

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0440645	(X3) Date Survey Completed 04/18/2023
Name of Provider or Supplier Arthritis Consultants, Inc	Street Address, City, State 522 N New Ballas, Suite 240, Saint Louis, 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 DxH 560 hematology analyzer and interview with the technical consultant (TC), the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the DxH560 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, and white blood cell (WBC) prior to the beginning of patient testing in November 2022. 2. Interview with the TC on April 18, 2023 at 9:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.</p>