Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0887830	05/09/2024
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D), American Proficiency Institute (API) PT reports, as well as interview with the laboratory Testing Person (TP), the laboratory failed to perform and document corrective action for PT scores less than 100% for the following test analytes: FINDINGS: 1. 2022 First Event; Thyroid Stimulating Hormone (TSH) = 80%. 2. 2022 Third Event; TSH = 80%, Ferritin = 80%. 3. 2024 First Event; Calcium (Ca) = 80%, Uric Acid = 80%. 4. The current, approved standard operating procedures did not include instructions for performing such activity. 5. The TP confirmed the findings on May 9, 2024, at approximately 11:30 A.M.
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 laboratory's policy and procedure manual as well as interview with the TP, the laboratory failed to draft, approve written procedures for new QC lot number lot-to-lot validation, record retention, and Beckman Coulter Access 2 analyzer. FINDINGS: 1. The current, approved standard operating procedures did not include written instructions for new QC lot number lot-to-lot validation, record retention, and Beckman Coulter Access 2 analyzer utilized for chemistry and immunology patient specimen testing. 2. The TP confirmed the findings on May 9, 2024, at approximately 11:30 A.M.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of temperature and humidity records as well as interview with the TP, the laboratory failed to comply with analyzer humidity range specifications as well as the laboratory's temperature requirements from calendar year 2022 through the survey date. FINDINGS: 1. According to manufacturer user manual, Beckman Coulter Access 2 operation humidity range is 20-80% and Cobas Mira Plus operation humidity is 80% at 32?. 2. There was no documentation of temperature and humidity for calendar year 2022 through the survey date. 3. The TP confirmed the findings on May 9, 2024, at approximately 12:00 P.M.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by:

	Based on direct observation of laboratory aliquot bottle inventory and interview with the TP, the laboratory failed to label aliquot bottles utilized for patient specimen processing. FINDINGS: 1. Three aliquot bottles were not labeled with proper identification, concentration, preparation date, expiration date, and lot number of reagent. 2. The current, approved standard operating procedures did not include instructions for performing such activity. 3. The TP confirmed the findings on May 9, 2024, at approximately 12:00 P.M.
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 direct observation, lack of thermometer calibration records, and interview with the TP, the laboratory failed to perform and document thermometer calibrations for laboratory and refrigerator thermometers where patient specimen processing and reagent storage occurred. FINDINGS: 1. There was no documentation of 2022, 2023, and 2024 laboratory and refrigerator thermometer calibration performance. 2. This is contrary to the thermometer manufacturer's calibration specifications. 3. The TP confirmed the findings on May 9, 2024, at approximately 12:00 P.M.