Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 33D2102021	**(X3) Date Survey Completed** 02/28/2024
Name of Provider or Supplier Premier Cardiology Consultants Pllc	**Street Address, City, State** 2001 Marcus Avenue, Suite E247-E249, Lake Success, 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**
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 current, approved standard operating procedures (SOPs), the laboratory failed to draft, approve analyzer calibration protocols. FINDINGS: 1. The current, approved SOPs did not include instructions for performance and

	documentation of Abbott i-STAT analyzer calibration and frequency of calibration. 2. The practice manager (PM) confirmed the findings on February 28, 2024, at approximately 11:30 A.M.
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 current, approved SOPs and Quality Control (QC) records, the laboratory failed to establish or verify criteria for control material acceptability as well as perform lot number verifications. FINDINGS: 1. There was no documentation of new QC lot to lot validation verification performance for the i-STAT analyzer. 2. The current, approved SOPs did not include instructions for performing such activities. 3. The PM confirmed the findings on February 28, 2024, at 11:00 A.M.