

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2046907	<b>(X3) Date Survey Completed</b>  07/12/2018
<b>Name of Provider or Supplier</b>  Clearway Laboratory	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on temperature record review and interview with the technical specialist (TS), the laboratory did not define criteria for those conditions that are essential for proper storage of reagents for accurate and reliable test system operation, and test result reporting. Findings: 1. The laboratory put three new refrigerators in to use in March, 2018. The refrigerators and the freezers above them were labeled, "R2" and "F2," "R3" and "F3," and "R4" and "F4." 2. "R2" is used as storage for reagents, controls, and calibrators for an in-use chemistry analyzer, as well as urine specimens in tubes which are to be run for toxicology analysis; "R3" is used as storage for cups of urine from satellite offices which have not been processed; and "R4" is used as storage for cups of urine from satellite offices which have not been processed, as well as urine toxicology samples which are to be sent out to a reference laboratory or for stat analysis. Nothing is stored in "F2," "F3," or "F4." 3. Daily temperatures were recorded, but the temperature logs did not include the acceptable temperature range for the refrigerators or freezers in order to determine if daily temperatures were within range; and 4. During an interview on 7/12/18 at 1:15 PM, the TS stated that they "wanted to let it run for a while" before establishing the temperature range and confirmed that the laboratory did not define the acceptable temperature range for the new refrigerators and freezers.</p>

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on review of the proficiency testing (PT) records and interview with the laboratory manager, the laboratory director did not ensure that the PT final summary reports were reviewed and corrective actions taken when necessary. Findings: 1. The PT records from the second event of 2016 through the first event of second event or 2018 were reviewed. The PT final summary reports showed that seven of nine summaries did not include a documented review (signature and date) by the laboratory director. 2. During the exit interview on 07/12/18 at 1:15 PM the manager confirmed that seven of nine summaries did not include a documented review by the laboratory director.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

I. Based on review of the quality assessment (QA) records and interview with the laboratory manager, the laboratory director did not ensure that the QA documentation included problems with proficiency testing events. Findings: 1. During the survey the monthly laboratory director QA worksheets for 2017 and 2018 were reviewed. The section labeled "PT problems" indicated that no problems were found each month during that time period. 2. The PT records showed that for the first event in 2017, UDC-A, there were no records. When interviewed the laboratory manager stated that the laboratory had not contacted the PT agency to renew their subscription to receive Forensic urine drug specimens for 2017. The laboratory enrolled late and only received 3 of the 4 events for 2017. 3. The monthly laboratory director QA worksheets did not indicate the failure to enroll in PT in a timely manner and that the PT summary reports were not being reviewed (signed and dated) for 7 of 9 events. Cross refer to D6091 for details. 4. During the survey on 07/12/18 at 1:15 PM the laboratory manager confirmed that the monthly QA worksheets did not include documentation of the failure to enroll in PT and that the PT summaries were not being documented as having been reviewed as required. II. Based on record review and interview with the laboratory manager, the laboratory director (LD) did not ensure that quality assurance (QA) reviews included a review of refrigerator temperature and instrument maintenance logs. Findings: 1. A review of "Urine Drug Pain Management Daily Maintenance" logs from January, 2017 to June, 2018 showed that monthly maintenance logs were not reviewed by the LD for 4 of 18 months; and 2. A review of refrigerator temperature logs from January to June, 2018 showed that the monthly refrigerator log for the "R1" refrigerator was not reviewed in February, 2018. 3. During an interview on 7/12/18 at 1:15 PM, the laboratory manager confirmed that the QA reviews did not include a review of temperature and instrument maintenance logs.