

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2270202	(X3) Date Survey Completed 11/21/2024
Name of Provider or Supplier Atrium Health Primary Care One Health	Street Address, City, State 136 E 36th Street Ste 200, Charlotte, NC	
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
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 review of performance verification records, review of the laboratory's procedure, and interview with TC (technical consultant) 11/21/24, the laboratory failed to verify the reportable range for HGB (hemoglobin) on the Beckman Coulter DxH 520 hematology analyzer. Findings: Review of performance verification records for the Beckman Coulter DxH 520 hematology analyzer revealed the analyzer was installed 12/8/22 and patient testing began 12/20/22. Review of performance verification records revealed "Evaluation of Results The Accuracy of HGB was analyzed on DxH520 SN BR040205 over a range of 0.05 to 19.20 g/dL. Reportable Range was not verified. The accuracy test PASSED. ..." The highest value obtained for HGB during the performance verification testing was 19.05 g/dL. Review of the laboratory's "Beckman Coulter DXH 520" procedure revealed the highest reportable value for HGB was listed as 25.0 g/dL. During interview at approximately 12:15 p.m., the TC confirmed the highest value obtained for HGB during performance verification testing on the Beckman Coulter DxH 520 analyzer was 19.05 g/dL. She stated that due to the laboratory's low test volume, there were likely no patient results released with a HGB higher than 19.05 g/dL from 12/20/22 - 11/21/24.</p>