Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0447995	(X3) Date Survey Completed 06/07/2023
Name of Provider or Supplier Adult Medicine & Endocrinology Specialists	**Street Address, City, State** 960 E Walnut Lawn, Ste 201, Springfield, 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	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the Vitros 5600 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 Vitros 5600 chemistry 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: calcium, total protein, albumin, aspartate aminotransferase, alanine transaminase, alkaline phosphatase, total bilirubin, triglycerides, high density lipoproteins, cholesterol, low density lipoproteins, micralbumin, hemoglobin A1C, TSH, Free T4, Free T3, follicle stimulating hormone, luteinizing hormone, prolactin, testosterone, prostate specific antigen, and cortisol prior to the beginning of patient testing. 2. Interview with the TC on June 7, 2023 at 9:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview, review of Vitros 5600 chemistry quality control (QC) and interview with the technical consultant (TC), the laboratory failed to perform two levels of acceptable chemistry QC each day of patient testing. Findings: 1. Interview with TC stated laboratory uses assayed chemistry controls, they also establish ranges. The laboratory could not provide ranges of current chemistry lot number QC with corresponding established ranges. 2. Review of total bilirubin QC on April 24, 2023 and May 1, 2023 showed both levels of total bilirubin QC was not within acceptable ranges. 3. Interview with the TC on June 7, 2023 at 9:00 AM confirmed the laboratory failed to perform two levels of acceptable chemistry QC each day of patient testing.