Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226367	09/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Patient First-Genito	11020 Hull Street Rd, Midlothian, 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 the Patient First- Genito on September 23, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and in compliance with the applicable COVID-19 reporting requirements.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), daily patient logs, instrument

	printouts, lack of documentation, and interview, the lab failed to follow the established P&P for printing and logging the internal electronic simulator calibration for 16 of 304 days of testing from 08/1/20 up to 05/31/21. Findings include: 1. The lab utilizes the Abbott i-STAT hand-held analyzer to perform chemistry (Chem 8+) blood panels on patient samples. The lab utilizes an i-STAT daily log sheet to record patient and quality control (QC) procedures to include the performance of the daily internal electronic simulatory calibrations. 2. A review of the P&P "Quality Assessment-Overview" (approved by the lab director on 02/21/20), "Chemistry, i-STAT, Calibration" revealed the following statements: "the performance of each handheld analyzer is verified each day of testing by using either an internal or external electronic simulator every 24 hours of use. The results are printed and logged each day of testing." 3. Review of the daily patient log sheets from 08/01/20 up to 05/31/21 revealed lack of documentation of printed and logged internal electronic simulator calibration for the following dates: 10/12/20 and 11/16/20; 11/11/20, 11/17/20, 11/21 /20, and 11/26/20; 12/2/20, 12/8/20, and 12/15/20; 1/29/21; 2/3/21, 2/9/21, and 2/11 /21; 3/6/21 and 3/20/21; and 4/2/21. Total of 16 days. 4. An exit interview with two technical consultants on 09/22/21 at approximately 3 PM confirmed the findings.