Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1091586	06/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Long Island Queens Medical Associates Pc	300 Old Country Road, Suite 211, Mineola, 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
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on surveyor's review of the laboratory's Quidel Sofia analyzer Quality Control (QC) results, the lot numbers, expiration date and an interview with the laboratory director the laboratory failed to a have a written procedure for reporting the patient's tests results for the to the New York Bureau of Surveillance and Data systems, via the Electronic Clinical Laboratory Reporting System (ECLRS) from 10/21/20 through survey date. 1. The laboratory director confirmed on June 29, 2022, at approximately 11:30 AM, the laboratory failed to establish a written procedure for reporting the reporting the patient's tests results for the SARS-CoV-2 to the New York Bureau of Surveillance and Data systems.
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 American Proficiency Institute (API) Proficiency Testing (PT) program, the laboratory failed to participate and perform successfully in a PT program approved by CMS program for the test analyte Red Blood Cell (RBC) count. The following scores were assigned: 2021 second event = 60% 2021 Third event = 40% 2022 first event = 60% This is considered repeatedly unsuccessful PT performance Refer 2130
D2121	HEMATOLOGY CFR(s): 493.851(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 review of American Proficiency Institute (API) Proficiency Testing (PT) program, the laboratory failed to participate and perform successfully in a PT program approved by CMS program for the test analyte Red Blood Cell (RBC) count. The following scores were assigned: 2021 second event = 60% 2021 Third event = 40% 2022 first event = 60% This is considered repeatedly unsuccessful 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 review of American Proficiency Institute (API) Proficiency Testing (PT) program, the laboratory failed to participate and perform successfully in a PT program approved by CMS program for the test analyte Red Blood Cell (RBC) count. The following scores were assigned: 2021 second event = 60% 2021 Third event = 40% 2022 first event = 60% This is considered repeatedly unsuccessful PT performance
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) program and interview with the testing personnel, the laboratory failed perform and document remedial action for the PT scores less than 100% for Red blood Cell Count (RBC). FINDINGS: RBC 2021 second event = 60% 2021 Third event = 40% 2022 first event = 60%
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 API 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, approved by CMS, for the specialty Hematology Refer to D2016, D2130, D2121, D5211.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's API PT records and an interview with the laboratory director/pathologist and testing person, the laboratory director failed to ensure that corrective action was performed and documented for the laboratory's unsatisfactory PT performance for the 2021 second event, 2021 third event, and 2022 first event of RBC Refer to D2016, D2130, D2121, D5211.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory Quality Assurance Report and confirmed in an interview with the testing person at the time of this survey, the

	laboratory director failed to ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer D2016, D2130, D2121, D1002, D5211