

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2113834	(X3) Date Survey Completed 05/20/2021
Name of Provider or Supplier Tox Testing Inc	Street Address, City, State 16100 19 Mile Road Suite 200, Clinton Township, MI	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel #2 (TP2), the laboratory failed to label reagents and solutions with the strength or concentration, preparation dates, and expiration dates for three containers observed during the laboratory tour. Findings include: 1. During a tour of the laboratory on 5/20/21 at 8:52 am, the surveyor observed three reagent bottles that lacked strength or concentration of the solutions, preparation dates, and expiration dates labeled with the following: a. "Water + 4 mL FA" connected to the 4000 Qtrap toxicology analyzer. b. "LC/MS Needle Wash" connected to the 4000 Qtrap toxicology analyzer. c. "Needle Wash" found on the counter in the laboratory. 2. The surveyor requested the laboratory's reagent labeling policy on 5/27/21 at 12:51 pm and it was not made available 3. An interview on 5/20/21 at 8:51 am with TP2 revealed the reagent bottles listed above are all reagents that are prepared by the laboratory. "FA" stands for formic acid and the "Needle Wash" contains methanol, water, and isopropanol. TP2 confirmed the lack of strength or concentration of the solutions, preparation dates, and expiration dates listed on the reagent bottles listed above.</p>