Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2046907	07/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Clearway Laboratory	7920 Mcdonogh Rd #204, Owings Mills, MD	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 the laboratory written procedure and interview with the technical supervisor, the toxicology laboratory's written procedure failed to state how long between calibrations (or calibration verification) patient testing may be performed before recalibrating the analytes tested using the Mindray analyzer. Findings: 1. The laboratory performed toxicology screens on patient urine samples using the Mindray analyzer. 2. The laboratory written procedure stated that calibration of the toxicology analytes (oxycodone, methadone, cocaine, phencyclodine, cannabinoids,

	benzodiazepines, barbiturates, amphetamines, MDMA, opiates, creatinine) must be performed when new lots of reagent are used or when quality control testing failed, but the procedure did not state the maximum amount of time that can pass before each analyte requires recalibrating. 3. The laboratory must cite references in the written procedure to support the maximum allowable period of time between calibrations. 4. This was confirmed during interview with the technical supervisor on 7/30/26 at 11:30 am.