Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 29D2079031	**(X3) Date Survey Completed** 03/06/2024
Name of Provider or Supplier American Toxicology	**Street Address, City, State** 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 March 6, 2024. 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.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: General Laboratory Systems was not met. The laboratory failed to obtain acceptable twice per year verification of accuracy results for high complexity toxicology for 2022 and 2023, the laboratory failed to evaluate the inaccurate results obtained and perform corrective action (see D5217), and the laboratory failed to establish a quality assessment program to detect and correct errors in the general laboratory systems when they occurred (see D5291).
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 laboratory proficiency testing policy and procedure, a review of the summaries of the 2022 test event number 2, and the 2023 test events 1 and 2 In-House Blind Spike proficiency testing results for those analytes not included in an approved proficiency testing program, and an interview with the laboratory technical supervisor on March 6, 2024 at approximately 11:30 AM, the laboratory failed to verify the accuracy of the LCMS-MS urine toxicology analytes twice annually, and failed to perform corrective action for the analytes that failed to meet the stated criteria for acceptability. Findings include: 1. The proficiency testing policy and procedure failed to define the criteria for acceptablility in order to evaluate the results of the In-House Blind Spike proficiency test specimens. The technical supervisor stated that the criteria for acceptability between the blind spike expected value of the analytes and the measured value obtained for the analytes was to be within 20%. 2. A review of the summary of the 2022 Blind Spike proficiency testing results event number two, dated 11/17/22 revealed that 37 of 42 analytes failed to meet the criteria for acceptability of less than 20% difference between the expected value and the measured value. There was no corrective action taken for the 37 unacceptable analytes. 3. A review of the summary of the 2023 Blind Spike proficiency testing results event number one dated 5/23/23 revealed that 34 of 36 analytes failed to meet the criteria for acceptability of less than 20% difference between the expected value and the measured value. There was no corrective action taken for the 34 unacceptable analytes. 4. A review of the summary of the 2023 Blind Spike proficiency testing results event number two dated 12/28/23 revealed that 35 of 39 analytes failed to meet the criteria for acceptability of less than 20% difference between the expected value and the measured value. There was no corrective action taken for the 35 unacceptable analytes. 5. There were four analytes that were not tested on the 2023 test event number one but were tested on event number two. Those four analytes were: maprotiline, mitragynine, quetiapine and sertraline. These four analytes tested during the second event failed to meet the criteria for acceptability of less than 20% difference between the expected value and the measured value. 6. The technical supervisor confirmed the findings during an interview conducted on March 6, 2024 at approximately 11:30 AM.
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 a review of the director approved quality assessment procedure, the laboratory quality assessment records between the dates of May 2022 and January 2024, and email correspondence with technical supervisor number 1 on March 13, 2024 at approximately 5:00 PM, the laboratory established quality assessment program failed to detect and correct failures in the general laboratory systems, specifically for the In-House Blind Spike twice per year verification of accuracy for

	analytes not included in a commercially available proficiency testing program. Findings include: 1. The director approved quality assessment policy failed to specify how to detect and correct failures in quality for all items that the laboratory monthly checklist indicated were to be reviewed each month. The policy stated, "The General Supervisor of the lab or designee will carry out the evaluation of Form F-003." Step 3 of the policy states, "For ten randomly selected Toxicology samples, verify that the monitoring aspects on F-003 are all met by placing a checkmark in each box." 2. A review of Form F-003 revealed that page 1 of 3 followed the items under review as referred to in the director approved policy. Instructions for evaluation of the items on page 2 of 3 of Form F-003 were not specified as part of the established quality assessment policy. 