

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1088333	(X3) Date Survey Completed 09/13/2022
Name of Provider or Supplier Rxtox Inc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) proficiency testing (PT) records and interview with the Technical Supervisor (TS)#2, the laboratory failed to verify the accuracy for 1 of 3 Toxicology samples in 2021. Findings Include: 1. On the day of survey, 09/13/2022 at 09:30 am, review of 2021 CAP PT records revealed, the laboratory did not verify the accuracy for the following analytes that were not graded by the proficiency testing agency due to non consensus: - Clonazepam - Opiate Group - Buprenorphine - Norbuprenorphine - Fentanyl 2. The TS #2 confirmed the finding above on 09/13/2022 around 11:30 am.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Technical Supervisor (TS)#2,</p>

the laboratory failed to establish a quality assurance policy from 03/12/2020 to the date of survey. Findings Include: 1. On the day of survey, 09/13/2022 at 11:55 am, the laboratory could not provide a policy for monitoring its pre-analytical, analytical, and post analytic programs from 03/12/2020 to the date of survey. 2. The TS#2 confirmed the finding above on 09/13/2022 at 11:30 am.

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:
Based on lack of documentation and interview with the Technical Supervisor (TS)#2 , the laboratory failed to evaluate twice a year the relationship between test results for 4 of 4 Liquid Chromatography Mass Spectrometry (LCMS) from 03/12/2020 to 09/13 /2022. Findings include: 1. On the day of survey 09/13/2022 at 10:43 am, The TS#2 could not provide comparison of test results between the following instruments from 03/12/2020 to 09/13/2022: - 2 of 2 Agilent 6430 - 2 of 2 Agilent 6460 2. The TS#2 confirmed the finding above on 09/13/2022 at 11:30 am.