Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2062750	01/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Toxicology, Llc	1809 E 13th Street, Ste 301, Tulsa, OK	

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 recertification survey was performed on 01/28/2021. The findings were reviewed with the technical supervisor and testing person #3 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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 review of records, written policies and procedures, and interview with the technical supervisor, the laboratory failed to follow written policies and procedures to ensure the optimum integrity of patient specimens from the time of collection through the reporting of results for 28 of 28 patient specimens. Findings include: (1) On 01/28 /2021 at 10:25 am, the technical supervisor stated to the surveyor the laboratory performed urine drug confirmation testing using the Shimadzu LCMS 8040 analyzer; (2) The surveyor reviewed the "Specimen Collection" procedure under the section of "Urine Specimen Collection" which stated: (a) "9. Analyze the sample immediately. If this is not possible, the sample should be stored refrigerated, for up to 5 days."; (3) The surveyor reviewed 28 patient reports tested between 08/06/2020 and 09/11/2020 and identified the following for 28 of 28 patient reports: (a) 12 specimens were collected on 08/06/2020, received and analyzed in the laboratory on 08/12/2020 (7 days after collection); (b) 7 specimens were collected on 08/11/2020, received and analyzed in the laboratory on 08/17/2020 (7 days after collection); (c) 9 specimen were collected on 09/11/2020, received and analyzed in the laboratory on 09/17/2020

	(7 days after collection). (4) The surveyor reviewed the reports with the technical supervisor. The technical supervisor stated on 01/28/2021 at 01:10 pm the patient specimens were tested beyond the laboratory's specimen stability as indicated above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical supervisor, the laboratory failed to perform a clinical consultant competency based on the position responsibilities as listed in Subpart M for 1 of 1 clinical consultant. Findings include: (1) On 01/28/2021, the surveyor reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence a competency assessment for the clinical consultant, based on their job responsibilities, had been performed; (2) The surveyor asked the technical supervisor if a competency assessment based on job responsibilities had been performed for the clinical consultant; (3) The surveyor asked the technical supervisor if a written policy to evaluate the clinical consultant based on job responsibilities was available. The technical supervisor stated on 01/28/2021 at 11:15 a policy had not been written and the above competencies had not been performed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical supervisor, the laboratory failed to ensure materials were stored as required by the manufacturer for 4 of 4 months. Findings include: (1) On 01/28/2021 at 09:55 am, the technical supervisor stated the following to the surveyor: (a) Certified Reference Material 7-Aminoclonazepam was stored in the laboratory refrigerator and used for the following: (i) Urine Drug Confirmatory testing performed on the Shimadzu LCMS-8030 analyzer. (2) The surveyor reviewed the manufacturer's environmental requirements for the 7-Aminoclonazepam reference material, which required a storage temperature 2 to 8 degrees C (Celsius); (3) The surveyor reviewed laboratory temperature records from September 2020 through December 2020 and identified the following for 4 months of 4 months: (a) Temperatures had been documented as warmer than 8 degrees C as follows: (i) September 2020 - 7 of 11 days the documented temperature was greater than 8 degrees C (days 2,8,10,14,23,24,30); (ii) October 2020 - 5 of 8 days the documented temperature was greater than 8

	degrees C (days 5,7,12,21,28); (iii) November 2020 - 4 of 8 days the documented temperature was greater than 8 degrees C (days 4,9,18,23); (iv) December 2020 - 6 of 9 days the documented temperature was greater than 8 degrees C (days 2,5,7,14,21,28. (4) The surveyor reviewed the records with the technical supervisor. The technical supervisor stated on 01/28/2021 at 01:00 pm the laboratory failed to ensure materials were stored as required by the manufacturer as indicated above.
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 a patient test report and interview with the technical supervisor, the laboratory failed to ensure test reports included the name and address of the laboratory where the testing was performed for 1 of 1 patient report. Findings include: (1) On 01/28/2021 at 11:00 am, the surveyor asked the technical supervisor to explain the laboratory's process when the analyzer was inoperable. The technical supervisor stated on 01/28/2021 at 11:03 am, the samples were sent to a reference laboratory.; (2) The surveyor then asked at 11:05 to review 1 patient report that had been sent to the reference laboratory: (a) Report #1 - The testing was reported on 01/13/2021, and included a result for qualitative results for a confirmatory urine drug screen. (2) The surveyor identified the following: (a) The report included the name and address of the laboratory instead of the name and address of the reference laboratory where the testing was performed. (3) The surveyor reviewed the report with the technical supervisor. The technical supervisor stated on 01/28/2021 at 11:20 am the name and address where the test was performed was not included on the report.