

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D1091069	<b>(X3) Date Survey Completed</b> 05/27/2021
<b>Name of Provider or Supplier</b> Patient First - Taylor Road	<b>Street Address, City, State</b> 2425 Taylor Road, Chesapeake, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted for Patient First-Taylor Road on May 26, 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:
<b>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of instrument maintenance logs, manufacturer's operations manual, interviews, and lack of documentation, the laboratory failed to document performance of required monthly hematology analyzer maintenance protocols for four (4) of twelve (12) months reviewed in calendar year 2020. Findings include: 1. During the onsite inspection on 5/26/21 at approximately 10:00 AM, a review of the laboratory's Pentra 60+ hematology analyzer's maintenance logs for calendar year 2020 revealed a required procedure "emptying the cap filter piercing" listed as "perform biweekly /monthly based on volume". The inspector noted no documentation of the maintenance was recorded in the months of January, February, March, or September. The inspector noted that the procedure was documented twice monthly for the remaining months of the year. The inspector inquired regarding the 4 month lack of documentation and to review corrective action. No documentation was available for review. 2. During a tour of the laboratory at approximately 11:30 AM, the inspector inquired of the testing personnel to describe the Pentra biweekly maintenance. The testing personnel stated: "It is a supervisor task. The testing personnel do not perform</p>

it. It is related to cleaning the filter and requires the supervisor to open the machine. It is to prevent having issues with pieces of rubber in the valve and they want it done biweekly." 3. Review of the Pentra operations manual revealed manufacturer's maintenance instructions (on page 63) related to the protocol outlined above: "the filter below the rinse chamber should be cleaned at least every other month." 4. The inspector inquired of the laboratory's policy related to the frequency of the maintenance. The technical consultant (TC) requested time to look into the matter. On 5/27/21 at 3:00 PM, the TC stated in an emailed response: "It appears that there was a period of time in which it was not signed off. I have not been able to locate a QA and the supervisor and the former lab consultant during that time are no longer here. However, on March 13, 2020 the service engineer performed a calibration and a PM on October 26, 2020 during which time "emptying the cap filter piercing" would have been performed. Since I began the role of consultant in January 2021, the protocols have been to document monthly." 5. In an exit interview with the TC on 5/27/21 at approximately 4 PM the above findings were confirmed.