Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1027412	04/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Gregory Shifrin Md Pc Ob Gyn	1766 East 12th Street, Basement, Brooklyn, 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
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 the Centers of Medicare and Medicaid Services (CMS) CASPER 155D Report and the American Proficiency Institute (API) proficiency testing (PT) reports, the laboratory failed to obtain successful PT performance for four of four PT events reviewed for the analyte Alpha-fetoprotein (AFP). Findings: 1. The laboratory failed to attain a score of at least 80% for four of four events reviewed for the analyte AFP. The following scores were assigned: Alpha-Fetoprotein Test Analyte: 2023 First Event = 40% 2023 Second Event = 0% 2023 Third Event = 0% 2024 First Event = 40% This is considered repeatedly unsuccessful PT performance. Refer to D2084.

D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(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 review of the CMS CASPER 155D Report and the API PT reports, the laboratory failed to achieve satisfactory performance for the alpha-fetoprotein test analyte in two consecutive testing events. Findings: 1. The laboratory failed to attain a score of at least 80% for four of four events reviewed for the analyte AFP. The following scores were assigned: Alpha-Fetoprotein Test Analyte: 2023 First Event = 40% 2023 Second Event = 0% 2023 Third Event = 0% 2024 First Event = 40% This is considered repeatedly unsuccessful PT performance.
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 the CMS CASPER 155D Report and the API PT reports, the laboratory director (LD) failed to fulfill LD responsibilities and ensure that the laboratory achieved a satisfactory performance for the alpha-fetoprotein test analyte as well as successfully participate in the CMS approved PT program. Findings: 1. The laboratory failed to attain a score of at least 80% for four of four events reviewed for the analyte AFP. The following scores were assigned: Alpha-Fetoprotein Test Analyte: 2023 First Event = 40% 2023 Second Event = 0% 2023 Third Event = 0% 2024 First Event = 40% This is considered repeatedly unsuccessful PT performance. Refer to D6016.
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 the CMS CASPER 155D Report and the API PT reports, the LD failed to test the alpha-fetoprotein analyte as required as well as achieve a satisfactory performance in the CMS approved PT program. Findings: 1. The laboratory failed to attain a score of at least 80% for four of four events reviewed for the analyte AFP. The following scores were assigned: Alpha-Fetoprotein Test Analyte: 2023 First

	Event = 40% 2023 Second Event = 0% 2023 Third Event = 0% 2024 First Event = 40% This is considered repeatedly unsuccessful PT performance.