Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0227481	08/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Patient First - Woodman	2300 East Parham Road, Richmond, 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 CLIA recertification survey was conducted at Patient First-Woodman on August 10, 2021 by the Virginia Department of Health's Office of Licensure and Certification. 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:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of procedures, instrument maintenance logs, analyzer verification records, patient test logs, and an interview, the laboratory failed to retain evaluation /verification documentation per the lab director's approved procedure for a newly installed chemistry analyzer utilized for reporting non-waived analytes Sodium (Na+), Potassium (K+), Chloride (Cl-), Ionized Calcium (iCa), Carbon Dioxide (CO2), Glucose (GLU), Blood Urea Nitrogen (BUN), and Creatinine prior to reporting four thousand six hundred four (4,604) patient Chem 8 panels between June, 18 2020 and the date of the inspection on August, 10, 2021. Findings include: 1. Review of the laboratory procedure manual revealed a quality assurance procedure (titled: iSTAT Chem8 Validation Process). The procedure outlined "verification process to collect statistically valid data to assess the performance of the Abbott iSTAT handheld

	instrument". The procedure outlined: Accuracy and Precision: "will be confirmed by running 20 sets of Level 1 and Level 3 controls. Do not change lot numbers during the accuracy and precision studies; Correlation Data and Reference Range: "results will be correlated by comparing patient results to patient results run on an established analyzer"; Calibration Verification/Reportable Range: "Run Levels 1, 3, 5 iSTAT calibration verification samples to substantiate the instrument's calibration throughout the reportable range; The inspector noted that the validation procedure outlined above was approved by the lab director (LD) on January 23, 2020 and reviewed/signed again in March 2021. 2. During a review of Abbott iSTAT chemistry analyzer maintenance and quality control logs (from January 2020 through August 10, 2021), the inspector noted a new iSTAT chemistry analyzer was in use as of June 2020 (Serial Number SN324412 was put in use for Chem8 testing on 06/18/20). 3. Review of the available analyzer performance verification documentation revealed no records of evaluation /verification of accuracy/precision or correlation/reference range studies for the analyzer outlined above. The inspector requested to review documentation that the LD approved/verified the newly installed Abbott iSTAT prior to patient testing in June 2020. The technical consultant (TC) stated on 8/10/21 at approximately 2:30 PM: "We switched out the handheld for a new device during that time. I did verify three levels of controls during the installation month." No additional LD approved validation documentation was available for review. 4. Review of the patient test logs revealed that the laboratory reported 4,604 patient Chem 8 panels (Na+, K+, Cl-, iCa, CO2, GLU, BUN, and Creatinine) from 6/18/20 to 8/10/21. 5. In an exit interview with the TC, on 8/10/21 at approximately 3:30 PM, the above findings were confirmed.