

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2264897	<b>(X3) Date Survey Completed</b>  01/31/2025
<b>Name of Provider or Supplier</b>  Eastern Laboratory Associates	<b>Street Address, City, State</b>  2470 Emerald Place Suite C, Greenville, NC	
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>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of Centers for Medicare &amp; Medicaid Services (CMS) form 116, 2023 and 2024 laboratory verification of accuracy records, lack of documentation, and interview with general supervisor (GS) 01/31/25, the laboratory failed to perform a twice annual verification of accuracy for the toxicology testing performed on the Diatron Pictus 500 analyzer 2 of 2 times in 2023 and 1 of 2 times in 2024. The laboratory also failed to perform a twice annual verification of accuracy for the toxicology testing performed on the Liquid Chromatography Mass Spectrometry (LCMS) analyzer 2 of 2 times in 2024. The laboratory performs approximately 215,644 toxicology tests annually. Review of CMS form 116 submitted at time of survey revealed the laboratory performs approximately 215,644 toxicology tests annually. 1. The laboratory failed to verify the accuracy of the toxicology testing performed on the Diatron Pictus 500 2 of 2 times in 2023 and 1 of 2 times in 2024. Findings: Review of 2023 and 2024 laboratory verification of accuracy records revealed the following: a. 2023 - no documentation of a twice annual verification of accuracy. b. 2024 - the laboratory participated in one American Proficiency Institute (API) proficiency testing (PT) event - Chemistry Miscellaneous 2nd event. Interview with GS at approximately 1:30 p.m. confirmed the laboratory had not performed a twice annual verification of accuracy in 2023. They also confirmed one verification of accuracy was performed in 2024. 2. The laboratory failed to verify the accuracy of the toxicology testing performed on the LCMS analyzer 2 of 2 times in 2024. Review of laboratory records revealed the laboratory began performing toxicology testing on the LCMS analyzer in January of 2024. Review of 2024 laboratory verification of accuracy records revealed no documentation of a twice annual verification of</p>

accuracy for the toxicology testing performed on the LCMS analyzer. Interview with GS at approximately 1:30 confirmed the laboratory had not performed a twice annual verification of accuracy in 2024 for the testing performed on the LCMS analyzer. They also confirmed the laboratory began testing on the LCMS analyzer in January of 2024.

**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 review of the Pictus 500 chemistry analyzer user manual, review of 2024 and 2025 Pictus 500 Maintenance Logs, and interview with Technical Supervisor (TS) #1 on 1/31/2025, the laboratory failed to document monthly maintenance for the Pictus 500 chemistry analyzer since testing began in January 2024, a period of approximately 13 months. Findings: Review of Pictus 500 user manual revealed manufacturer's monthly requirements: 1. Page 112, Section 9.1, "MAINTENANCE TASKS...Monthly...Perform Photometer Calibration...Perform intensive washer cleaning." 1. Page 117, Section 9.5.7, "PHOTOMETER CALIBRATION STATUS... is scheduled monthly." 2. Page 122, Section 9.9 MONTHLY MAINTENANCE, sub section 9.9.2, "INTENSIVE WASHER CLEANING...At the end of the process a normal washing and drying cycle is performed." 3. Page 122, Section 9.9 MONTHLY MAINTENANCE, sub section 9.9.3, "OTHER TASKS Perform a full photometer calibration..." Review of Pictus 500 Maintenance Logs for 2024 and 2025 revealed no documentation of the performance of monthly maintenance since testing started in January 2024. Interview with TS #1 at approximately 2:05 p.m. confirmed monthly maintenance was not documented.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:

Based on deficiency cited at D5217, review of laboratory procedure manual, and lack of documentation 01/31/25, the laboratory director (LD) failed to establish a procedure for the biannual verification of accuracy of the toxicology testing performed on the LCMS analyzer. Findings: The laboratory failed to perform a biannual verification of accuracy for the toxicology testing performed on the LCMS analyzer. See D5217. Review of laboratory procedure manual revealed no documentation of a procedure for the performance of a biannual verification of accuracy for the toxicology testing performed on the LCMS analyzer.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure

that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure manual, laboratory records, lack of documentation and interviews with LD and technical supervisors (TS's) 01/31/25, the LD failed to ensure a competency assessment policy or procedure was established for the specific duties of 3 of 3 TS's and failed to perform 6 month competency assessments on 2 of 3 TS's. 1. The LD failed to ensure a competency policy or procedure was established for the specific duties of 3 of 3 TS's; TS #1, TS #2 and TS #3. Findings: Review of laboratory procedure manual revealed a "Personnel Competency Assessment" policy that states; "Six months and annually: Laboratory staff who conducts the pre-analytical, analytical, and post-analytical phases of testing will be monitored as it applies to their specific duties, at six months and annually." The policy fails to define what specific duties will be assessed for each TS and fails to define how the duties will be assessed. Interview with TS #1 at approximately 12:00 p. m. confirmed the "Personnel Competency Assessment" policy fails to define what specific duties will be assessed and how the duties will be assessed for TS competency. 2. The LD failed to perform 6 month competency assessments for TS #2 and TS #3. Findings: Review of laboratory records revealed TS #2 and TS #3 were hired in January of 2024. Review of laboratory records revealed no documentation of 6 month competency assessments for TS #2 and TS #3. Interview with LD at approximately 12:00 p.m. confirmed they had not performed 6 month competency assessments for TS #2 and TS #3.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, and interviews with TS's and LD 01/31/25, the LD failed to specify in writing the specific responsibilities and duties of 3 of 3 TS's. Findings: Review of laboratory policy "Delegation of Responsibility" revealed "Effective 11/01/24, I hereby delegate the responsibility for Quality Assurance, Policy and Procedure Manual and Presidency Testing review to the Laboratory Technical Consultant/Supervisor. Should any new policy of procedure be written, I reserve the right for review and approval myself." The policy fails to state the specific duties and responsibilities delegated to each technical supervisor; TS #1, TS #2, and TS #3. During interview with TS #1 at approximately 11:30 a.m., the TS stated they were responsible for the oversight of the testing performed on the Diatron Pictus 500 chemistry analyzer. They also confirmed the laboratory policy "Delegation of Responsibility" fails to include the specific duties and responsibilities delegated to them. During interview with TS #2 at approximately 1:30 p.m., the TS stated they and

TS #3 were responsible for oversight of the testing performed on the LCMS analyzer. They also confirmed the laboratory policy "Delegation of Responsibility" fails to include the specific duties and responsibilities delegated to them and TS #3. During interview with LD at approximately 12:00 p.m., the LD confirmed they did not specify in writing the specific duties and responsibilities of 3 of 3 TS's.