

|  |   |   |
|--|---|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>39D1088333      | <b>(X3) Date Survey Completed</b><br>03/12/2020 |
| <b>Name of Provider or Supplier</b><br>Rxtox Inc   | <b>Street Address, City, State</b><br>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>D5429</b>              | <p><b>MAINTENANCE AND FUNCTION CHECKS</b><br/>CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation, interview with the laboratory Testing Personnel, and review of the toxicology maintenance records on the date of the survey, the laboratory failed to document maintenance with at least the frequency specified by the manufacturer's frequency for 4 of 4 Kewaunee fume hoods &amp; 2 of 2 Thermo Fisher Scientific Sorval ST40 centrifuges. Findings include: 1. The surveyor observed service stickers dated 06/08/2016 on 2 of 2 Thermo Fisher Scientific Sorval ST40 centrifuges, no other centrifuge service stickers were observed required by the manufacture, 2. Thermo Fisher Scientific specifies annual tachometer checks for the Sorval ST40 centrifuges. 3. The surveyor observed service stickers dated 08/07/2017 on 4 of 4 Kewaunee fume hoods, no other fume hood service stickers were observed. 4. Kewaunee specifies annual maintenance checks for Kewaunee fume hoods. 5. During the survey at 3 pm 03/12/2020), the Toxicology Supervisor confirmed the above findings.</p> |
| <b>D6127</b>              | <p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b><br/>CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:</p>   |

Based on review of the competency records and interview of the Toxicology Supervisor on the date of the survey, Technical Supervisor #1 failed to evaluate the competency for 3 of 3 Technical Supervisors and 2 of 2 General Supervisors responsible for high complexity testing, from February 2018 to the date of survey. Findings include: 1. On the date of the survey (02/26/2019), Technical Supervisor #1 failed to produce annual competency documentation for 3 of 3 Technical Supervisors and 2 of 2 General Supervisors responsible for high complexity testing, from 02/15/2018 to the date of survey. 2. During the survey at 3:30 pm, the Toxicology Supervisor confirmed above finding.