Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0994451	05/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kakossian Medical Woman Care Pc	1180 Brighton Beach Avenue, First Floor, 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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT records and the verified with the College of American Pathologists (CAP) PT program, the laboratory failed to have the PT test results released to New York State Department of Health (NYSDOH), Physician Office Laboratory Evaluation Program (POLEP) in the calendar year 2018 and 2019.
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 proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT data reports and PT records from the College of American Pathologists (CAP) PT program, the laboratory failed to participate successfully in proficiency testing for the test analyte Glucose. The following scores were assigned: 2018 third event = 0% 2019 first event = 20% This is considered unsuccessful PT performance. Refer to 2096.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports and PT records from the CAP PT program, the laboratory failed to participate successfully in proficiency testing for the test analyte Amylase. The following scores were assigned: 2019 first event = 0% This is considered unsatisfactory PT performance.
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 PT desk review of the CMS PT data reports and PT records from the CAP PT program, the laboratory failed to participate successfully in proficiency testing for the test analyte Glucose. The following scores were assigned: 2018 third event = 0% 2019 first event = 20% This is considered unsuccessful PT performance.
D2109	TOXICOLOGY CFR(s): 493.845(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports and PT records from the CAP PT

	program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analyte Lithium. The following scores were assigned: 2019 first event = 0% This is considered unsatisfactory PT performance.
D2110	TOXICOLOGY CFR(s): 493.845(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports and PT records from the CAP PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the subspecialty Toxicology. The following scores were assigned: 2019 first event = 0% This is considered unsatisfactory 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 PT desk review of the PT CMS data reports and CAP PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, for the subspecialty Toxicology and the test analytes Glucose, Amylase and Lithium. 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 PT desk review of the PT CMS data reports and CAP PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, for the subspecialty Toxicology and the test analytes Glucose, Amylase and Lithium. The following scores were assigned: Glucose 2018 third event = 0% 2019 first event = 20% This is considered unsuccessful PT performance. Toxicology, Lithium and Amylase 2019 first event = 0% This is considered unsatisfactory PT performance.