

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0960320	(X3) Date Survey Completed 06/06/2023
Name of Provider or Supplier Midwest Regional Allergy, Asthma, Arthritis	Street Address, City, State 1027 S Main Suite 202, Joplin, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of microscope maintenance and interview with the technical consultant (TC), the laboratory failed to perform annual microscope maintenance from 2021 to date June 6, 2023. Findings: 1. Review of microscope maintenance showed no maintenance documented from 2021 to date June 6, 2023. 2. Interview with the TC on June 6, 2023 at 10:00 AM confirmed the laboratory failed to perform annual microscope maintenance.</p>
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>

This STANDARD is not met as evidenced by:

Based on review of the performance verification procedures for the Beckman Coulter DxH520 hematology analyzer, Beckman Coulter Au480 chemistry 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 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 July 2022. 2. Review of the performance specifications for the Beckman Coulter Au480 chemistry analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's population for the analytes: glucose, BUN, creatinine, sodium, potassium, chloride, CO₂, calcium, total protein, albumin, alkaline phosphatase, ALT, AST, triglycerides, and HDL prior to the beginning of patient testing in August 2022. 3. Interview with the TC on June 6, 2023 at 9:30 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.