

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1067760	(X3) Date Survey Completed 02/05/2026
Name of Provider or Supplier Matthew Cohen Md Pc	Street Address, City, State 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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Standard Operating Procedure (SOP) manual, lack of analyzer Quality Control (QC) records, as well as interview with Testing Person (TP) #2, the laboratory failed to retain QC records documenting all analytic systems activities for at least two years. FINDINGS: 1. There was no documentation of Beckman and Coulter AcT Diff II hematology analyzer revalidation performance after relocation to new laboratory address on November 24, 2024. 2. This is contrary to instructions indicated in the current, approved SOP manual record retention policy. 3. TP #2 confirmed the findings on February 5, 2026, at approximately 11:30 A.M.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's SOPs, Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D), American Proficiency Institute (API) PT summary reports, lack of corrective action records, as well as interview with TP #2,</p>

the laboratory failed to document review and evaluation for the results obtained on PT performed. FINDINGS: 1. There was no documentation of review, evaluation, and plan of correction performance for the following CASPER 0155 and API PT scores from 2025: a. Red Blood Cell (RBC) Test Analyte: 2025 Third Event = 80% b. Hematocrit (HCT) (Non-Waived) Test Analyte: 2025 Third Event = 80% 2. This is contrary to instructions indicated in the laboratory's current, approved SOP PT protocols. 3. The TP #2 confirmed the findings on February 5, 2026, at approximately 12:00 P.M.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(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, review of the laboratory's SOP manual, as well as interview with the Office Manager (OM), the laboratory failed to remove from inventory reagents when they have exceeded their expiration date. FINDINGS: 1. The surveyor's observations in the patient specimen processing laboratory confirmed on February 5, 2026, at approximately 12:00 P.M. the following reagents and processing materials were not removed from inventory as required by the current, approved SOP inventory control protocol: a. Quantiferon TBI tubes - Lot# A240833S Expiration: November 30, 2025: 25 tubes. b. Quantiferon Mitogen tubes - Lot# A240834B Expiration: November 30, 2025: 25 tubes. c. Quantiferon Nil tubes - Lot#A2408346 Expiration November 30, 2025: 25 tubes. d. Quantiferon TB2 tubes - Lot#A240833X Expiration: November 30, 2025: 25 tubes. 2. The OM informed the surveyor that the respective expired reagents were not utilized for patient specimen processing. 3. The OM confirmed the findings on February 5, 2026, at approximately 12:30 P.M.