

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D1062215	<b>(X3) Date Survey Completed</b>  07/20/2022
<b>Name of Provider or Supplier</b>  Cpn, Inc DbA Atrium Health Urgent Care	<b>Street Address, City, State</b>  10210 Couloak Drive, Suite E, Charlotte, NC	
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>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> 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 review of manufacturer's instructions, review of the laboratory's calibration checklist, and review of 2020, 2021, and 2022 quality control and calibration records 7 /20/22, the laboratory failed to follow the manufacturer's instructions for calibration of the Coulter AcT diff hematology analyzer for 4 of 6 calibrations performed. Findings: Review of the Coulter Operator's Guide revealed "CALIBRATION OVERVIEW ... When necessary, perform calibration by following the procedures given in this section. ... 16 Verify calibration by running 4C PLUS Cell Control ...". The laboratory's AcT Diff Calibration Checklist states "... 11. Verify calibration by analyzing Post-Calibration Controls. (Retain) ..." Review of 2020, 2021, and 2022 Coulter AcT diff quality control and calibration records revealed the laboratory failed to analyze quality control material after calibration for 4 of the 6 calibrations. The laboratory ran controls prior to calibration, but failed to analyze control material after the calibrations performed on 10/29/20, 4/3/21, 10/20/21, and 12/22/21.</p>