Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2065738	06/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
New York Heart And Vascular Services Pc	1471 Dekalb Avenue, 4th Floor, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the College of American Pathologist (CAP) proficiency testing (PT) 3rd event records for 2021 and 2022, the lack of chemistry PT records, and an interview with the technical consultant and laboratory testing person, the laboratory failed to enroll in an approved PT program for the specialty chemistry for all three events in 2021. Refer to D6015. FINDINGS 1. Review of CAP records for the 3rd event of 2021, hematology event records for 2022, and lack of chemistry records for 2021, the laboratory failed to enroll in the CAP chemistry module for all three events in 2021. a. The laboratory was enrolled in CAP for all three modules ACT /hematology and chemistry in 2022 and 2023. 2. The technical consultant and laboratory testing person confirmed on June 22, 2023, at approximately 2:30 P.M., that the laboratory did not enroll in CAP PT program for the specialty chemistry for all three events in 2021. a. The laboratory was performing the Chem 8+ panel, Hgb, and Hct on the Abbott I-Stat analyzer.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment policy (QA), QA record review, and an interview with the technical consultant and laboratory testing person, the laboratory failed to follow established QA policies for performing Abbott I-Stat chemistry analyzer calibration verification in the calendar years 2021 and 2022, failure to enroll in PT for the chemistry specialty in 2021 and take corrective action and resolve errors as they occurred. FINDINGS: 1. The laboratory QA policies includes a monthly review for the following General Laboratory Systems: Preanalytic, Analytic, and Preanalytic Systems. 2. Review of the monthly QA records and documents for 2021 and 2022 confirmed the lack of corrective action to resolve PT and QC system errors. a. The laboratory failed to enroll in a PT program for chemistry in 2021. b. The laboratory failed to perform Abbott I-Stat chemistry analyzer calibration verification for the calendar years 2021 and 2022. 3. The technical consultant and laboratory testing person confirmed on June 22, 2023, at approximately 3:00 P.M., the laboratory failed to perform Abbott I-Stat chemistry analyzer calibration verification for the calendar years 2021 and 2022, failure to enroll in PT for the chemistry specialty in 2021 and take corrective action and resolve errors as they occurred.
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 Abbott I-Stat chemistry analyzer, I-Stat operation's manual, lack of the calibration verification records for 2021 and 2022, and an interview with the technical consultant and laboratory testing person, the laboratory failed to perform and document the calibration verification

	every six-months for the calendar years 2021 and 2022. FINDINGS: 1. The Abbott I-Stat operations manual required calibration verification every six months using the Trical (3 levels) calibration material. 2. The laboratory failed to perform the required calibration verification for the calendar year 2021 and 2022. a. The laboratory performed calibration verification on the I-Stat analyzer on 11/17/2020 and again on 5 /3/2023. b. Approximately 200 patients were tested during the calendar years 2021 and 2022.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the PT CAP records, the lack of 2021 CAP PT chemistry records, and confirmed by an interview with the technical consultant and laboratory testing person at the time of survey, the laboratory director failed to ensure that the laboratory was enrolled in an approved PT program for the specialty chemistry for all three events in 2021. Refer to D2000.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the Quality Assessment policy (QA), QA record review, and confirmed by an interview with the technical consultant and laboratory testing person at the time of this survey, the laboratory director failed to follow established QA policies regarding Abbott I-Stat chemistry analyzer calibration verification for the calendar years 2021 and 2022, failed to enroll in PT for the specialty chemistry specialty in 2021, and take corrective action and resolve errors as they occurred. Refer to D5291 and D5439.