Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2079031	11/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
American Toxicology	3340 Sunrise Ave Stes 103, 104, & 105, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on November 19, 2019. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a random audit of patient chemistry and toxicology requisitions and patient final reports from 1/17/18 through 10/29/19 and an interview with the laboratory manager, the laboratory failed to follow policies and procedures to ensure positive identification of patients's specimens from the time of collection through the completion of the testing and the reporting of the results. Findings include: A random audit of ten patient requisitions and the associated final test reports from 1/17/18 through 10/29/19 revealed one of ten patient requisitions with a collection date of 1/04 /18, indicated a date of birth (DOB) of 2/9/1979 on the requisition and a DOB of 2/9 /1974 on the patient final report. This was confirmed by the laboratory manager on November 19, 2019 at approximately 3:30 PM. The laboratory performs approximately 1,277,200 Chemistry and Toxicology tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the proficiency testing records for Chemistry and Toxicology for testing years 2018 and 2019 and an interview with the laboratory manager, the laboratory failed to, at least twice annually, verify the accuracy of all non-waived, non-regulated analytes in which the laboratory performs. Findings include: 1. The laboratory failed two of two events in testing year 2018 for Ethyl Glucuronide quantitative, Ethyl Glucuronide qualitative and Ethyl Sulfate. 2. There were no subsequent proficiency testing (PT) samples acquired from an accredited PT agency or other methods used to determine, at least twice annually, the verification of the accuracy of these three analytes for testing year 2018. This was confirmed by the laboratory manager on November 19, 2019 at approximately 1:30 PM. The laboratory performs approximately 1,277,200 Chemistry and Toxicology tests annually.
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 a random audit of Chemistry and Toxicology quality control performed from 1/17/18 through 10/29/19 and an interview with the laboratory manager, the laboratory failed to follow the director approved policy and procedure manual which states that both levels of quality control must be acceptable before patient test reports may be released. Findings include: 1. The laboratory failed to follow the director approved policy for quality control which states that both levels of quality control must be within the established acceptable range before patient results can be released. 2. A random audit of quality control performed from 1/17/18 through 10/29/19 found on 1/17/18, the quality control performed for PCP was outside of the acceptable range for PCP 1 and was within the acceptable range for PCP 2. There was no additional quality control performed on that date for PCP 1. 3. There was 1 of 90 patient Toxicology tests that were reported on 1/17/18 with a positive PCP. This was confirmed by the laboratory manager on November 19, 2019 at approximately 3:30 PM. The laboratory performs approximately 1,277,200 Chemistry and Toxicology tests annually.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure manual and an interview with the laboratory manager, the laboratory director failed to establish and maintain a quality assessment program to assure the quality of the laboratory services provided and identify failures in quality as it occurs. Findings include: 1. The laboratory director failed to have a policy established to assess the quality of the laboratory services provided on a regular basis for the pre-analytic, the analytic and the post-analytic phases of laboratory testing. 2. There was no documentation of quality assessment being performed for testing years 2018 and 2019. This was confirmed by the laboratory manager on November 19, 2019 at approximately 3:00 PM. The laboratory performs approximately 1,277,200 Chemistry and Toxicology tests annually.