

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0242812	<b>(X3) Date Survey Completed</b>  11/22/2024
<b>Name of Provider or Supplier</b>  Cpn Inc DbA Atrium Health Levine Children's	<b>Street Address, City, State</b>  66 Lake Concord Road, Concord, 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>D5421</b>	<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 review of performance verification records, review of laboratory procedure and interview with technical consultant (TC) 11/22/24, the laboratory failed to verify the reportable range for hemoglobin (HGB) on the Beckman Coulter DXH 520 hematology analyzer. No patients were reported for Hgb above the verified range of 19.49 grams per deciliter (g/dL) from August of 2022 until time of survey November 22, 2024. Findings: Review of performance verification records for the Beckman Coulter DXH 520 hematology analyzer revealed the analyzer was put into use and the performance was verified in August of 2022. Review of performance verification records for the Beckman Coulter DXH 520 hematology analyzer revealed the highest reportable range verified for HGB is 19.49 g/dL. Review of laboratory procedure "Beckman Coulter DXH 520" revealed the highest reportable range for HGB as 25.0 g/dL. Interview with TC at approximately 11:00 a.m. confirmed the HGB on the Beckman Coulter DXH 520 analyzer has a reportable range up to 25.0 g/dL. She also confirmed the performance verification records verified a reportable range for HGB up to 19.49 g/dL and there were no patient test results released with a HGB greater than the 19.49 g/dL from August of 2022 until time of survey 11/22/24.</p>