Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0984337	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier Hematology Oncology Assoc Of Brooklyn	**Street Address, City, State** 1660 E 14th Street Ste 501, 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
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), College of American Pathologists (CAP) and Center for Medicaid and Medicare Services (CMS) Proficiency Testing (PT) reports, and an interview with the testing person at 12:00PM on 3/28/19, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2017 third event: IgA = 80% 2018 first event: Total Calcium = 80% Chloride = 80% 2018 second event: Total Calcium = 80% Chloride = 80% 2019 first event: Total Calcium = 80% ALT (SGPT) = 80%
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's procedure manual and the maintenance

	records for the laboratory's instruments and interview with the testing person, the laboratory failed to establish a procedure that allows for a reduction of certain maintenance requirements for their analyzers based on their limited use. Findings: 1. During the review of maintenance sheets on the Pentra 400 Chemistry analyzer and the TOSOH Immunoassay analyzer and confirmed in an interview with the testing person at approximately 11:30 AM on March 28, 2019, the laboratory had spread out the weekly and monthly requirements based on the limited use of the analyzers. 2. The laboratory had no procedure allowing for a reduction of the maintenance schedule.
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 surveyor's review of the laboratory's Quality Control (QC) records for hematology, chemistry and general immunology and confirmed in a interview with the supervisor/testing person, the laboratory failed to perform a lot to lot comparison of assayed QC materials. Findings: 1. The supervisor/testing person confirmed at 12: 30 PM on 3/28/18 that the laboratory does not test new lots of control againist the current lot before using the new lot as primary QC. 2. This was noted for the Horiba controls used for general immunology, chemistry and hematology.