Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0911241	04/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Drugs Of Abuse Testing Laboratory, Inc	2626 South Sheridan Road, Suite 500, 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 findings were reviewed with the laboratory director at the conclusion of the survey.
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 review of records, policies and procedures, and interview with the laboratory director, the laboratory failed to have a written policy for verification of the accuracy of urine creatinine testing. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor, urine drug screen testing was performed using 2 Beckman Coulter AU480 analyzers, which were put into use on 08 /04/17 to replace the MGC analyzers. In addition, the laboratory director stated to the surveyor urine creatinine testing was performed to ensure the urine had not been adulterated prior to drug screen testing. (Because urine creatinine is not a regulated analyte, twice per year accuracy verification is required); (2) The surveyor reviewed records from 08/04/17 through the day of the survey for accuracy verification of urine creatinine testing performed on the Beckman Coulter AU480 analyzers. The surveyor identified the laboratory performed comparison testing of urine creatinine, as follows: (a) 2017: (i) 2 patient samples were split and analyzed in-house and at a reference laboratory on 09/28/17; (ii) There was no documentation the results had been evaluated and found to be acceptable; (iiii) There was no documentation the accuracy of the testing had been verified. (b) 2018: (i) 2 patient samples were split and analyzed in-house and at a reference laboratory on 01/19/18 and on 03/19/18; (ii) There was no documentation the results had been evaluated and found to be

	acceptable. (3) The surveyor asked the laboratory director how the results of the split sample testing listed above had been evaluated. The laboratory director stated to the surveyor the results were compared and if they were close, the testing was determined to be acceptable; (4) The surveyor then reviewed the laboratory procedure manual but could not locate a procedure for the performance and evaluation of the twice per year accuracy verification of urine creatinine testing; (5) The surveyor then asked the laboratory director if the laboratory had a written policy and procedure for the twice per year accuracy verification of urine creatinine testing that would include guidance on the evaluation of results and determination of the accuracy of the testing. The laboratory director stated to the surveyor, the laboratory did not have a written policy and procedure for the accuracy verification.