Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1086270	06/06/2024
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
D0000	A routine recetification survey was conducted at WV Drug Testing Laboratories Inc. Mercer Day Report on June 6, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of analyzer validation records, patient test results, and interview the laboratory failed to update the (6) reportable range for one of 13 analytes to reflect the

	Thermofisher Indiko Plus toxicology analyzer performance specifications. Findings: 1. Review of the Thermofisher Indiko Plus toxicology analyzer validation records (put into use January 2023) identified an established reportable range (cutoff) for fentanyl testing as 100% (1 ng/ml). 2. Review of a patient test report (6/6/24) identified the reportable range (cutoff) for fentanyl as 100 ng/ml. 3. An interview with the laboratory director (LD), 6/6/24 at 9:30 AM, confirmed the discrepant cutoff values for one of 13 analytes (fentanyl).