Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0921605	01/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Leon Nitkin Md Ob/Gyn	1120 Brighton Beach Ave Apt 1x, 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 the surveyor's review of proficiency testing (PT) records from the College of American Pathologists (CAP) and an interview with the testing person and the technical consultant, the laboratory failed to participate and perform successfully in a PT program approved by the Centers for Medicare and Medicaid Services (CMS) for the Hematology specialty and for the following analyte: Cell Identification/White Blood Cell Differential. The following scores were assigned: Cell Identification/White Blood Cell Differential 2018 first event = 0% (failure to participate) 2018 third event = 0% This is considered unsuccessful PT performance. Refer to D2130

D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on the surveyor's review of proficiency testing (PT) records from the College of American Pathologists (CAP) PT program and an interview with the testing person and the technical consultant, the laboratory failed to successfully participate in a PT program approved by the Centers for Medicare and Medicaid Services (CMS) for the specialty Hematology. The following score was assigned: Hematology Specialty 2018 first event = 0 (failure to participate) This is considered unsatisfactory PT performance.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the surveyor's review of proficiency testing (PT) records from the College of American Pathologists (CAP) program and an interview with the testing person and the technical consultant, the laboratory failed to achieve a satisfactory performance for the following analyte: Cell Identification/White Blood Cell Differential. The following scores were assigned: Cell Identification/White Blood Cell Differential 2018 first event = 0% (failure to participate) 2018 third event = 0% This is considered 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 the surveyor's review of proficiency testing (PT) records from the (CAP) PT program and an interview with the testing person and the technical consultant, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure

	that the laboratory achieved a satisfactory performance and successfully participated in a PT program for the Hematology Specialty and for the following analyte: Cell Identification/White Blood Cell Differential. 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 the surveyor's review of proficiency testing (PT) records from the College of American Pathologists (CAP), and an interview with the testing person and the technical consultant, the laboratory director failed to ensure that the laboratory achieved a satisfactory performance and successfully participated and in a PT program for the Hematology specialty and the test analyte: Cell Identification/White Blood Cell Differential. The following scores were assigned: Hematology Specialty 2018 first event = 0% This is considered unsatisfactory performance. Cell Identification/White Blood Cell Differential 2018 first event = 0% (failure to participate) 2018 third event = 0% This is considered unsuccessful PT performance.