Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0665314	10/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Patient First-General Booth	1605 General Booth Blvd, Virginia Beach, VA	

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
D0000	An announced virtual CLIA recertification survey was conducted for Patient First-General Booth on October 15, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included a remote initial record review conducted on 10/14/21. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
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 a review of calibration verification records for the Abbott point of care chemistry analyzer, manufacturer's technical support representative, and interviews, the laboratory failed to follow the six (6) month calibration verification protocols for eight (8) of 8 chemistry analytes during the twenty-four (24) months reviewed. Findings include: 1. Review of the laboratory's calibration verification records (timeframe of October 2019 to October 2021) for Sodium (Na), Potassium (K), Chloride (Cl), TCO2, Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN) /Urea, and Creatinine (Creat) reported on the iSTAT analyzer (Serial Number 337556), revealed the following documentation: 02/05/20 Calibration Validation to establish reportable range studies performed and accepted by TC and lab director; 08 /01/20 Calibration Verification performed and accepted by site supervisor; 06/02/21 Calibration Verification performed and accepted by site supervisor. The inspector requested to review documentation of calibration verification performed in the timeframe of February 2021 for Na, K, Cl, TCO2, iCa, Glu, BUN, and Creat on the iSTAT. The documentation was not available for review. The Director of Laboratory Services stated at approximately 12:30 PM: "We are in the process of updating the iSTAT procedure that should eliminate confusion on the six month requirement. The supervisor previously performed the iSTAT calibration verification at each of Abbott's software updates. The updates do not always coincide with the 6 month cal verification due date." 2. During a call to Abbott Technical support on 10/15/21 at 1: 00 PM, the inspector inquired of calibration verification protocols for the non-waived Chem 8 test cartridges. The technical support representative stated: "Calibration verification of analytical measurement ranges are to be validated by the lab after each CLEW software update and at six month intervals. The test levels within the tri level linearity kit cover the complete measurement range of the test cartridge parameters". 3. An interview with the TC and Director of Laboratory Services on 10/15/21 at approximately 1:30 PM confirmed the above findings.