

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2189533	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Empire Medical Office Pc	Street Address, City, State 16 E 40th Street - 2nd Floor, New York, 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
D2105	<p>ENDOCRINOLOGY CFR(s): 493.843(e)</p> <p>(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting System (CASPER 0155D) and American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) PT summary reports, as well as interview with the Technical Supervisor (TS), the laboratory failed to perform, document, and retain remedial action for unacceptable subspecialty and analyte testing event scores. FINDINGS: a. A review of the CASPER 155 report revealed the following unsatisfactory scores: 1. Endocrinology Subspecialty: 2022 Third Event = 50% 2. TSH Test Analyte: 2022 Third Event = 0% b. A review of the PT scores from AAB-MLE (2022) confirmed the above test event findings. 2. There was no documentation of plan of correction for the respective subspecialty and test analyte unsatisfactory scores. 3. The TS confirmed the findings on May 14, 2025, at approximately 1:30 P.M.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on direct observation, review of the Standard Operating Procedure (SOPs), as well as interview with the TS, the Laboratory Director (LD) failed to perform and document competency evaluation for Testing Personnel (TP). FINDINGS: 1. There was no documentation of initial competency evaluation for two TP within first year of employment. 2. This is contrary to the instructions indicated in the current, approved competency assessment SOPs. 3. The TS confirmed the findings on May 14, 2025, at approximately 1:30 P.M.