Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1067760	10/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Matthew Cohen Md Pc	255 W Park Ave, Long Beach, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review and lack of documentation, the laboratory failed to retain facility records for two years. FINDINGS: 1. There was no documentation of Annual Quality Assurance records, room temperature logs, humidity logs, staff 2021 competency logs, instrument calibration records, Coulter Act Diff II hematology analyzer validation records, laboratory standard operation procedure manual, and proficiency testing attestation records. 2. Confirmed findings by interview with the Laboratory Director (LD) on October 19, 2023, at approximately 12:00 P.M.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and lack of documentation, the laboratory failed to draft, approve, and maintain policies and procedures for on-site laboratory testing. FINDINGS: 1. There was no documentation of current laboratory policies and procedures. 2. No laboratory Safety Manual was available for review. 3.

	Approximately 3000 patients were tested. 4. Confirmed findings by interview with the LD on October 19, 2023, at approximately 11:00 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 record review and lack of documentation, the laboratory failed to draft, approve, and maintain step by step protocols for calibration, control procedures, reportable ranges, and patient specimen preparation. Confirmed findings by interview with the LD on October 19, 2023, at approximately 11:00 A.M.