

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0956861	<b>(X3) Date Survey Completed</b> 12/03/2024
<b>Name of Provider or Supplier</b> Ammon Analytical Laboratories Llc	<b>Street Address, City, State</b> 35 East Blancke Street, Linden, NJ	
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>D2003</b>	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to establish and maintain the accuracy of Urine Toxicology specimen validity testing in the calendar years 2023 and 2024. The findings include. 1. The PT provider used by the laboratory College of American Pathologists (CAP) did not include all analytes run on the Urine Toxicology specimen validity testing panel performed by the laboratory. 2. Oxidants and nitrite urine testing was not included in the panel in the calendar years 2023 and 2024 3. The TS confirmed on 12/3/24 at 12:45 pm not all analytes for the above mention testing were performed.</p>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), it was revealed that the laboratory failed to review PT performance codes "See note [30]" (Scientific committee decision) results obtained for PT performed with the College of American Pathologists (CAP) for Urine Drug</p>

Screening (UDS) event A and B of 2023. The findings include: 1. Event UDS-A 2023 Urine Drug testing (screenings) Ethanol samples UDS 01,02,03,04, and 05 and had coded results for see note 30 which were not evaluated. 2. Event UDS-B 2023 Urine Drug testing (screenings) Ethanol samples UDS 06,08,09, and 10 and had coded results for see note 30 which were not evaluated. 3. The TS confirmed on 12/2/24 at 2:00 pm, the laboratory did not evaluate coded results for PT results obtained for the aforementioned PT events.

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on the lack of Quality Control Verification (QCV) records and interview with the Technical Supervisor (TS), the laboratory failed to verify QC material before patient testing for toxicology tests performed on the Olympus AU5000 and AU5800 analyzers from December 2022 to 12/2/24. The findings include: 1) There was no documented evidence that QCV was performed on the aforementioned analyzers. 2) The TS confirmed 12/2/2024 at 1:15 pm there was no documented evidence that QC material was verified before patient testing.

**D5775**

**COMPARISON OF TEST RESULTS**  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
A) Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Supervisor (TS), the laboratory lacked a written procedure that twice a year evaluated and defined the relationship for Toxicology test results performed on the two Liquid chromatography-mass spectrometry (LC-MS) 4503 and 4504 analyzers from 11/29/24 to 12/3/24. The finding includes: 1. There was no written procedure available for review for correlation studies performed between the two LC-MS analyzers on 11/29/24. 2. The TS confirmed on 12/3/24 at 2:00pm there was no written procedure for correlation studies for the LC-MS analyzers available for

review. B) Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Supervisor (TS), the laboratory lacked a written procedure that twice a year evaluated and defined the relationship for Chemistry test results performed on the two Beckman Coulter AU analyzers from 10/1/24 to 12/3/24. The finding includes: 1. There was no written procedure available for review for correlation studies performed between the two Beckman Coulter AU analyzers. 2. The TS confirmed on 12/3/24 at 2:05pm there was no written procedure for correlation studies for the Beckman Coulter AU analyzers available for review.