Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0447995	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Adult Medicine & Endocrinology Specialists	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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the Vitros Eci chemistry procedure, Free T4 quality control (QC) and interview with the laboratory director the laboratory failed to follow chemistry QC procedure. Findings: 1. Review of Vitros Eci chemistry procedure states if any result falls outside of +/- 2SD "first repeat, if still outside, open new controls, if still outside, recalibrate, if still outside, do not report out patients and call Ortho Clinical Diagnostic Customer Center". 2. Review of QC level 1 for Free T4 showed on 4/6/18 QC was out by 3 SD, QC was accepted with not further investigation. 3. Review of QC level 1 for Free T4 showed on 5/9/18 QC was out by 3 SD, QC ran two times both out by 3 SD, QC was accepted with no further investigation. 4. Review of QC level 1 for Free T4 showed on 5/18/18 QC was out by 3 SD, QC was accepted with not further investigation. 5. Interview with the laboratory director on January 15, 2019 at 4:00 PM confirmed the laboratory failed to follow chemistry QC procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the urinalysis procedure manual and interview with the laboratory director on January 15, 2019 at 4:00 PM confirmed, the procedure manual failed to include reference intervals (normal values) for microscopic examination of urine sediment.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the Vitros Eci chemistry procedure, Free T4 quality control (QC) and interview with the laboratory director the laboratory failed to review the effectiveness of QC corrective actions taken to resolve problems. Findings: 1. Review of Vitros Eci chemistry procedure states if any result falls outside of +/- 2SD "first repeat, if still outside, open new controls, if still outside, recalibrate, if still outside, do not report out patients and call Ortho Clinical Diagnostic Customer Center". 2. Review of QC level 1 for Free T4 showed on 4/6/18, 5/9/18 and 5/18/18 QC was out by 3 SD, QC was accepted with not further investigation. 5. Interview with the laboratory director on January 15, 2019 at 4:00 PM confirmed the laboratory failed to review the effectiveness of QC corrective actions taken to resolve problems.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of hematology patient test reports, approved laboratory procedure manual and interview with the laboratory director, the laboratory failed to ensure

	pertinent patient normal were available for interpretation. Findings: 1. The differences between normal values on patient test reports and those included in the approved procedure manual are as follows: Normal values included on patient test reports: Red blood cells (RBC) (million/mm3) male (4.6-6.2) female (4.2-5.40) Normal values included in the procedure manual approved by the laboratory director: Red blood cells (RBC) (million/mm3) male (4.5-6.0) female (4.0-5.2) 2. Interview with the laboratory director on January 15, 2019 at 4:00 PM confirmed the normal values stated in the approved laboratory procedure manual differed from those included on the test reports.