Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2046907	07/16/2021
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory procedure manual and temperature log review, and interview with the technical supervisor (TS), the laboratory did not ensure that the procedure for taking refrigerator and freezer temperatures accurately reflected the current practice in the laboratory. Findings: 1. The procedure, "LAB 105.0 Daily Temperature Checks" states that "Each thermometer in use is checked to monitor reagent storage temperatures daily. If any storage area exceeds its recommended temperature and cannot be immediately corrected, the contents must be transferred to another temperature-controlled environment. Any out-of-range documentation must include corrective action taken, a recheck of temperature to ensure corrective action remedy, and an evaluation of the integrity of the reagent or product contents before reagent or product can be used for laboratory testing." 2. The temperature range for laboratory refrigerator "R3" is 2 to 8 degrees C. From July through December, 2020 the laboratory documented the "max" (maximum) and "min" (minimum) temperatures recorded on the digital thermometer when daily temperatures were not documented while the laboratory was closed. On 25 occasions, the recorded "max" and "min" temperatures were outside of the laboratory's acceptable range with no corrective action documented. 3. The laboratory is not recording refrigerator and freezer temperature every day as stated in the "Daily Temperature Checks" procedure, and the procedure does not state what actions to take if the "max" and "min" temperatures fall outside of the laboratory's acceptable range while the laboratory is closed. 4. During an interview on 7/16/2021 at 9:00 AM, the TS confirmed that the laboratory did not

	ensure that the procedure for taking refrigerator and freezer temperatures accurately reflected the current practice in the laboratory.
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 procedure and instrument manual and temperature log record review, email communication with the laboratory consultant, and interview with the technical supervisor (TS), the laboratory failed to define, monitor, and document laboratory room temperature and room humidity to ensure proper reagent storage and reliable test system operation. Findings: 1. The laboratory performs urine toxicology testing on a Mindray BA-800M chemistry analyzer and an AB Sciex 4500MD LC-MS/MS. 2. Instrument manual review showed that the "Working Conditions" required for the Mindray BA-800M analyzer are listed as "Temperature: 15-30 C" and "Humidity: 35-85%" and; 3. The "Environmental Conditions" required for the AB Sciex 4500 MD LC-MS/MS are "an ambient temperature of 15 C to 30 C (59 F to 86 F)" and "Relative humidity from 20% to 80%, non-condensing." 4. The "Site Planning Guide" for the AB Sciex 4500 MD also states, "Over time, the temperature must remain within a range of 4 C (7.2 F), with the rate of the change in temperature not exceeding 2 C (3.6 F) per hour. Ambient temperature fluctuations exceeding the limits might result in mass shifts in spectra." 5. In an email from 4/21/2021 the laboratory consultant stated, "There are no specified temp ranges for the instruments - they shut down automatically if necessary" and in an email from 6/1/2021 they stated, "We are not keeping humidity records because neither instrument states that is a requirement." 6. Laboratory temperature log review from 2019 and 2020 showed that neither room temperatures nor room humidity was documented. 7. During an interview on 7/16 /2021 at 9:00 AM the TS confirmed that the laboratory failed ensure reliable test system operation by defining acceptable room temperature and humidity ranges and documenting room temperatures and humidity in the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on chemistry instrument maintenance record review and interview with the technical supervisor (TS), the laboratory did not ensure that maintenance was performed on the chemistry analyzer as recommended by the manufacturer. Findings: 1. The laboratory uses a Mindray BA-800M chemistry analyzer to perform urine

	toxicology analysis. 2. A review of monthly chemistry analyzer maintenance records from 2019 and 2020 showed that monthly instrument maintenance was not documented 6 out of 12 months in 2019 and 3 out of 12 months in 2020. "Three Month" maintenance was not documented 2 out of 4 times in 2019 and 3 out of 4 times in 2020, and "Six Month" maintenance was documented 1 out of 2 times in 2020. 3. "Weekly Maintenance" was not documented 1 of 4 weeks in Jan, 2020; 2 of 5 tasks ("Clean Wash Wells" and "Clean Filter Core") were not documented in August 2020; and 2 of 5 tasks ("Clean Rotors" and "Clean Filter Core") were not documented in October 2020. 4. During an interview on 7/16/2021 at 9:00 AM, the TS confirmed that the laboratory did not perform and document maintenance on the Mindray BA-800M chemistry analyzer as defined by the manufacturer and with at least the frequency specified by the manufacturer. II. Based on chemistry instrument maintenance record review and interview with the technical supervisor (TS), the laboratory did not ensure that maintenance was performed on the chemistry analyzer as recommended by the manufacturer. Findings: 1. The laboratory uses an AB Sciex 4500MD LC-MS/MS chemistry analyzer to perform urine toxicology analysis. 2. The "Urine Drug Pain Management Daily Maintenance for 4500MD AB-1" log lists 2 tasks under "Weekly (Monday)" maintenance: 1. "clean curtain plate surface with HPLC water and then Methanol" and 2. "Make 20% IPA and water (seal wash) in pump A and Pump B." 3. A review of monthly chemistry analyzer maintenance records from 2019 and 2020 showed that in 2019, "task 1" was performed 7 of 11 weeks in January, February, and October, and "task 2" was performed 7 of 41 weeks in January through December; and 4. In 2020, "task 1" was performed 4 of 6 weeks in May and October, and "task 2" was performed 13 of 40 weeks in January through December. 5. During an interview on 7/16/2021 at 9:00 AM, the TS confirmed that the laboratory did not perform and document maintenance on the AB Sciex 4500MD LC-MS/MS chemistry analyzer as defined by the manufacturer and with at least the frequency specified by the manufacturer.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on temperature log record review and interview with the technical supervisor (TS), the laboratory failed to document corrective action when the laboratory refrigerator and freezer temperatures were out of range. Findings: 1. Laboratory refrigerator and freezer temperature logs were reviewed from July through December, 2020. 2. The temperature range for laboratory refrigerator "R1" is 3.9 to 5 degrees Celsius (C). From September through November, 2020, temperatures were out of range 6 out of 65 times taken on "R1" with no corrective action documented. 3. The temperature range for laboratory freezer "F1" is -17 to -20 degrees C. From August through September, 2020, temperatures were out of range 3 out of 43 times taken on

	"F1" with no corrective action documented. 4. Maximum and minimum temperatures documented for laboratory refrigerator "R3" during weekends and times when the laboratory was not open were out of range with no corrective action documented. Cross-refer to D5401. 5. In an email from 4/21/21 the laboratory consultant stated, "We do not take temps on weekends, but our thermometers do track if they're out." 6. During an interview on 7/16/2021 at 9:00 AM, the TS confirmed that there were no corrective actions documented for the days that the refrigerator and freezer temperatures were out of range.