Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2064080	09/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Benemed Physician Pc	101-19 39th Avenue, Suite 101, Corona, 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 American Proficiency Institute (API) proficiency testing (PT) records for 2022 and 2023, the lack of chemistry PT records, and an interview with the chief operations officer, the laboratory failed to enroll in an approved PT program for the Abbott I-Stat Chem 8+ panel for all three events in 2022 and 2023. Refer to D6015. FINDINGS 1. Review of API records for the test analyte's Troponin and Brain /B-type natriuretic peptide (BNP) 2022 and 1st & 2nd events of 2023, and lack of chemistry I-Stat Chem 8+ panel API records for 2022 and 1st & 2nd events of 2023, the laboratory failed to enroll in the API chemistry module for I-Stat Chem 8+ panel for all three events in 2022 and 1st & 2nd event of 2023. a. The laboratory was enrolled in API for all three modules Troponin and BNP in 2022 and 2023. 2. The chief operations officer confirmed on September 19, 2023, at approximately 10:30 A. M., that the laboratory did not enroll in API PT program for I-Stat Chem 8+ panel for all three events in 2022 and 1st & 2nd event of 2023. a. The laboratory was performing the Chem 8+ panel on the Abbott I-Stat analyzer.
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 lack of the 2022 and 2023 calibration verification records for the Abbott I-Stat chemistry analyzer, I-Stat operation's manual, and an interview with the chief operations officer, the laboratory failed to perform and document the calibration verification every six-months for the I-Stat Chem 8+ panel calendar years 2022 and 2023. 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 2022 and 2023 3. The chief operations officer confirmed on September 19, 2023, at approximately 11:30 A.M., that the laboratory failed to perform the required calibration verification for the calendar year 2022 and 2023. a. Approximately 700 patients were tested during the calendar years 2022 and 2023.
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 API records for 2022 and 2023, the lack of chemistry PT records, and an interview with the chief operations officer, the laboratory director failed to ensure that the laboratory was enrolled in an approved PT program for the Abbott I-Stat Chem 8+ panel for all three events in 2022 and 2023. Refer to D2000.