview with the General Supervisor (GS), the laboratory failed to have a procedure in place that monitors the accuracy and precision of test performance over time. This was noted since the previous survey (3-16-2023) to the current survey (4-23-2025). The findings include: 1. A review of BC DxC700 AU, BC Access 2, ACL Elite, Sysmex XN 1000 and 550 QC records revealed only raw data from the instrument. No evidence of Levy Jennings charts or peer group data was available for review at the time of survey. 2. During an interview on 4-24-2025 at 1:37 PM, the Surveyor inquired about the review of Levy Jennings charts for the Hematology, Chemistry, Coagulation, and Immunology analyzers. The GS confirmed that the laboratory was not monitoring Levy Jennings charts for shifts or trends for those testing systems.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:

Based on a review of the IL ACL Elite coagulation analyzer quality control (QC) records, patient test records, and an interview with the General Supervisor (GS) and Technical Consultant (TC), the laboratory failed to analyze two control materials of different concentration for each day of patient testing. This was noted for one out of thirty one days reviewed in July 2023. The findings include: 1. A review of the ACL coagulation QC records revealed on 7-27-2023 Partial Thromboplastin Time (PTT) level 1 was out of manufacturer's ranges; 2 patients were affected. 2. During an interview on 4-24-2025 at 1:37 PM, the GS confirmed the above findings.

D6054

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

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on a review of the personnel records and an interview with the General Supervisor (GS) and Technical Consultant (TC), the previous TC failed to ensure all testing personnel had documentation of annual competency assessments. The surveyor noted no documentation of the 2023 annual competency assessment for two of nine testing personnel listed on the CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed no evidence of 2023 annual competency documentation for Testing Personnel #4 and Testing Personnel #6. 2. During an interview on 4-23-2025, at 5:00 PM, the GS and TC confirmed the above findings.