Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2007155	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Wv Drug Testing Laboratories	1531 Garfield Avenue, Parkersburg, 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
D0000	An announced, on site recertification survey was conducted at WV Drug Testing Laboratories on March 12, 2020 by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratories Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
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 laboratory College of American Pathologist (CAP) proficiency testing (PT) records, the test menu for the Au 400 chemistry/toxicology analyzer, quality assurance (QA) records, and an interview with testing personnel (TP1) and the laboratory director (LD), the laboratory failed to verify the accuracy of Tramadol and 6AM testing, which are not included in Subpart I, twice a year. Findings: 1. A review of CAP PT records from 2018 and 2019 identified no enrollment for the analytes Tramadol and 6AM in the CAP PT program. 2. A review of the test menu for the Au 400 chemistry/toxicology analyzer identified testing for the analytes Tramadol and 6AM. 3. A review of QA records for the moderate complexity testing identified no documentation of verifying the accuracy of Tramadol and 6AM testing twice a year. 4. During an interview with TP1, on 3/12/2020 at approximately 9:30 AM, TP1 stated that there was no documentation for verifying the accuracy of Tramadol and 6AM testing twice a year. TP1 stated that the laboratory was not enrolled in commercial PT for the analytes Tramadol and 6AM. 5. During an interview with the LD, on 3/12 /2020 at approximately 2:00 PM, the LD stated that the laboratory had not performed

	commercial PT or alternate accuracy verification for Tramadol and 6AM. The LD stated that a written policy and procedure would be established and adhered to for verifying the accuracy of Tramadol and 6AM twice a year.
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 written laboratory policies and procedures (P&P), monthly maintenance logs, and an interview with testing personnel (TP1) and the laboratory director (LD), the laboratory failed to define, monitor, and document criteria for conditions of (1) water quality for accurate and reliable test system operation and test result reporting for the Au 400 chemistry/toxicology analyzer. Findings: 1. The laboratory written P&P were reviewed. No written P&P defining suitable water quality for the operation of the Au 400 chemistry/toxicology analyzer was found. 2. Monthly instrument maintenance logs were reviewed. No documentation of monitoring for water quality was found. 3. During an interview with TP1, on 3/12 /2020 at approximately 10:00 AM, TP1 stated the only documentation of monitoring the water quality of the Evoqua water system for the Au 400 chemistry/toxicology analyzer were Evoqua service invoices. TP1 stated Evoqua came to the facility twice a year for preventative maintenance or service on the water system. 4. During the exit interview with the LD, on 3/12/2020 at approximately 2:00 PM, the LD stated there was no written P&P to define, monitor, and document the water quality for the Au 400 but one will be established and implemented.