Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2062750	11/05/2018
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	Recertification survey was perfomed on 11/05/18. The findings were reviewed with the technical supervisor/testing person #1 at the conclusion of the survey. The laboratory was found to be in compliance with standard-level deficiencies cited.
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/testing person #1, the laboratory failed to perform a technical supervisor competency based on the position responsibilities as listed in Subpart M. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed personnel records for competency assessments performed during 2017 and 2018. There was no evidence a technical supervisor competency for technical supervisor, based on their job responsibilities, had been performed; (2) Surveyor #2 asked the technical supervisor/testing person #1 if a technical supervisor competency based on job responsibilities had been performed for technical supervisor. The technical supervisor stated a technical supervisor competency based on job responsibilities had not been performed.
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 records and interview with the technical supervisor/testing person #1, the laboratory failed to verify the accuracy of specimen adulteration testing at least twice annually. Findings include: (1) At the beginning of the survey, the technical supervisor/testing person #1 stated to the surveyors the laboratory performed adulteration testing for urine drug specimens using the UrineCheck 7 Drug Adulteration Test Strips. The adulteration testing included: Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Bleach, and Pyridinium Chlorochromate; (2) Later during the survey, surveyor #1 reviewed 2017 and 2018 testing records. There was no documentation the testing had been verified for accuracy in 2017 and to date in 2018; (3) Surveyor #1 asked the technical supervisor/testing person #1 if specimen adulteration testing had not been verified for accuracy in 2017 and to date in 2018. The technical supervisor/testing person #1 stated the testing had not been verified for accuracy during the review period.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the technical supervisor/testing person #1, the laboratory failed to perform a negative and positive control each day of patient testing. Findings include: (1) At the beginning of the survey, the technical supervisor/testing person #1, stated to the surveyors the laboratory performed adulteration testing for urine drug specimens using the UrineCheck 7 Drug Adulteration Test Strip. The testing included: Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Bleach, and Pyridinium Chlorochromate; (2) Later during the survey, surveyor #1 reviewed records for patient testing performed from April through October 2018. The review indicated negative QC (quality control) testing had not been performed for each constituent on the test strips for 57 of 57 days of patient testing. The laboratory had only performed QC testing with results that were positive for adulteration. The testing did not include negative results for Creatinine, Nitrite, Glutaraldehyde, Specific Gravity, Bleach, and Pyridinium Chlorochromate. The specific days were: (a) April - 05,10,12,17,20,24,27 (b) May - 01,04,08,11,16,22,24,29,31 (c) June - 05,07,12,14,20,25,28 (d) July - 02,05,10,12,17,20,24,26,31 (e) August - 02,07,09,14,16,20,22,28 (f) September - 04,06,11,13,18,20,25,27 (g) October - 02,04,09,11,16,18,22,25,30 (3) Surveyor #1 reviewed the records with the technical supervisor/testing person #1 who stated that negative QC materials had not been performed each day of patient testing.