3. A review of the laboratory quality assessment records between the dates of May 2022 and January 2024 revealed that the laboratory quality assessment program failed to detect the unacceptable results for the In-House Blind Spike twice per year verification of accuracy studies, and failed to document the corrective action in the quality assessment reviews. (refer to D5217) 4. The findings were confirmed via email correspondence with technical supervisor number 1 on March 13, 2024 at approximately 5:00 PM. The laboratory performs approximately 1,800,000 toxicology tests annually.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation and an interview conducted on March 6, 2024 at approximately 1:30 PM with the technical supervisor and personnel number 9 listed on the CMS-209 form, the laboratory failed to ensure that calibration material used as for quality control procedures was from a different lot number than the lot number used to calibrate the pH validity and the urine creatinine test. Findings include: 1. During an interview with the technical supervisor and the testing personnel number 9 listed on the CMS-209 form conducted on March 6, 2024 at approximately 1:30 PM, it was revealed that the laboratory failed to ensure that calibrators used as quality control material for the pH validity and the urine creatinine were taken from a different lot number than that used to calibrate the test method. 2. It was observed during the course of the interview that the calibrators used for controls were from the same lot number as the lot used to calibrate the instrument for the pH validity test. It was stated that the calibration solutions used for control material were taken from a different shipment of the same lot number of material. The laboratory performs approximately 240,000 routine chemistry tests annually.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

	laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory records for the twice per year instrument comparisons between the LCMS-MS instruments, and an interview with the technical supervisors numbers 1 and 2 conducted on March 6, 2024 at approximately 3:45 PM, and email correspondence with technical supervisor number 1 on March 11. 2024, the director failed to establish a procedure for the performance of the twice per year instrument comparisons, the laboratory failed to perform instrument comparisons twice annually in 2022 and 2023 for all analytes tested on three of three LCMS-MS instruments, the laboratory failed to perform the instrument comparisons between three of three LCMS-MS instruments performing the same testing twice annually, and the laboratory failed to ensure that corrective action was taken for results that did not fall within the criteria for aceptability stated on the summaries for each of the comparison studies dated 6/16/22, 3/9/23, 7/17/23 and 2/29/24. Findings include: 1. A review of the summaries for the instrument comparisons performed on 6/16/22, 3/9 /23, 7/17/23, and 2/29/24 revealed that there was no consistent procedure for the performance of the instrument comparisons. A. The summary dated 6/16/22 stated that 30 samples were processed. B. The summary dated 3/9/23 stated that 40 samples were processed. C. The summary dated 7/17/23 stated that 20 samples were processed. D. The summary dated 2/29/24 stated that 20 samples were processed. E. An interview with technical supervisor number 1 on March 6, 2024 at approximately 3:45 PM revealed that there was no policy and procedure established for the performance of the twice per year instrument comparisons. 2. A review of each of the summaries revealed the laboratory failed to perform corrective action for the analytes that the laboratory detected a lack of correlation for between two LCMS-MS instruments. The summaries indicated that even though a percentage of the analytes did not correlate with each other, the overall correlation greater than 80% was acceptable between two instruments. Interviews conducted on March 6, 2024 at approximately 3:45 PM with the technical consultants 1 and 2 confirmed the finding. 3. Email correspondence on March 11, 2024 at approximately 8:00 AM with technical supervisor number 1 confirmed that the laboratory failed to perform the twice per year instrument comparisons on all analytes performed on three of three LCMS-MS instruments. 4. A review of the instrument comparison summaries dated 6/16/22, 3/9 /23, 7/17/23, and 2/29/24 revealed that the comparisons were performed between two of three instruments each time. A. The comparison study dated 6/16/22 indicated that the comparison was between LCMS1 and LCMS2, but did not specify which two of the three instruments were used for the study. B. The comparison study dated 3/9/23 indicated that the comparison was between LCMS 3 (API 4000) and LCMS 1 (API 3000). The 3/9/23 study did not indicate by serial number which API 4000 was used for the study. C. The comparison study dated 7/17/23 indicated that the comparison was between LCMS 2 (API 4000) and LCMS 1 (API 3000). The 7/17/23 study did not indicate by serial number which API 4000 was used for the study. D. The comparison study dated 2/29/24 indicated that the comparison was between LCMS 2 (API 4000) and LCMS 3 (API 4000). E. Email correspondence on March 11, 2024 at approximately 5:00 PM confirmed that the laboratory failed to perform the instrument comparisons on three of three LCMS-MS instruments during each study. This is a repeat deficiency that was previously cited on the recertification survey conducted on April 7, 2022.