Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0906022	02/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
North Shore Hematology Oncology Associates	2330 Eastchester Road, Bronx, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records and an interview with the laboratory Quality Control (QA) Coordinator, assistant QA coordinator, and the supervisor, the laboratory failed to enroll in an approved Proficiency Testing (PT) program to verify the accuracy and reliability for hematology testing for the year 2018. Approximately 4200 patient specimens were tested and results reported for hematology testing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of laboratory competency records and an interview with the laboratory QA coordinator, assistant QA coordinator, and supervisor/testing person,

	the laboratory failed to follow their written policies and procedures to assess the competency of the laboratory testing personnel semi-annually for the first year of patient testing. Findings Include: It was confirmed by the laboratory QA coordinator on February 7, 2019, at approximately 12:15 pm, that the laboratory director acting as the technical consultant failed to have documentation of semi-annual competency for three of three testing personnel who perform hematology testing.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel records and an interview with the laboratory QA coordinator, assistant QA coordinator, and supervisor/testing person, the laboratory director failed to ensure that appropriate training was documented for three of three testing personnel who perform moderate complexity testing for hematology.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the laboratory QA coordinator, assistant QA coordinator and supervisor/testing person, the laboratory director, acting as the technical consultant, failed to perform the semi-annual evaluation for the three of three testing personnel during the first year of patient testing in calendar year 2018. Refer to D5209.