Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0208053	07/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
B & W Stat Laboratory	3104 Georgia Ave Nw, Washington, DC	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with technical consultant (TC), the lab failed to document the lot numbers and expiration dates of all Toxicology reagents and controls. Findings: 1. The lab failed to document the lot numbers and expiration dates of the Toxicology calibrators when running patient samples on the Olympus AU640. 2. Review of quality control (QC) data performed during the year 2025. Showed on the day of the survey July 24, 2025, at 11:00 AM that lab testing personnel did not document the analyzer calibrator lot numbers and expiration dates to ensure accurate and reliable patient testing. 3. The TC confirmed on the day of the survey July 24, 2025, at 11:00 AM that lab testing personnel failed to document the analyzer calibrator lot numbers and expiration dates to ensure accurate and reliable patient testing.
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 review of the written procedure manual, review of the analyzer maintenance logs, and interview with the technical consultant (TC), the lab failed to document corrective action procedures when the Chemistry analyzer was not functioning. Findings: 1. The lab failed to document corrective action procedures on the Chemistry analyzer when the analyzer was not working during the month of June 2025. 2. The lab did not document the reason the analyzer was not working, the time frame the analyzer was down, did not document that patients were not tested during the time that the analyzer was down, and did not document that service was completed on the analyzer on June 20, 2025. 3. Review of the Toxicology Chemistry analyzer Olympus AU640 "1" maintenance log for June 2025 on the day of the survey July 24, 2025, at 12:30 PM showed that maintenance procedures were performed and documented on the Olympus AU640 "1" log sheet for Toxicology testing. 4. The TC stated on the day of the survey July 24, 2025, at 12:30 PM that the analyzer for performing Toxicology testing was down for the whole month of June 2025. 5. The testing person stated to the TC on the day of the survey July 24, 2025, at 12:30 PM that he performed maintenance procedures on the Olympus AU640 "2" which was not used to perform Toxicology testing and he documented the maintenance procedures on the incorrect Chemistry analyzer log which was the Chemistry analyzer Olympus AU640 "1" the analyzer that is used to perform Toxicology testing. 6. The TC confirmed on the day of the survey July 24, 2025, at 12:30 PM that the lab failed to document corrective action procedures when the Chemistry analyzer was not functioning.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys established performance specifications; This STANDARD is not met as evidenced by: Based on review of the written procedure manual, review of the analyzer maintenance logs, and interview with the technical consultant (TC), the TC failed to ensure that corrective action procedures were performed when the Chemistry analyzer was not functioning. Findings: Refer to D5781