Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1067760	06/18/2024
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare & Medicaid Services (CMS) PT Certification and Survey Provider Enhanced Reporting system (CASPER 0096D and 0155D) and American Proficiency Institute (API) Proficiency Testing (PT) summary records, as well as interview with the Office Manager (OM), the laboratory failed to document attestation that routine integration of PT samples into the patient workload using the laboratory's routine methods occurred. FINDINGS: 1. There was no documentation of laboratory director (LD) and testing person (TP) signature as well as date of signature for the API 2024 Hematology first event attestation form. 2. The OM confirmed the findings on June 18, 2024, at 11:00 A.M. 3. It was noted that the laboratory scored 96% for the API 2024 Hematology first event.
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 observations and interview with the OM, the laboratory failed to remove from inventory expired reagents in the patient specimen processing laboratory

	as required by the current, approved standard operating procedures. FINDINGS: 1. The surveyor's observations in the patient specimen processing laboratory confirmed on June 11, 2024, at approximately 12:00 P.M. the following reagents and processing materials were not removed from inventory as required by the standard operating procedures: a. OC - Auto Sampling Bottle Lot#: 2X295; Expiration: April 17, 2024; Fifty vials. b. OC - Auto Sampling Bottle Lot#: 29247; Expiration: March 6, 2024; Fifty vials. c. Urine HCG Lot#: 2052060; Expiration: April 30, 2024; Thirty-three kits. d. Mononucleosis Lot#: 221158; Expiration: March 31, 2023; One box. 2. The OM confirmed on June 18, 2024, at approximately 12:00 P.M. that the respective expired reagents and processing materials were not utilized for patient specimen processing.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of Beckman Coulter DxH 500 hematology analyzer Quality Control (QC) reports, current, approved standard operating procedures, as well as interview with the OM, the LD failed to document quality control review and corrective action performance for patient specimen normal control reagent deviations. FINDINGS: 1. There was no documentation of review and corrective action performance for Normal Control Lot#: 362416012; Expiration: July 5, 2024; "R" Flagged: May 17, 2024, May 18, 2024, May 21, 2024, May 22, 2024, May 23, 2024, June 4, 2024, June 11, 2024, and June 14, 2024. 2. This is contrary to instructions indicated in the standard operating procedures. 3. Approximately one hundred patient specimens were tested and results reported during the respective period. 4. The OM confirmed the findings on June 18, 2024, at approximately 11:30 A.M.
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 review of equipment temperature records, current, approved standard operating procedures, as well as interview with the OM, the LD failed to comply with quality assessment protocols to assure quality of laboratory services. FINDINGS: 1. There was no documentation of LD signature and date of signature for the quality control reagent storage refrigerator temperature logs from March 28, 2024, through

	June 18, 2024. 2. This is contrary to instructions indicated in the standard operating procedures. 3. The OM confirmed the findings on June 18, 2024, at approximately 10: 30 A.M.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of TP employment and competency records as well as interview with the OM, the LD failed to ensure that TP had appropriate education prior to performing hematology specialty moderate complexity testing. FINDINGS: 1. There was no documentation of TP #5 high school diploma or equivalent. 2. The OM confirmed the findings on June 18, 2024, at approximately 10:30 A.M.