

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2046907	(X3) Date Survey Completed 11/21/2022
Name of Provider or Supplier Clearway Laboratory	Street Address, City, State 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory worksheets for recording maintenance on the liquid chromatography tandem mass spectrometry (LC-MS/MS) toxicology analyzers, standard operating procedure (SOP), and interview with the technical supervisor (TS), the laboratory's procedure manual failed to include ranges of acceptability on one worksheet and identification of the worksheet used for comparison of the three LC-MS /MS toxicology analyzers. Findings: 1. On the worksheet labeled "Urine Drug Pain Management Daily Maintenance for 4500MD" the testing personnel are required to record the "Record Source", "Record Curtain", and "Record Exhaust." The SOP listed</p>

a mean for the "source", "curtain" and "exhaust", but did not provide an acceptable range for each and corrective actions to be taken when the value is outside of the limits of acceptability. 2. The worksheet used to evaluate the three LC-MS/MS analyzers using proficiency testing (PT) samples does not include a title explaining the purpose of the worksheet and what are the ranges for acceptability of the values recorded for the three LC-MS/MS analyzers. The SOP does not define the acceptable limits between the three analyzers and corrective actions to be taken when the comparisons are not within the defined limits of acceptability. 3. During the survey on 11/21/2022 at 12:45 PM, the TS confirmed that the laboratory's SOP did not include written acceptable ranges for the "source", "curtain" and "exhaust" for the maintenance performed on the 4500MD analyzer, acceptable comparison limits between the three LC-MS/MS analyzers, and corrective actions to be taken when the recorded values are not within the limits of acceptability.