Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0129618	07/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Daniel M Libby Md Pllc	407 E 70 St 3rd 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 July 11, 2024, 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 of three consecutive testing events in the Routine Chemistry subspecialty for the Glucose (Non-Waived) test analyte in 2024, resulting in unsuccessful performance. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(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 2024, the laboratory failed to achieve satisfactory performance (80% or greater) for two of three consecutive testing events in the Routine Chemistry subspecialty for the Glucose (Non-Waived) test analyte. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: Glucose (Non-Waived) Test Analyte: 2024 First Event = 60% 2024 Second Event = 60% 2. A review of the proficiency testing scores from API (2024) 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 2024, the laboratory director (LD) failed to failed to provide overall management and direction of the laboratory services. Refer to D2016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that 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 2024-1 and 2024-2 summary reports, the LD failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2096.