Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2164245	03/24/2023
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
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 the review of thermometer used in laboratory to monitor temperature and humidity, the laboratory failed to document serial number, calibration certificate, and calibration expiration date. Confirmed finding on an interview with technical consultant and testing person #1 on 3/24/2023 about 11:45am.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 the calibration verification records for the I-Stat, Abbott I-Stat operation's manual, lack of the calibration records, the laboratory failed to perform and document the calibration verification every six-months. FINDINGS: 1. The Abbott I-Stat operations manual requires calibration verification every six months using the Trical (3 levels) material. 2. Calibration not performed 2020 through survey date. Approximately 591 patients tested for calendar year 2022. 3. Confirmed finding on an interview with technical consultant and testing person #1 on 3/24/2023 about 11am.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control (QC) records, the laboratory failed to perform a verification of current lot number to new lot number of the hematology analyzer Sysmex pocH-100i and chemistry analyzer Abbott i-STAT. FINDINGS: 1. The new QC lot to lot validation documentations of hematology analyzer Sysmex pocH-100i and chemistry analyzer Abbott i-STAT not available from implementation date to survey date. Approximately 591 patients tested for calendar year 2022. 2. The laboratory technical consultant confirmed finding on an interview on 3/24/2023 about 11:30am.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 laboratory policies and procedures, and laboratory records, the laboratory director, and technical consultant failed to quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5439, D5469, D5413