

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1056669	(X3) Date Survey Completed 02/05/2021
Name of Provider or Supplier Patient First - Denbigh	Street Address, City, State 611 Denbigh Boulevard, Newport News, 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 for Patient First-Denbigh on February 5, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey included virtual record review conducted from 02/01/21 to 02/02/21 with virtual interviews/tour on 02/05/21. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. Specific deficiency cited is as follows:
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of analyzer performance verification documentation, and interviews, the laboratory director (LD) failed to evaluate and verify the accuracy, precision, and reportable ranges for Complete Blood Count (CBC) on a newly installed hematology analyzer from the installation date of March 12, 2020 to the date of the survey, February 5, 2021. Findings include: 1. Review of the laboratory's instrument validation records revealed a new Horiba Pentra C60+ analyzer (Serial Number 902PCP15229) installation by Horiba Technical Specialist occurred March 2020. During a virtual interview on 02/05/21 at approximately 12:30 PM, the inspector requested to review validation studies for the new analyzer. The lab supervisor presented a Verified Medical Research performance analysis report (dated</p>

03/12/20) that included instructions highlighted to review risks for exceeding reportable limits for white blood cell (WBC) and platelet (PLT) on the unsigned review page. The inspector requested to review documentation that the LD reviewed /validated the new Pentra instrument's accuracy, precision, and reportable ranges prior to patient testing. The records were not available for review. The technical consultant (TC) stated in an email communication at approximately 5:00 PM: "Unfortunately the paperwork had not been signed by the Lab Director. I had him review and sign today." 2. In an interview with the TC on 02/05/21, at approximately 5:00 PM, the above findings were confirmed.