Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2099716	06/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Yecheiel Y Zagelbaum Do	58 Route 59, Monsey, 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 review of the laboratory procedure manual and an interview with the laboratory's chief operating Officer (COO), the laboratory failed to have a complete procedure manual. Finding Include: The laboratory COO confirmed in an interview on June 5, 2019, at approximately 12:15 pm, that the laboratory failed to have a complete procedure for lot to lot verification of new control material.
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 a review of incubator temperature records and an interview with the COO, the laboratory failed to follow the manufacturer's instructions for monitoring and maintaining incubator temperatures for incubating throat cultures. Findings Include: 1. The testing person confirmed on June 5, 2019, at approximately 1:00 pm that the laboratory did not follow the manufacturer's instruction for the incubation temperature of throat cultures. 2. Throat cultures are to be incubated at temperature ranges of 33 - 37 C. The documented incubator temperatures from August 2018 through December 31, 2018 and January 1, 2019 through May 31, 2019 ranged between 38 C and 40 C for 294 of 299 days of patient testing. 3. Approximately 2352 patient samples were tested and results reported during this time period.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of procedures and temperature records, and an interview with the COO, the laboratory director failed to ensure that the quality assessment and quality control programs for Bacteriology and Hematology were maintained to assure quality laboratory services. Refer to: D5403 and D5413