Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2161996	05/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Nicholas Halper Md Pc	145 Pinelawn Rd Suite 100 North Lower Level, Melville, 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 laboratory director, the laboratory failed to have a procedure manual that is comprehensive. FINDINGS: The procedure manual did not include: 1. A written procedure describing transportation of specimens from one other location in Rockville Centre to the Amityville office for testing. 2. A written procedure describing calibration of the pipettes.

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 laboratory director, the laboratory failed to perform and document a complete method validation for the new Coulter AcT Diff 2 analyzer prior to patient testing in March 2019. Findings: 1. On May 7, 2019 at approximately 11:30 AM the laboratory director confirmed that although the method comparison was performed for the hematology analytes, there were no records of accuracy, precision, and reportable ranges as part of a complete validation of the Coulter AcT Diff 2 analyzer prior to patient testing in March 2019. 2. Approximately 100 patient specimens were tested and reported for hematology during above time frame.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor's review of endocrinology quality control (QC) records and an interview with the laboratory director, the laboratory failed to ensure that endocrinology QC test results were within acceptable range prior to testing patient specimens. Findings Include: Review of QC records found and it was confirmed with the laboratory director on May 7, 2019 at approximately 11:30 AM during review of QC data that the following level of control materials were out of acceptable range and remediation was not performed: 1. On 4/5, 8, 10, 18/19 one out of two controls were out of acceptable range for Estradiol (E2). 2. On 4/8/19 one out of two controls were out of acceptable range for Ferritin. 3. On 4/15/19 one out of two controls were out of acceptable range for Prostate Serum Antigen (PSA). 4. On 4/19, 24/19 one out of two controls were out of acceptable range for Parathyroid Hormone (PTH). 5. On 4/26, 29 /19 one out of two controls were out of acceptable range for Vitamin D.