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the director approved quality assessment procedure, the laboratory quality assessment records between the dates of May 2022 and January 2024, and email correspondence with technical supervisor number 1 on March 13, 2024 at approximately 5:00 PM, the laboratory established quality assessment program failed to detect and correct failures in the analytic systems, specifically for the LCMS-MS instrument comparisons. Findings include: 1. The director approved quality assessment policy failed to specify how to detect and correct failures in quality for all items that the laboratory monthly checklist indicated were to be reviewed each month. The policy stated, "The General Supervisor of the lab or designee will carry out the evaluation of Form F-003." Step 3 of the policy states, "For ten randomly selected Toxicology samples, verify that the monitoring aspects on F-003 are all met by placing a checkmark in each box." 2. A review of Form F-003 revealed that page 1 of 3 followed the items under review as referred to in the director approved policy. Instructions for evaluation of the items on page 2 of 3 of Form F-003 were not specified as part of the established quality assessment policy. 3. A review of the laboratory quality assessment records between the dates of May 2022 and January 2024 revealed that the laboratory quality assessment program failed detect the unacceptable results for the instrument comparisons, and failed to document the corrective action in the quality assessment reviews for analytes that were unacceptable in the instrument to instrument comparisons performed. 4. The findings were confirmed via email correspondence with technical supervisor number 1 on March 13, 2024 at approximately 5:00 PM. The laboratory performs approximately 1,800,000 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 laboratory records of the 2022 and 2023 In-House Blind Spike proficiency testing for analytes not included in a commercially available proficiency testing program, a review of the laboratory records for the instrument comparisons for all LCMS-MS instruments used to perform the same analytes, a review of the laboratory quality assessment records between the dates of May, 2022 and January, 2024, an interview with technical supervisors numbers 1 and 2 on March 6, 2024 at approximately 1:30 PM, and email correspondence with technical supervisor number 1 on March 8, 2024, March 11, 2024, and March 13, 2024, the director failed to ensure that the established quality assessment program was maintained to assure the quality of the laboratory services provided and to identify failures in quality when they occurred. Findings include: 1. A review of the summary of the 2022 Blind Spike proficiency testing results event number two, dated 11/17/22

revealed that 37 of 42 analytes failed to meet the criteria for acceptability of less than 20% difference between the expected value and the measured value. There was no corrective action taken for the 37 unacceptable analytes. 2. A review of the summary of the 2023 Blind Spike proficiency testing results event number one dated 5/23/23 revealed that 34 of 36 analytes failed to meet the criteria for acceptability of less than 20% difference between the expected value and the measured value. There was no corrective action taken for the 34 unacceptable analytes. 3. A review of the summary of the 2023 Blind Spike proficiency testing results event number two dated 12/28/23 revealed that 35 of 39 analytes failed to meet the criteria for acceptability of less than 20% difference between the expected value and the measured value. There was no corrective action taken for the 35 unacceptable analytes. 4. There were four analytes that were not tested on event number one but were tested on event number two. Those four analytes were: maprotiline, mitragynine, quetiapine and sertraline. These four analytes tested during the second event failed to meet the criteria for acceptability of less than 20% difference between the expected value and the measured value. 5. A review of each of the 2022, 2023 and 2024 instrument comparison summaries for analytes performed on multiple analyzers revealed that the laboratory failed to perform corrective action for the analytes that the laboratory detected a lack of correlation for between two LCMS-MS instruments. The summaries indicated that even though a percentage of the analytes did not correlate with each other, the overall correlation greater than 80% was acceptable between two instruments. Interviews conducted on March 6, 2024 at approximately 3:45 PM with the technical consultants 1 and 2 confirmed the finding. 