

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2105504	<b>(X3) Date Survey Completed</b> 04/18/2018
<b>Name of Provider or Supplier</b> Bio Tox Laboratory Llc	<b>Street Address, City, State</b> 4619 Allen Road, Allen Park, MI	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain 1) patients report in the laboratory information system (LIS) and 2) the testing personnel performing the toxicology testing, and 3) the quality control records for three (#2-#4) of seven patient charts audited. Findings include: 1. On April 18, 2018 at 1:54 PM, record review for three of seven patient charts audited revealed 1) the patient's final report 2) the testing personnel performing the toxicology testing and 3) the quality control records for the toxicology testing was not available to the surveyor on the day of the survey. Results were on the old LIS system and irretrievable at the time of the survey. 2. During the interview on April 18, 2018 at 1:54 PM, general supervisor #1 as listed on the CMS-209 confirmed the patient test results, testing personnel, and the quality control records were not available to the surveyor at the time of the survey.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to verify the accuracy of testing for the urine toxicology testing for one (2017) of two years at least twice</p>

annually. Findings include: 1. On April 18, 2018 at 1:02 PM, record review for the verification of accuracy of the urine toxicology testing revealed there was no documentation to show the testing was completed at least twice annually in 2017 for the following panels and corresponding individual drugs as follows: a. Anti-Epileptics 1. Carbamazepine 2. Gabapentin 3. Pregabalin b. Anti-Psychotics 1. 9-Hydroxyrisperidone 2. Dehydro aripiprazole 3. Desmethylolanzapine 4. Haloperidol 5. Ioperidone 6. Ziprasidone c. Barbiturates 1. Butalbital 2. Phenobarbital 3. Secobarbital d. Benzodiazepines 1. 7-Amino Clonazepam 2. Alpha Hydroxyalprazolam 3. Alpha Hydroxytriazolam 4. Alprazolam 5. Lorazepam 6. Nordiazepam 7. Oxazepam 8. Temazepam e. Illicits 1. Benzoylcegonine 2. MDMA 3. PCP 4. THC-COOH f. Muscle Relaxants/Sedatives 1. Cyclobenzaprine 2. Meprobamate g. Opioids 1. 6-Acetylmorphine 2. Burprenorphine 3. Codeine 4. Fentanyl 5. Hydrocodone 6. Hydromorphone 7. Meperidine 8. Methadone 9. Morphine 10. Norbuprenorphine 11. Norfentanyl 12. Norhydrocodone 13. Normeperidine 14. Oxycodone 15. Oxymorphone 16. Tapentadol 17. Tramadol h. Others 1. 7-Hydroxymitragynine 2. Cotinine 3. Ketamine 4. Mitragynine 5. Norketamine 6. Zolpidem 7. Zolpidem P4CA i. - SSRI/SNRI 1. Duloxetine 2. Fluoxetine 3. N-Desmethylycitalopram 4. Paroxetine 5. Venlafaxine j. - Stimulants 1. Amphetamine 2. Methamphetamine 3. Phentermine 4. Ritalinic acid k. - TCA: Tricyclic Antidepressants 1. Amitriptyline 2. Desipramine 3. Imipramine 4. Nortriptyline 2. During the interview on April 18, 2018 at 1:02 PM, general supervisor #1 as listed on the CMS-209 confirmed the testing was not completed.

**D5415**

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

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.

This STANDARD is not met as evidenced by:  
. Based on observation and interview, the laboratory failed to label the toxicology reagents with the preparation and/or expiration date for the reagents "AA, MeOH, 5mm no FA, AB ammonium acetate + LCMS H2O + formic acid, B Acetonitrile Rinse 75% methanol 25% LCMS H2O and the IPA {needle rinse}" on the day of the survey. Findings include: 1. On April 18, 2018 at 9:20 AM during a tour of the laboratory, the surveyor observed bottled reagents in use that did not have documentation of a preparation and/or expiration date as follows: a. prep room - 1. AA - no preparation or expiration date 2. MeOH - no preparation or expiration date 3. 5mm no FA - no preparation or expiration date b. processing room - 1. AB ammonium acetate + LCMS H2O + formic acid - no expiration date 2. B Acetonitrile - no preparation or expiration date 3. Rinse 75% methanol 25% LCMS H2O - no expiration date 4. IPA - no preparation or expiration date 2. During the tour on April 18, 2018 at 9:20 AM, general supervisor #1 as listed on the CMS-209 confirmed the reagent bottles did not contain a preparation and/or expiration date.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview, the laboratory failed to perform and document 1) thermometer calibrations for 24 (April 18, 2016 to April 18, 2018) of 24 months, 2) pipette calibration for one (2017) of two years, and 3) weekly eyewash flush maintenance for one (November 2016) of 19 months reviewed. Findings include: 1. During a tour of the laboratory on April 18, 2018 at 9:20 AM, the surveyor observed a MarketLab thermometer in refrigerator #1 and one for room temperature with a calibration due date of 10/31/09. 2. On April 18, 2018 at 11:31 AM and 11:33 AM, record review of the "Maintenance, Temperatures, Pipettes, and Eyewash" manual revealed the lab did not have any documentation for the following: a. annual pipette calibration for one (2017) of two years reviewed from April 18, 2016 to April 18, 2018. b. eyewash flush revealed the laboratory did not have any documentation to show the weekly flush was completed for one (November 2016) of 19 months reviewed. 3. On April 18, at 9:20 AM, 11:31 AM, and 11:33 AM, general supervisor #1 as listed on the CMS-209 confirmed the thermometers and pipettes were not calibrated annually and the eyewash flush was not performed weekly in November of 2016. \*\*\*Repeat Deficiency from the October 3, 2016 survey\*\*\*

**D5785**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

. Based on document review and interview, the laboratory failed to document corrective action taken for the refrigerator temperatures for nine of 104 days of testing reviewed in 2017. Findings include: 1. On April 18, 2018 at 12:30 p.m., document review of the "Refrigerator Temperature Log" log sheets revealed there was no corrective action taken for the temperatures below the stated range of 2-8 degree C for nine of 104 days of testing reviewed in 2017 as follows: a. January - 30 (0.4) b. March - 28 (0.0), 29 (0.1), and 30 (0.0) c. April 5 (0.3), 6 (0.0), and 26 (1.6) d. May - 5 (1.7) and 12 (1.1) 2. During the interview on April 18, 2018 at 12:30 p.m., general supervisor #1 as listed on the CMS-209 confirmed no corrective action was documented for the out of range temperatures.