

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0918355	<b>(X3) Date Survey Completed</b>  08/10/2022
<b>Name of Provider or Supplier</b>  Patient First Medical Center-Carytown	<b>Street Address, City, State</b>  12 N Thompson Street, Richmond, 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>	<p>An announced CLIA Recertification survey was conducted at the Patient First Medical Center-Carytown on 08/10/22 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 is in compliance with the applicable COVID-19 reporting requirements.</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&amp;P), maintenance records, lack of documentation and interview, the lab failed to follow quality assurance (QA) policy of performing and documenting the weekly maintenance for the Horiba Pentra Micros 60 hematology analyzer for 26 of 62 weeks reviewed. Dates of record review include 01/01/21 up to 03/01/22. Findings include: 1. Review of the laboratory's P&amp;P QA policy revealed the following statements, "Pentra 60 C+- Concentrated cleaning, a backflush and rinsing of the cytometer is performed at least weekly. These operations are documented on the Pentra 60 C+ Maintenance log." 2. Review of the Pentra 60 C+ (serial number 407PCP13135) maintenance logs from 01/01/21 up to 03/01/22 revealed lacked of documentation of the performance of the weekly maintenance procedures for the following weeks: January 3-9, 17-23 and 24-30, 2021, February 1-6, and 21-27, 2021, March 14-20, 2021, March 28- April 3, 2021, April 4-10 and 25-30, 2021, May 2-8, 2021, May 30-June 5, 2021, June 13-19 and 20-26, 2021, July 11-17 and 25-31, 2021, August 29- September 4, 2021, September 12-18, and 26-30,</p>

2021, October 17-23, 24-30, 2021, November 14-20, 2021, December 19-25 and 26-31, 2021. January 16-23, 2022, January 30-February 5, 2022 and February 20-26, 2022. Total 26 weeks. The surveyor requested to review documentation of the weekly maintenance as defined by the P&P. The documentation was not available for review.

3. An exit interview with the technical consultant on 08/10/22 at 11:30 AM confirmed the findings.