Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0887830	05/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Theofanis Mitsinikos Do Pc	2500 Nesconset Highway #3c, Stony Brook, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a surveyor's review of the American Proficiency Institute (API) Proficiency Test (PT) records and an interview with the laboratory supervisor/testing person, the laboratory failed to rotate proficiency testing for urine albumin/creatinine and hemoglobin A1C between the three testing persons for all three events in 2016, 2017 and the first event in 2018. Findings: The laboratory supervisor/testing person confirmed on May 30, 2018 at approximately 11:30 AM that All three API PT events for urine albumin/creatinine and hemoglobin A1C for all three events in 2016, 2017 and the first event in 2018 were consistently performed by the laboratory supervisor and were not rotated among the two other testing personnel who routinely performed patient testing.
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 supervisor/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, immunology and chemistry testing which are collected daily but tested twice per week; 2. Procedure describing the laboratory's turnaround time for the chemistry, immunology, and endocrinology testing from sample collection to processing and to when final results are entered into the lab computer system; 3. The current procedure manual describes laboratory's policy for hematology quality control testing. The laboratory does not perform hematology; 4. The current procedure manual still lists the previous laboratory's name, Sound Endocrinology PLLC. The laboratory has changed the name of the laboratory in May 2017.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a surveyor's review of the immunology, endocrinology and chemistry quality Control (QC) records and an interview with the laboratory supervisor/testing person, the laboratory failed to discontinue the use of the expired quality control materials. FINDINGS: 1. On May 30, 2018 at approximately 12:00 PM the laboratory supervisor/testing person confirmed surveyor's findings that the laboratory used 2 levels of expired QC for 19 chemistry analytes testing level 1 lot # 1403014D Exp date 6/30/17, level 2 lot # 1403015B Exp date 6/30/17 from July 2017 through November 2017. 2. Approximately 1000 patients were tested for routine chemistry and hsCRP using the expired quality control materials during the above time frame.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)

	(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a surveyor's review of chemistry calibration records and interview with the laboratory supervisor/testing person, calibration of the chemistry analyzer was not performed at the frequencies required by the manufacturer of the analyzer. FINDINGS: 1. The laboratory is using the Cobas Mira analyzer. The manufacturer of the Cobas Mira analyzer requires analyzer calibration once per month. 2. On May 30, 2018 at approximately 12: 00 PM the laboratory supervisor/testing person confirmed surveyor's findings that the chemistry analytes were calibrated every 3 to 4 months in calendar years 2016, 2017 and up to survey date. 3. Approximately 1000 patient specimens were tested and reported for chemistry during the above time frames when analyzer was out of calibration.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor findings and interview with the laboratory supervisor/testing person, the laboratory director failed to provide overall management of the laboratory. Findings: The laboratory director failed to ensure that the laboratory maintained it's established QA program for all phases of laboratory testing, refer to D6021
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory records and confirmed by the laboratory supervisor/testing person in an interview on May 30, 2018 at approximately 12:00 PM, the laboratory director failed to ensure that the QA program for chemistry, endocrinology and immunology testing was maintained to ensure quality laboratory services. Refer to D5403, D5417, D5437