| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 26D2300831 | 02/05/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ammo Labs - Carthage | 3071 Grand Ave, Carthage, MO | |

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 |
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| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedures and interview with the general supervisor (GS), the laboratory failed to ensure the current laboratory director approved, signed and dated laboratory procedures before use. Findings: 1. Review of laboratory procedures showed no approval by the current laboratory director for the following procedures: Beckman Coulter AU-480 chemistry analyzer Beckman Coulter Access 2 chemistry analyzer Beckman Coulter DXH 560 hematology analyzer 2. Interview with the GS on February 5, 2025 at 10:30 AM confirmed the laboratory failed to ensure the current laboratory director approved, signed and dated laboratory procedures before use. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of the performance verification procedures for the Beckman Coulter AU-480 chemistry analyzer, Beckman Coulter Access 2 chemistry analyzer, patient results, and interview with the general supervisor (GS), the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Beckman Coulter Au480 chemistry analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: albumin, alkaline phosphatase, alanine transaminase (ALT), aspartate aminotransferase (AST), bilirubin, urea nitrogen (BUN), calcium, chloride, cholesterol, cholesterol high density lipoprotein, carbon dioxide (CO2), creatinine, glucose, potassium, sodium, total protein, triglycerides, and uric acid prior to the beginning of patient testing in April 2024. 2. Review of the performance specifications for the Beckman Coulter Access 2 chemistry analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: vitamin B12, vitamin D25 hydroxy, serum pregnancy, triiodothronine (T3), thyroxine (T4), free T4, thyroid stimulating hormone (TSH), thyroid peroxidase (TPO), thryoglobuline, follicle-stimulating hormone (FSH), luteinizing hormone (LH), estradiol, total testosterone, free testosterone, progesterone, and prolactin prior to the beginning of patient testing in April 2024. 3. Review of patient results showed the laboratory performs approximately 30,000 chemistry tests per year. 4. Interview with the GS on February 5, 2025 at 11:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>(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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the analyzer manufacturer's guide, lack of the verification of performance specifications for the Applied Biosystems Sciex 4000 for screening toxicology testing, and interview with the general supervisor (GS), the laboratory failed to provide documentation of verification of performance specifications for eleven of eleven urine drug screening toxicology analytes performed on the Applied Biosystems Sciex API 4000. Findings: 1. Review of the Applied Biosystems Sciex API 4000 Site Planning Guide states that the Applied Biosystems Sciex API 4000 test system is "For Research Use Only. Not for use in Diagnostic Procedures." 2. Lack of verification of performance specifications for the Applied Biosystems Sciex 4000 for urine drug screening toxicology testing showed the laboratory failed to verify the performance specifications for the analytes: opiate, benzodiazepine, amphetamine, cocaine, methadone, 6-MAM, methamphetamine, fentanyl, tricyclic antidepressants, buprenorphine, and cannabis prior to the beginning of testing in November 2024. 3. |

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| | Interview with the general supervisor on February 5, 2025 at 1:00 PM confirmed, the laboratory failed to provide documentation of verification of performance specifications for the Applied Biosystems Sciex 4000 for urine drug screening toxicology testing. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of November 1, 2024 to date February 5, 2025 Beckman Coulter AU-480 chemistry analyzer quality control (QC) records, Beckman Coulter Access 2 chemistry analyzer QC records, and interview with the general supervisor (GS), the laboratory failed to ensure QC was acceptable before reporting patients results for the analytes glucose and total T3. Findings: 1. Review of the Beckman Coulter AU-480 chemistry analyzer showed level 1 glucose QC was not within acceptable limits on November 18, 2024. The laboratory was unable to provide patient's performed on November 18, 2024. 2. Review of Beckman Coulter Access 2 chemistry analyzer showed level 3 total T3 QC was not within acceptable limits on December 19, 2024. The laboratory was unable to provide patient's performed on December 19, 2024. 3. Interview with the GS on February 5, 2025 at 12:00 PM confirmed the laboratory failed to ensure QC was acceptable before reporting patient results for glucose and total T3. |
| **D6098** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(8)<br><br>(e)(8) Ensure that reports of test results include pertinent information required for interpretation;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test reports printed on February 5, 2025 for the laboratory developed urine drug screening and urine drug confirmation testing and interview with the general supervisor (GS), the laboratory director failed to ensure that test reports include pertinent information required for interpretation. Findings: 1. Review of patient test reports printed on February 5, 2025 for the laboratory developed tests for urine drug screening and urine drug confirmation testing showed the laboratory director failed to include a statement on the patient test report stating that the performance characteristics of the urine drug screening and urine drug confirmation testing were determined by the laboratory and have not been cleared or approved by the U.S. Food and Drug Administration. 2. Interview with the general supervisor (GS) on February 5, 2025 at 1:00 PM confirmed the laboratory director failed to ensure that test reports include pertinent information required for interpretation. |