Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0870766	(X3) Date Survey Completed 12/18/2020
Name of Provider or Supplier North Shore Hematology Oncology Associates	**Street Address, City, State** 805 Northern Blvd Suite 101, Great Neck, 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
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on a surveyor review of Proficiency Testing (PT) records and confirmed in an interview with the laboratory quality assurance associate, the laboratory failed to enroll in an approved PT program for the hematology testing for the second event in 2019. FINDINGS: The laboratory quality assurance associate confirmed on December 18, 2020 at approximately 11:00 AM that the laboratory failed to enroll in PT for the second event of 2019 for hematology. The laboratory is currently enrolled in PT for hematology for the calendar year 2020.
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 College of American Pathologist (CAP) Proficiency Testing (PT) reports and an interview with the laboratory quality assurance associate,

	the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2019 first event: Cell ID = 80% 2019 third event: Platelets = 80% MPV = 40%
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a surveyor review of personnel records and confirmed in an interview with the laboratory quality assurance associate, the laboratory director failed to ensure that one of two testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing. Refer to D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a surveyor's review of personnel records and confirmed in an interview with the laboratory quality assurance associate at the time of the survey, the laboratory director failed to ensure that one of two testing personnel performing moderate complexity testing met the minimum educational requirements of a high school diploma and/or had foreign education diploma evaluated prior to performing patient testing.