

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0688601	(X3) Date Survey Completed 05/23/2023
Name of Provider or Supplier Ozarks Community Health Center	Street Address, City, State 18614 Jackson Street, Hermitage, MO	
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 the performance verification procedures for the Beckman Coulter DxH520 hematology analyzer and interview with the technical consultant (TC) #1, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Beckman Coulter DxH520 hematology analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing in October 2022. 2. Interview with the TC #1 on May 23, 2023 at 9:30 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.</p>