Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2167720	10/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Tox Testing Inc	1190 E 12 Mile Road Suite 2, Madison Heights, 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
D0000	The Tox Testing, INC laboratory survey was conducted for complaint MI000120992 in conjunction with the recertification survey. The allegation was found to be unsubstantiated. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003) for the following Condition: D5022: Toxicology
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to maintain test requisitions used to order toxicology testing for at least 2 years for 3 (October-December 2019) of 24 months reviewed. Findings include: 1. The surveyor requested test requisitions from October 2019 to October 2021 on 10/19/21 at 10:15 am and requisitions from October-December 2019 were not made available. 2. A review of the laboratory's "Laboratory Record Policy" revealed a section stating, "All requisition forms will be kept in the laboratory for three years or as mandated by the State." 3. An interview on 10/19/21 at 10:15 am with TP1 confirmed the laboratory did not have test requisitions available prior to January 2020.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

	This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to retain all proficiency testing records for at least 2 years for 3 (Events 1 and 2 in 2020 and Event 1 in 2021) of 3 testing events reviewed. Findings include: 1. A review of the laboratories American Proficiency Institute (API) proficiency testing records revealed a lack of documentation of results obtained from the test system for each of the proficiency testing samples for the following testing events: a. Chemistry Miscellaneous Event 1 2020 b. Chemsitry Miscellaneous Event 2 2020 c. Chemistry Miscellaneous Event 1 2021 2. A review of the laboratory's "Preservation of Records, Reports, and Specimens" revealed a lack of policy regarding proficiency testing records. 3. An interview on 10/19/21 at 11:36 am with TP1 confirmed the results of the proficiency testing samples from the test system were not available.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to maintain test reports of patient toxicology testing for at least 2 years for 3 (October-December 2019) of 24 months reviewed. Findings include: 1. The surveyor requested test reports from October 2019 to October 2021 on 10/19/21 at 10:15 am and requisitions from October-December 2019 were not made available. 2. A review of the laboratory's "Laboratory Record Policy" revealed a section stating, "All laboratory reports are stored in Laboratory computer. These reports will be kept in the laboratory computer for a period of two years or as mandated by State." 3. An interview on 10/19/21 at 10:15 am with TP1 confirmed the laboratory did not have test reports available prior to January 2020.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to meet the requirements for the specialty in Toxicology as specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to perform quality control testing each day of patient testing. Refer to D5445. 2. The laboratory failed to follow corrective action policies when quality control testing was not acceptable. Refer to D5779. ***This is a repeated Condition from the 3/16/20 initial certification survey***

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1, the laboratory failed to perform quality control testing each day of patient testing for 2 (1/8/21 and 3 /30/21) of 10 patient testing dates reviewed. Findings include: 1. A review of patient test records revealed a lack of quality control results for the following dates: a. Patient #7 was tested on 1/8/21 b. Patient #8 was tested on 3/20/21 2. A review of the laboratory's "Quality Control" procedure revealed it did not include how often quality control testing is required. 3. An interview on 10/19/21 at 1:52 pm with TP1 confirmed the laboratory did not have quality control documentation available for the dates listed above.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to follow corrective action policies when quality control testing was not acceptable for 1 (3/22/21) of 27 patient testing dates reviewed. Findings include: 1. A review of the laboratory's quality control records revealed the positive control tested negative for the Barbiturates assay. 2. A review of the laboratory's "Quality Control" policy revealed a section stating, "All qualitative controls for all kit testing and microbiology testing and stain QC (Wrights, Methylene Blue and Gram Stain) must be documented and initialed by the Operator in the appropriate quality control log. In the event that a qualitative control does not produce the acceptable result as stated 1n the control package insert, corrective action should be performed and documented. No patient results should be reported until the problem is resolved." 3. A review of the laboratory's "Corrective Action Protocol" revealed a section stating, "All problems and corrections must be documented to ensure continuity and communication in the laboratory and resolve future problems." and "All problems arising in the laboratory must be documented in the Corrective Action section of each manual." 4. A review of the laboratory's "Procedure for Out of Control Controls" revealed a section stating, "IF THE CONTROLS ARE "OUT OF CONTROL" the following steps will be followed to correct the problem: 1. Check controls and reagents for contamination, out dating or poor storage. 2. Re-analyze the same control - if results are. OK run patient -if they are still out of limits - 3. Use a fresh vial of

	controls - if they are O.K. run patient- if they are still out oflimits - 4. Calibrate the instrument (if applicable) and run 9ontrols again- if they are O.K. run patient - if they are still out of limits - 5. Call manufacturers for help or service if problem can be corrected by phone and controls come out - run patient - if not corrected - notify the ordering physician, send specimen out to reference lab for testing - or - specimens may be stored until problem is corrected - if storage is acceptable for test and result is not needed immediately. The decision to send out or store will be made by the ordering physician or laboratory director. 6. Record all QC corrective action and/or maintenance on instrument that was needed to correct control problem on remedial action logs. 5. An interview on 10/19/21 at 1:42 pm with TP1 revealed 7 patients had testing performed and reported on 3/22/21 and documentation of corrective action was not available.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to have the name of the laboratory on the test report for 10 (Patients 1-10) of 10 patient test records reviewed. Findings include: 1. A review of the laboratory test reports for patients 1-10 revealed the laboratory name listed was "Pro Toxicology Testing". 2. An interview on 10/19/21 at 9:55 am with TP1 confirmed the laboratory name on the test report was not the name of the laboratory.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the Laboratory Director failed to ensure proficiency testing reports were reviewed for 3 (Events 1 and 2 in 2020 and Event 1 in 2021) of 3 testing events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed a lack of review by the Laboratory Director. 2. A review of the laboratory's "Quality Assurance" policy revealed a section stating,

	"Proficiency Testing- must be performed according to the policy end procedures set forth In this manual. After results ere returned to the lab, the operator will review them end perform end document any corrective actions. The Technical Supervisor and Lab Director will review the results end corrective action, If applicable, will be implemented." 3. An interview on 10/19/21 at 11:36 am with TP1 confirmed there was no documentation of the Laboratory Director reviewing proficiency testing event performance. ***This is a repeated deficiency from the 3/16/20 initial certification survey***
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the Laboratory Director failed to ensure the quality assessment program was maintained for 2 (October 2019 to October 2021) of 2 years reviewed. Findings include: 1. The surveyor requested the laboratory's quality assessment documentation from October 2019 to October 2021 on 10/19/21 at 11:39 am and it was not made available. 2. A review of the laboratory's "Quality Assurance" policy revealed a section stating, "Quarterly. Quality Assurance Meeting- The Laboratory Director, Technical 'Supervisor, and all Technical Staff (if possible) will meet quarterly to assess the performance of the laboratory. The following agenda should be followed: Review follow up from previous quality assurance meeting. System Reviews: i) Reviews; Quality Control, Calibrations, Maintenance ii) Proficiency testing scores and corrective action iii) Patient Test Management: Case Studies iv) Personnel assessment v) Split Samples vi) Communications vii) Complaints viii) Patient demographics ix) Lab errors x) Lab review of QA" 3. An interview on 10/19/21 at 11:41 am with TP1 confirmed quality assessment documentation was not available.