Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2227488	05/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Brookhaven Heart Pllc	915 Hillside Avenue, Suite C, New Hyde Park, 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
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 Quality Control (QC) records, Standard Operating Procedures (SOPs), as well as interview with the Technical Consultant (TC), the laboratory failed to perform and document corrective action for analyzer calibration materials failing to meet laboratory's established criteria for acceptability. FINDINGS: 1) FT3 Immunoplus 3 Lot #85293, Expiration: August 31, 2023, was out three standard deviations from March 1, 2023, and March 3, 2023. 2) Approximately 1000 patients were tested. 3) There was no documentation of QC corrective action performance and evaluation of patient test results to determine if test results were adversely affected. 4) This is contrary to instructions indicated in the current, approved SOPs. 5) The TC confirmed the findings on May 7, 2025, at approximately 11:30 A.M.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on review of QC records, SOPs, as well as interview with the TC, the TC failed to ensure QC and established parameters for acceptable levels of analytic performance were maintained throughout the entire testing process. Refer to D5783.