Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0228735	08/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Patient First - Holland Road	3432 Holland Road, 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 CLIA recertification survey was conducted at Patient First-Holland Road on August 16, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of daily temperature/environment logs, lack of documentation, procedures, and interviews, the laboratory failed to retain documentation of monitoring daily relative humidity percent (%) and room/refrigerator/freezer temperatures per their protocols for two (2) of twelve (12) months in calendar year 2022 as reviewed on the date of the inspection on August 16, 2023. Findings include: 1. Review of the laboratory environmental log records for calendar year 2022 revealed no record of laboratory room temperature/humidity or refrigerator/freezer temperature monitoring for the following months: January and February - a total of 2 months lacked temperature log records. The inspector requested to review documentation of temperature logs for the 2 months outlined above. No additional records were available for review. The supervisor stated on 8/16/23 at 1:30 PM, "The monitoring is required to be documented as outlined on the temperature log sheets. These two months' requested logs have possibly been misfiled". The technical consultant (TC)

	requested time to look into the matter. 2. Review of the laboratory's procedures revealed Quality Assurance protocol that outlined daily monitoring of environmental conditions that included laboratory room temperature/ humidity and refrigerator /freezer temperatures. The inspector noted that the protocol outlined the following equipment to record: Thermometer Serial CCC04749 (Refrigerator) Thermometer Serial V53093-V53860 (Freezer) Thermometer Serial 181713367 (Room Temperature) Thermometer Serial Catalog # 240046 (Stand alone) Lot #40-041 (Refrigerator) Lot #01780551 (Freezer) Lot #913005551 (Stand alone) 3. An interview with the TC and supervisor on 8/16/23 at 2:30 PM confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of instrument maintenance logs, lack of documentation, and interviews, the laboratory failed to retain documentation of required hematology analyzer maintenance protocols for two (2) of twelve (12) months in calendar year 2022 as reviewed on the date of the inspection on August 16, 2023. Findings include: 1. A review of the laboratory's Pentra 60+ hematology analyzer's maintenance logs revealed the following schedule of required procedures: Daily - check reagents, perform start up, general cleaning, shutdown Weekly - perform concentrated cleaning, back flush, rinse cytometer Bi-Weekly - empty cap piercing filter-monthly based on volume The inspector noted no record of the above required maintenance documentation for the months of January and February in calendar year 2022. 2. The inspector inquired regarding the above 2 month lack of documentation and requested to review corrective action. No documentation was available for review. The inspector inquired of the laboratory's policy related to the frequency of the maintenance. The supervisor stated on 8/16/23 at 1:30 PM, "The maintenance is required to be documented as outlined on the log sheets. These two months' requested logs have possibly been misfiled". The technical consultant (TC) requested time to look into the matter. 3. An interview with the TC and supervisor on 8/16/23 at 2:30 PM confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) records, lack of documentation, and interviews, the technical consultant (TC) failed to retain documentation of annual competency evaluations performed for eight (8) of 8 TP in calendar year 2022. Findings include: 1. Review of the CMS 209 form revealed that

	the laboratory director identified one TC and 8 TP as responsible for performing non waived patient chemistry iSTAT Chem 8 Panel, hematology Complete Blood Cell (CBC), endocrinology serum Human Chorionic Gonadotropin (hCG), and Microscopic examination of Potassium Hydroxide (KOH)/Pinworm/Fecal Leukocyte Prep/Urine Sediment testing during the review timeframe of January 2022 to the date of the inspection on 8/16/23. 2. Review of the laboratory personnel files for the review timeframe (January 2022 to 8/16/23) revealed annual competency assessments for the non waived testing outlined above was documented in March 2023 by the TC. The inspector requested to review annual competency assessments for TP 1 - 8 performed in calendar year 2022. No records were available for review. (See Personnel Code Sheet.) The laboratory supervisor stated on 8/16/23 at 1:00 PM, "The competencies should be in the personnel book. I will look for them." The TC stated on 8/16/23 at 2: 00 PM, "We will have to go up to the main office to look for the competency assessments in storage." 3. An interview with the TC and supervisor on 8/16/23 at approximately 2:30 PM confirmed the above findings.