6. Email correspondence on March 11, 2024 at approximately 8:00 AM with technical supervisor number 1 confirmed that the laboratory failed to perform the twice per year instrument comparisons on all analytes performed on three of three LCMS-MS instruments. 7. A review of the instrument comparison summaries dated 6/16/22, 3/9/23, 7/17/23, and 2/29/24 revealed that the comparisons were performed between two of three instruments each time. A. The comparison study dated 6/16/22 indicated that the comparison was between LCMS1 and LCMS2, but did not specify which two of the three instruments were used for the study. B. The comparison study dated 3/9/23 indicated that the comparison was between LCMS 3 (API 4000) and LCMS 1 (API 3000). The 3/9/23 study did not indicate by serial number which API 4000 was used for the study. C. The comparison study dated 7/17/23 indicated that the comparison was between LCMS 2 (API 4000) and LCMS 1 (API 3000). The 7/17/23 study did not indicate by serial number which API 4000 was used for the study. D. The comparison study dated 2/29/24 indicated that the comparison was between LCMS 2 (API 4000) and LCMS 3 (API 4000). 8. The director approved quality assessment policy failed to specify how to detect and correct failures in quality for all items that the laboratory monthly checklist indicated were to be reviewed each month. The policy stated, "The General Supervisor of the lab or designee will carry out the evaluation of Form F-003." Step 3 of the policy states, "For ten randomly selected Toxicology samples, verify that the monitoring aspects on F-003 are all met by placing a checkmark in each box." 9. A review of Form F-003 revealed that page 1 of 3 followed the items under review as referred to in the director approved policy. Instructions for evaluation of the items on page 2 of 3 of Form F-003 were not specified as part of the established quality assessment policy. 10. A review of the laboratory quality assessment records between the dates of May 2022 and January 2024 revealed that the laboratory quality assessment program failed to detect the unacceptable results for the In-House Blind Spike twice per year verification of accuracy studies, and failed to document the corrective action in the quality assessment reviews. (refer to D5291) 11. A review of the laboratory quality assessment records between the dates of May 2022 and January 2024 revealed that the laboratory quality assessment program failed detect the unacceptable results for the

	instrument comparisons, and failed to document the corrective action in the quality assessment reviews for analytes that were unacceptable in the instrument to instrument comparisons performed. (refer to D5791). The laboratory performs approximately 1,800,000 toxicology tests annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on a review of the director approved policies and procedures and an interview with technical supervisor 1 on March 6, 2024 at between approximately 2:00 PM and 4:00 PM, the director failed to ensure that there was a procedure manual that was current for all of tests and activities conducted by the laboratory. Findings include: 1. There was no director approved policy and procedure established for the performance of the twice per year instrument comparisons for analytes tested on more than one analyzer. 2. There was no director approved policy and procedure for the performance of annual pipette calibration that the laboratory performs. 3. There was no criteria for acceptability established for the blind spike proficiency testing samples in the director approved proficiency testing policy. 4. The findings were confirmed during an interview with technical supervisor 1 on March 6, 2024 between approximately 2:00 PM and 4:00 PM. The laboratory performs approximately 1,800,000 toxicology tests annually.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory personnel training and competency records, a review of the CMS-209 form, and an interview with technical supervisor number 1 on March 6, 2024 at approximately 10:00 AM, the technical supervisor failed to ensure that semi-annual training and competency assessment was completed during the first year of employment for one of four personnel that perform LCMS-MS toxicology testing. Findings include: 1. A review of the laboratory personnel training and competency records revealed that the technical supervisor failed to ensure that one of four testing personnel underwent semi-annual training and competency assessment for the performance of the LCMS-MS toxicology testing. 2. The training and competency assessment records revealed that the LCMS-MS training document was mislabeled as six month training for personnel number 4 listed on the CMS-209 form. The technical supervisor stated during an interview conducted on March 6, 2024 at approximately 10:00 AM that personnel number 4 was initially performing only moderate complexity testing, and confirmed that the LCMS-MS training document should have been labeled as an initial training document. The laboratory performs approximately 1,800,000 toxicolog tests annually.