Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0226367	06/25/2025
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 Patient First-Genito on June 25, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on a review of procedures, moderate complexity analytic system records, lack of documentation, and interviews, the laboratory failed to retain their documentation of monitoring humidity percent (%), room/refrigerator/freezer temperatures, hematology analyzer maintenance, and Wright stain quality logs according to retention protocol for thirty-one (31) of 31 days in July 2024 as observed on the date of the inspection, June 25, 2025 (review timeframe: 8/23/23-6/25/25). Findings include: 1. Review of the laboratory's procedures revealed the following protocols: Quality Assurance (QA) protocol (Section 14, Equipment-Temperature/Humidity Checks) that outlined daily monitoring of environmental conditions. The policy stated, "The temperature of the laboratory refrigerator and freezer and the temperature humidity of the room will be read and recorded on the Temperature Humidity Chart"; Wright Stain QA protocol that outlined, "After observing staining characteristics of control slide, complete Wright Stain Quality Control Log each day of testing each month." Pentra 60+ Hematology analyzer maintenance protocol that required documentation of checking reagents, performing start up, and general cleaning each day of operation; concentrated cleaning, back flush, and rinse cytometer at least once

	per week; and emptying cap piercing filter bi-weekly. 2. Review of the laboratory's "Moderate Complexity Testing Records Folder" files for the twenty-two month survey timeframe (8/22/23 - 6/25/25) revealed no logs documenting the above analytic system checks for July 2024. The inspector requested to review the temperature monitoring, hematology maintenance and stain quality documentation for the 31 days of laboratory operation July 2024. No records were available for review. The laboratory technical consultant (TC) stated on 6/24/25 at noon, "We cannot find the July 2024 file which included those logs. We have looked for the file and cannot locate the logs." 3. The inspector inquired regarding a protocol for analytic system records retention. The TC provided the laboratory's corporate online guide (form FMR-0001 dated 12/20/24) which outlined that "temperature charts, Pentra 60+ maintenance, and hematology stain logs be retained for 2 years". 4. An exit interview with the TC on 6/25/25 at 1:00 PM confirmed the above findings.