Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1036314	07/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Karen F Schwartz Md Pc	165 Froehlich Farm Blvd, Woodbury, NY	

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
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 a surveyor's review of the laboratory's procedure manual and an interview and confirmed with the technical consultant and the testing person, the laboratory failed to have a procedure manual that is comprehensive, up-to-date, and accurate. FINDINGS: The procedure manual did not include: 1. A procedure describing laboratory's batch testing system for endocrinology testing which are collected daily but tested once or twice per week; 2. Procedure describing the laboratory's turnaround time for endocrinology testing from sample collection to processing and to when final results are entered into the patients' charts; 3. A procedure describing calibration to

	include the frequency of calibration for each analytes tested; and, 4. A procedure describing a twice per year verification system for the non-regulated analytes such as thyroperoxidase antibodies (TPO), thyroglobulin antibodies (Tg) and testosterone testing which are not currently enrolled in Proficiency Testing (PT).
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 a surveyor's review of the validation records and an interview with the technical consultant and the testing person, the laboratory failed to perform and document a complete method validation for the new Beckman Coulter Access 2 analyzer prior to patient testing in May 2018. Findings: 1. On July 24, 2018 at approximately 10:30 AM the technical consultant and the testing person confirmed that method comparison/correlation study was not performed for the thyroperoxidase antibodies (TPO) analyte and for testosterone testing as part of a complete validation of the Beckman Coulter Access 2 analyzer prior to patient testing using the new analyzer in May 2018. 2. Approximately 25 patient specimens were tested and reported for TPO Antibodies and for testosterone during above time frame.