Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1086270	04/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wv Drug Testing Laboratories Inc	1422 East Main Street, Princeton, WV	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to enroll in proficiency testing for the analyte of Urine Creatinine for 6 of 6 PT events reviewed. Review was from May 2016 to April 2018. The findings: 1. Review of the laboratory's PT records identified no PT results for Urine Creatinine for 2016 Event 2, 2016 Event 3, 2017 Event 1, 2017 Event 2, 2017 Event 3 and 2018 Event 1. 2. On 4/3/18 at approximately 1:15 PM, the LD confirmed the findings.
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 review of the laboratory's proficiency testing records and interview with the

	Laboratory Director (LD), the laboratory failed to perform twice annual verification of accuracy of Urine Specific Gravity performed on the AU480 from May 2016 to April 2018. The findings include: 1. Review of the laboratory's records from May 2016 until April 2018 identified no documentation of twice annual verification of accuracy of Urine Specific Gravity performed on the AU480. 2. On 4/3/18 at approximately 1:15 PM, the LD confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration/calibration verification records and interview with the Laboratory Director (LD), the laboratory failed to perform and document calibration verification every 6 months for Urine Creatinine and Urine Specific Gravity performed on the Olympus 480. Record review was from May 2016 to April 2018. The findings include: 1. Review of the Olympus 480 calibration /calibration verification records from May 2016 to April 2018 identified no calibration verification from May 2016 to April 2018. 2. On 4/3/18 at approximately 2:00 PM, the LD confirmed the findings.