

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D1088333	<b>(X3) Date Survey Completed</b> 03/11/2026
<b>Name of Provider or Supplier</b> Rxtox Inc	<b>Street Address, City, State</b> 51 Professional Plaza, Pittsburgh, PA	
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>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on review of Pennsylvania Department of Health (PADOH) proficiency testing (PT) records and interview with Technical Supervisor (TS) #2 (CMS 209 Personnel #3, dated 03/06/2026) the Laboratory Director failed to ensure review and evaluation of the results obtained for 1 of 3 PADOH Toxicology PT events performed in 2025. Findings: 1. The PA Regulation 5.22(d) states, "The owner and director shall, if different persons, be jointly and severally responsible for the operation of the clinical laboratory in compliance with this section and with other pertinent regulatory and statutory requirements. They shall be responsible for the employment of personnel meeting qualifications specified in this chapter. They shall submit to the Department, on forms provided by the Department, an annual report of the number and types of laboratory examinations performed during the preceding year." 2. The laboratory's Proficiency Testing Procedure stated, "All of the results are reviewed by a technical supervisor to ensure a passing grade (100%)." 3. On the day of survey 03/11/2026 at 9:40 am, review of PADOH PT records revealed the technical supervisor failed to review the following 1 of 3 PA DOH PT events to ensure a passing grade was obtained for toxicology testing performed in 2025: - Event #3 in 2025, Drugs in Urine 2025-III, 11-15. 4. TS #2 confirmed the findings above on 03/11/2026 at 11:40am.</p>
<b>D5213</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>(b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or</p>

scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) policy, College of American Pathologist (CAP) PT records and interview with Technical Supervisor (TS) #2 (CMS 209 Personnel #3, dated 03/06/2026), the laboratory failed to verify the accuracy of the PT results obtained for 3 of 4 CAP Toxicology PT testing events performed in 2024 and 2025. Findings Include: 1. The laboratory's Proficiency Testing Procedure stated, "If an exception code exists, the technical supervisor must follow through with reviewing it and documenting if the results were acceptable. This must then be signed off on by the director." 2. The CAP's actions laboratories should take when a PT result is not graded document stated, "the laboratory is required to review participant summary for comparative results and document performance accordingly. Evaluation criteria is not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 3. On the day of survey, 03/11/2026 at 09:40 am review of the laboratory's CAP PT records revealed the laboratory did not verify the accuracy for the following analytes that were not scored by the PT agency for 3 of 4 CAP Toxicology PT testing events performed in 2024 and 2025: - 2nd event 2024 DAI B - DAI 04, DAI 05, and DAI 06 (Creatinine qual, pH qual, Specific Gravity qual) - 1st event 2025 DAI A - DAI 01, DAI 02, and DAI 03 (Creatinine qual, pH qual, Specific Gravity qual) - 2nd event 2025 DAI B - DAI 04, DAI 05, and DAI 06 (Creatinine qual, pH qual, Specific Gravity qual) 4. TS #2 confirmed the findings above on 03/11/2026 at 11:40 am.

**D5413**

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

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's temperature logs, lack of documentation and interview with technical supervisor (TS) #2 (CMS 209 Personnel #3, dated 03/06/2026), the laboratory failed to monitor and document humidity as required to ensure reliable test system operation and test result reporting for 7 of 7 instruments used to perform Chemistry testing from 05/22/2024 to date of survey. Findings include: 1. On the date of the survey, 03/11/2026 at 10:55 am, the laboratory could not provide documentation for monitoring room humidity (manufacturer's acceptable range 40-80% RH) to ensure operating conditions were met for the following 7 of 7 instruments used to perform Chemistry testing from 05/22/2024 to 03/11/2026: - 1 of 1 Beckman AU680 - 2 of 2 Agilent GC/MS - 4 of 4 Agilent 6430 TripleQuad LC/MS/MS 2. The laboratory performed 300,000 Chemistry tests in 2025. (CMS-116 estimated annual volume, dated 03/06/2026). 3. TS #2 confirmed the findings above on 03/11/2026 at 11:30 am.