Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D1091586	(X3) Date Survey Completed 11/13/2018
Name of Provider or Supplier Long Island Queens Medical Associates Pc	**Street Address, City, State** 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
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 the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the technical consultant and the testing person, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2016 third event: Red Blood Cells (RBC) = 20% Hematocrit (HCT) = 80%
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of laboratory QC records and an interview with the technical consultant and the testing person, the laboratory failed to perform lot to lot verification of Coulter AcT Diff hematology assayed controls. Findings: At approximately 3:00 PM on November 13, 2018, the technical consultant confirmed that the laboratory had not verified assayed hematology QC prior to use from June through September 2017.
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 review of the laboratory quality assessment records (QA), and interview with the technical consultant and the testing person, the laboratory director failed to follow their QA procedure for having an on going mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for hematology. Findings Include: It was confirmed with the technical consultant on the day of the survey at approximately 3:00 PM that although the QA reviews were performed by the technical consultant on 12/5/17, 2/22/18, 4/25/18, 5/23/18, 7/16/18, 8/13/18, 9/17/18, and 10/22/18, the laboratory director failed to sign the QA reviews as required by the laboratory's QA policy. Refer to : D5211, D5469