

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0232914	<b>(X3) Date Survey Completed</b>  02/04/2025
<b>Name of Provider or Supplier</b>  Chp-Cvfp - Internal Medicine	<b>Street Address, City, State</b>  2215 Landover Place, Lynchburg, 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 at CHP-CVFP-Internal Medicine on February 4, 2025 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:
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>(a )Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 manufacturer's user guide, hematology calibration records, lack of documentation, and interviews, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) testing according to their policy during the review timeframe of May 4, 2023 to the date of the inspection on February 4, 2025. Findings include: 1. Review of the Beckman Coulter DxH 600 user guide protocols revealed instructions "calibrate every 6 months, after major maintenance, and as needed". 2. Review of the laboratory's calibration records during the twenty-two month review timeframe (05/04/23 - 02/04/25) revealed the following three calibration records: 05/10/23 01/05/24 01/31/25 The lab inspector</p>

requested to review additional calibration procedures completed in November 2023 and July 2024. No additional calibration documentation was available. 3. An exit interview with the lead testing personnel and Director of Ancillary Services on 2/4/25 at 2:30 PM confirmed the above findings.