Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0706861	08/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Phyllis Hyde Md	46 Livingston Street, Brooklyn, NY	

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 direct observation, review of Quality Control (QC) records, control material manufacturer's specifications, Standard Operating Procedures (SOPs), as well as interview with the Laboratory Director (LD), the laboratory failed to remove from inventory control materials that exceeded their expiration date. FINDINGS: 1. The surveyor's observations confirmed on August 26, 2025, at approximately 11:00 A.M. the following control materials were not removed from inventory as required by the current, approved SOPs and manufacturer's specifications. a. Control Material, Boule Multi-Parameter Assayed Hematology Control, lot: 22503, expiration: August 12, 2025. 2. LD informed the surveyor that the respective expired control materials were utilized for patient specimen processing. Approximately four patient specimens were processed utilizing the respective expired control materials on August 13, 2025. 3. LD confirmed the findings on August 26, 2025, at approximately 11:00 A.M.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

	This STANDARD is not met as evidenced by: Based on review of QC records, SOPs, as well as interview with the LD, the laboratory failed to perform and document corrective action for unacceptable QC results which failed to meet the laboratory's established criteria for acceptability to ensure reporting of accurate and reliable patient results. FINDINGS: 1. Approximately four patient specimens were processed utilizing the respective expired control materials on August 13, 2025. 2. There was no documentation of repeated QC performance prior to patient specimen testing and result reporting. 3. This is contrary to instructions indicated in the current, approved SOPs. 4. The LD confirmed the findings on August 26, 2025, at 11:00 A.M. Refer to D5417.