Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2167720	03/16/2020
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to attest that proficiency testing samples were tested in the same manner as patient specimens for 1 (2nd event of 2019) of 1 proficiency testing event reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing data revealed a lack of attestation statement signed by testing personnel and the laboratory director. 2. An interview on 3/17/2020 at 10: 35 am with TP1 confirmed the laboratory did not have a signed attestation statement available for the testing event above.
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 the number and severity of the deficiencies cited herein, the Condition: Toxicology was not met. Findings include: 1. The laboratory failed to verify the performance specifications for cocaine toxicology testing. Refer to D5421.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to follow quality assessement policies for 5 (October 2019 to March 2020) of 5 months. Findings include: 1. A review of the laboratory's established "Quality Assurance" policy, approved by the laboratory director on 10/10/19 revealed a section titled "Quarterly" stating, "As part of the quality assurance policy, the Technical Supervisor and/or Technical Consultant or Laboratory Director will review Proficiency Testing results and will convene for quality assurance meetings: Proficiency Testing- must be performed according to the policy and procedures set forth in this manual. After results are returned to the lab, the Operator will review them and perform and document any corrective actions. The Technical Supervisor and Lab Director will review the results and corrective action, if applicable, will be implemented. 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: Reviews: Quality Control, Calibrations, Maintenance, Proficiency testing scores and corrective action, Patient Test Management: Case Studies, Split Samples, Communications, Complaints, Patient demographics, Lab errors, Lab review of QA." 2. A record review of the laboratory's documentation revealed a lack of documentation of quarterly quality assessments. 3. An interview on 3/16/2020 at 11:41 am with TP1 confirmed the laboratory has not followed quarterly quality assessment policies.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #1 (TP1), the laboratory failed to establish written procedures to perform toxicology testing for 5 (October 2019 to March 2020) of 5 months reviewed. Findings include: 1. An observation made by the surveyor on 3/16/2020 at 10:00 am revealed a Medica Easy

	RA toxicology analyzer present in the laboratory. 2. A review of the laboratory's procedures revealed a lack of procedure to perform toxicology testing using the Medica Easy RA analyzer. 2. An interview on 3/16/2020 at 10:46 am with TP1 confirmed the laboratory did not establish a procedure to perform toxicology testing.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to verify the performance specifications for cocaine toxicology testing for 5 (October 2019 to March 2020) of 5 months reviewed. Findings include: 1. A review of the laboratory's test menu revealed the laboratory performs cocaine testing. 2. A review of the laboratory's "Performance Validation Summary" revealed a lack of documentation of verification of performance specifications for cocaine testing. 3. When requested on 3/16/2020 at 10:53 am by the surveyor, the verification of performance specification data for cocaine testing was not made available. 4. An interview on 3/16/2020 at 10:53 am with TP1 confirmed the verification of performance specification data was not available.
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 results were reviewed for 1 (2nd Event 2019) of 1 event reviewed. Findings include: 1. A review of the laboratory's established "Quality Assurance" policy, approved by the laboratory director on 10/10/19 revealed a section titled "Quarterly" stating, "As part of the quality assurance policy, the Technical Supervisor and/or Technical Consultant or Laboratory Director will review Proficiency Testing results and will convene for quality assurance meetings: Proficiency Testing- must be performed according to the policy and procedures set forth in this manual. After results are returned to the lab, the Operator will review them and perform and document any corrective actions. The Technical Supervisor and Lab Director will review the results and corrective action, if

	applicable, will be implemented." 2. A review of the laboratory's American Proficiency Institute (API) "2019 Chemistry- Miscellaneous- 2nd Event" records revealed a lack of laboratory director and testing personnel reviews. 3. An interview on 3/16/2020 at 10:35 am with TP1 confirmed the laboratory director and testing personnel had not reviewed proficiency testing results.