

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0665314	(X3) Date Survey Completed 09/21/2023
Name of Provider or Supplier Patient First-General Booth	Street Address, City, State 1605 General Booth Blvd, 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-General Booth on September 21, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of procedures, calibration documentation, lack of documentation, and interviews, the laboratory failed to follow their written policy to perform Complete Blood Count (CBC) calibration procedures at least every six (6) months during the nine (9) month timeframe of December 24, 2022 to September 15, 2023. Findings include: 1. Review of the laboratory's Procedure Manual revealed a policy (Title: Hematology-ABX Pentra 60C+) that outlined a calibration protocol which stated, "Calibration is performed when the analyzer is installed and every 6 months or more frequently if indicated." 2. Review of the laboratory's Pentra hematology analyzer records revealed CBC calibrations were documented/dated as performed on 12/23/21, 6/23/22, 12/23/22, 12/24/22, and 9/15/23. 3. The inspector noted a 9 month</p>

lapse in the calibration documentation during the record review timeframe outlined above. A 6 month CBC calibration was due on 6/24/23. The inspector requested additional Pentra hematology calibration records for calendar year 2023. No additional records were available for review. 4. An interview with the technical consultant at 12:00 PM on 9/21/23 confirmed the above findings.