Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2164245	10/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Long Island Heart And Vascular Specialist Pc	1600 Stewart Avenue - Ste 105, Westbury, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's standard operating procedures (SOPs), lack of thermometer calibration records, as well as interviews with the Technical Consultant (TC) and Testing Personnel (TP) #1, the laboratory failed to draft and approve procedures for thermometer calibration. FINDINGS: 1. There was no calibration certificate documentation for the thermometer utilized for room temperature and humidity monitoring where patient specimen processing and waived test storage occurred. 2. The current, approved SOPs did not include instructions for thermometer

	calibration and calibration certificate retention. 3. The TC and TP #1 confirmed the findings on October 9, 2025, at approximately 11:30 A.M.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of analyzer system operations manuals, lack of analyzer calibration records, as well as interviews with the TC and TP #1, the laboratory failed to follow manufacturer's calibration and verification instructions. FINDINGS: 1. There was no documentation of Abbott i-Stat calibration verification performance in August 2025. It was noted that the analyzer calibration material was discarded due to expiration. 2. There was no documentation of Sysmex Pochi-100i calibration performance in April 2024. It was noted that analyzer calibration was performed and documented for October 14, 2024. Approximately 200 patients tested in calendar year 2024. 3. These are contrary to instructions indicated in the current, approved Abbott i-Stat and Sysmex Pochi-100i operations manuals which require calibration verification performance every six months using the Trical (3 levels) material. 4. The TC and TP #1 confirmed the findings on October 9, 2025, at approximately 11:00 A.M. Repeated citation from on-site survey conducted March 24, 2023.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

	This STANDARD is not met as evidenced by: Based on review of analyzer system operations manual, lack of Quality Control (QC) records, as well as interview with the TC, the laboratory failed to verify the criteria for acceptability of all control materials. FINDINGS: 1. There was no documentation of QC current lot to new lot validation performance for the Abbott i-STAT analyzer from date of implementation through the survey date. 2. This is contrary to instructions indicated in the current, approved Abbott i-STAT analyzer operations manual. 3. Approximately 300 patients were tested for calendar years 2023 and 2024. 4. The TC confirmed findings on October 9, 2025, at approximately 11:30 A.M. Repeated citation from on-site survey conducted March 24, 2023.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and 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: Based on the review of SOPs, analyzer system operations manuals, lack of analyzer calibration, QC, and thermometer calibration records, as well as interviews with the TC and TP #1, the Laboratory Director (LD) failed to ensure that the quality control and quality assessment programs were maintained to assure the quality of laboratory services provided and to identify failures in quality as the occur. Refer to D5403, D5439, and D5469.