Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2046630	(X3) Date Survey Completed 10/16/2025
Name of Provider or Supplier Maiden Lane Medical Pllcr	**Street Address, City, State** 90 Maiden Lane, Third 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
D0000	Based on a proficiency testing (PT) desk review survey performed on October 16, 2025, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation. D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D) and American Proficiency Institute (API) PT summary reports, the

	laboratory failed to successfully participate in the CMS approved PT program for two out of three consecutive testing events in the General Immunology specialty and two out of three consecutive testing events for the Anti-Human Immunodeficiency Virus (HIV) and Hepatitis B Surface Antigen (HBS Ag) test analytes in 2025 resulting in unsuccessful performance. Refer to D2084 and D2085.
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on CMS PT CASPER 0155D and API PT summary reports from 2025, the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three consecutive testing events for the analytes Anti-HIV and HBS Ag. FINDINGS: a. A review of the CASPER 155 report revealed the following unsatisfactory scores: 1. Anti-HIV Analyte: 2025 First Event = 0% 2025 Second Event = 0% 2. Anti-HIV Analyte: 2025 First Event = 0% 2025 Second Event = 0% b. A review of the PT scores from API (2025) confirmed the above findings.
D2085	GENERAL IMMUNOLOGY CFR(s): 493.837(g) (g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on CMS PT CASPER 0155D and API PT summary reports from 2025, the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three consecutive testing events for the specialty General Immunology. FINDINGS: a. A review of the CASPER 155 report revealed the following unsatisfactory scores: 1. General Immunology Specialty: 2025 First Event = 0% 2025 Second Event = 0% b. A review of the PT scores from API (2025) confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of CMS PT CASPER 0155D and API PT summary reports from 2025, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of CMS PT CASPER 0155D and API PT summary reports, the LD failed to ensure successful participation in an HHS approved PT program. Refer to D2084.