Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0948367	08/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Patient First - Newtown Road	332 Newton 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-Newtown Road on August 10, 2022 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 Requirements. 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. This STANDARD is not met as evidenced by: Based on a review of hematology quality control (QC) records, policies, hematology corrective action logs, lack of documentation, and an interview, the laboratory failed to retain documentation of Complete Blood Cell (CBC) QC for five of thirty-one (31) days in May 2021 and nine of twenty-eight (28) days in February 2022. Findings include: 1. During a review of the laboratory's Horiba Pentra 60+ ABXdifftrol CBC tri-level QC records (low, normal, high) from January 2021 up to the date of the inspection on August 10, 2022, the inspector noted fourteen (14) days with no QC documentation: No low, normal, or high QC data (three of three levels) documented for the following dates in May 2021: 5/17, 5/18, 5/19, 5/20, 5/21; No normal or high QC data (two of three levels) documented for the following dates in February 2022: 2 /16, 2/17, 2/18, 2/19, 2/20, 2/21, 2/22, 2/23, 2/24. 2. Review of the laboratory's procedure manual revealed a Hematology Pentra 60 Procedure that outlined: "On the last day of the month, all hematology three level control runs are printed, reviewed, and initialed/dated by the lab supervisor. The print out is then placed in the Hematology QC folder that contains the daily start up background print outs. Also, on

	the 15th and on the last day of the month, the electronic records of the daily AM and PM controls is printed. These print outs will provide the lab supervisor with the statistics needed for entry into the Hematology QCP peer program. The supervisor should initial and date both of these logs. The logs should be retained in the QC binder." 3. Review of the laboratory's Hematology Control/Corrective Action (Pentra 60 C+) logs for the timeframe outlined above revealed the following documentation: "Software updated, performed tech support installed, updated control and reagents, values stored, QC assayed" (dated 5/22/21). "Pentra 60 + experienced a software crash resulted in loss of QC data." (dated 6/29/21). "QC data for normal and high levels lost from PM on 2/15/22 to 2/24/22" (dated 2/29/22). The inspector requested to review documentation of either daily QC instrument print outs or onboard analyzer data for the 14 dates outlined above, or monthly Levey-jennings reports including the dates in May 2021 and February 2022. No records of the QC for the 14 dates were available for review. The technical consultant (TC) stated on 8/10/22 at approximately 12:30 PM: "We had a problem with Horiba's site crashing and lost data. The supervisor did perform a medical review when the QC was lost. We are working with Horiba to perform a daily QC backup but that too has not worked as well as we had hoped". 4. An exit interview with the TC on 8/10/22 at approximately 1:00 PM confirmed the above findings.