

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2079031	(X3) Date Survey Completed 04/07/2022
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	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on April 7, 2022. 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.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) proficiency testing (PT) original evaluations for the 2021 Ethanol Biomarkers (ETB) events A and B, and an interview with the technical supervisor and the laboratory director, the laboratory failed to evaluate the laboratory results obtained using the participant summary for those results not reported to CAP because they exceeded the analytical range for the tests or no credit was given due to the lack of a response. Findings include: 1. There was no documentation of a review of the participant summary for the 2021 Ethanol Biomarkers (ETB) test event A for the ethyl glucuronide immunoassay quantitative results for specimen numbers ETB-01 and ETB-03, and for the ethyl glucuronide and ethyl sulfate LCMS/MS quantitative results for specimen number ETB-01. The laboratory did not report the immunoassay ethyl glucuronide results for specimens ETB-01 and ETB-03 because the results obtained exceeded the analytical range for</p>

the test. The laboratory did not report the ethyl glucuronide and ethyl sulfate results for specimen ETB-01 because the laboratory indicated that quantitation would not be appropriate for those analytes as they were absent from the specimen. 2. There was no documentation of a review of the participant summary for the 2021 Ethanol Biomarkers (ETB) test event B for the ethyl glucuronide immunoassay quantitative results for specimen numbers ETB-05 and ETB-06, and for the ethyl glucuronide and ethyl sulfate LCMS/MS quantitative results for specimen number ETB-06. The laboratory did not report the immunoassay ethyl glucuronide results for specimens ETB-05 and ETB-06 because the results obtained exceeded the analytical range for the test. The laboratory did not report the ethyl sulfate result for specimen ETB-06 because the laboratory indicated that quantitation would not be appropriate for those analytes as they were absent from the specimen. The laboratory did not submit a result for the LCMS/MS ethyl glucuronide test, and received no credit due to lack of a response. 3. The findings were confirmed during an interview with the technical supervisor and the laboratory director conducted on April 7, 2022 at approximately 1:00 PM. The laboratory performs approximately 1,277,200 toxicology 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 2020 and 2021 laboratory records for the comparison of results for tests performed on more than one instrument and an interview with the laboratory director and the technical supervisor, the laboratory failed to ensure that comparison of the results for the urine drug screen tests, the urine adulterant tests, and the urine drug confirmatory tests performed on multiple instruments was performed twice a year. Findings include: 1. A review of the instrument comparison records for 2020 and 2021 revealed that the laboratory failed to perform the instrument comparisons for the urine drug screen and urine adulterant testing twice a year on the Abbott Architect chemistry analyzers. The laboratory performed the comparisons one time in 2020. The laboratory failed to perform the comparisons in 2021. 2. A review of the instrument comparison records for 2020 and 2021 revealed that the laboratory failed to perform the instrument comparisons for the urine drug confirmation testing twice a year on the AB Sciex LC-MS/MS analyzers. The laboratory performed the comparisons one time in 2020. The laboratory failed to perform the comparisons in 2021. 3. The findings were confirmed during an interview conducted on April 7, 2022 at approximately 1:00 PM with the laboratory director and the technical consultant. The laboratory performs approximately 1,277,200 toxicology tests annually.

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 a review of the laboratory test report and an interview with the laboratory director and the technical consultant, the laboratory failed to ensure that the address of the laboratory was correct on the final report. Findings include: 1. A review of the laboratory report revealed that the address listed on the laboratory final report was not correct. The laboratory address listed on the report neglected to include both Suite 104 and 105, as designated on the laboratory CLIA certificate. 2. The finding was confirmed during an interview with the laboratory director and the technical consultant during an interview conducted on April 7, 2022 at approximately 3:45 PM. The laboratory performs approximately 1,277,200 toxicology tests annually.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory training and competency assessment records, a review of the director approved policy and procedure, a review of the completed CMS-209 form, and an interview with the laboratory director and the technical supervisor, the director failed to ensure that initial training and competency assessment for the Abbott Architect chemistry analyzer was completed prior to the performance of testing for testing personnel number six listed on the CMS-209 form. Findings include: 1. A review of the laboratory training and competency assessment records revealed that there was no documentation of initial training and competency assessment for testing personnel number six listed on the CMS-209 form prior to the performance of laboratory testing for urine adulterants, and urine drug screens on the Abbott Architect chemistry analyzer. 2. The director approved policy and procedure entitled, "Training and Competency Testing," in the section entitled, "Training" stated, "New laboratory workers should be trained when first hired on the procedures they will be performing in the laboratory." 3. The findings were confirmed during an interview conducted on April 7, 2022 at approximately 10:30 AM with the laboratory director and the technical supervisor. The laboratory performs approximately 1,277,200 toxicology tests annually.

D6116

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(3)

The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.

This STANDARD is not met as evidenced by:
 Based on a review of the College of American Pathologists (CAP) 2020, and 2021 urine toxicology proficiency testing (PT) records, a review of the CAP 2022 Proficiency Testing catalog, a review of the laboratory 2022 CAP Proficiency Testing enrollment confirmation and an interview with the technical supervisor and the laboratory director, the technical supervisor failed to ensure that the laboratory enrolled in the proficiency testing program intended for the quantitative urine drug screen confirmation testing by liquid chromatography-mass spectrometry (LC-MS/MS). Findings include: 1. A review of the CAP proficiency testing records for 2020 urine toxicology events one, two and three, a review of the 2021 urine toxicology events one, two and three revealed that the evaluation of the submitted results were for qualitative urine drug screen testing. The laboratory performs quantitative confirmatory testing by LC-MS/MS for urine drug screens. 2. A review of the laboratory's 2022 CAP proficiency testing enrollment revealed that the laboratory was enrolled in the Urine Toxicology (UT) PT program. 3. A review of the CAP 2022 Proficiency Testing catalog revealed that the Urine Toxicology proficiency testing program that the laboratory was enrolled in was not intended for quantitative confirmation of urine drug screen results. The catalog stated that the Urine Toxicology proficiency testing program was intended for "Screening and/or confirmatory drug analysis WITHOUT quantitation (no quantitation)." 4. The findings were confirmed by the technical supervisor and laboratory director during an interview conducted on April 7, 2022 at approximately 10:00 AM. The laboratory performs approximately 1,277,200 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 director approved policy and procedure entitled, "Training and Competency Testing," a review of the laboratory CMS-209 form, a review of the laboratory training and competency assessment records, and an interview with the technical supervisor and the laboratory director, the technical supervisor failed to ensure that new personnel underwent semi-annual training and competency assessment during the first year of testing specimens. Findings include: 1. There was no documentation of the semi-annual training and competency assessment for testing personnel number five listed on CMS-209 form in the performance of the urine drug screen testing and the urine adulterant testing on the Abbott Architect chemistry analyzer. 2. The director approved policy and procedure entitled, "Training and Competency Testing" stated in the section entitled, "Training" in step five, the policy and procedure states, "For new employees, this training is to be repeated after six months and annually thereafter." 3. The technical supervisor stated that the testing person was not a new employee, but had moved into the testing personnel position after obtaining the education and certification to qualify for that position. The finding that the semi-annual training was not completed was confirmed during an interview with the technical supervisor and the laboratory director conducted on April 7, 2022 at approximately 10:30 AM. The laboratory performs approximately 1,277,200 toxicology tests annually.