Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0714172	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
North Shore Hematology-Oncology Associates Pc	2500 Nesconset Highway, Bldg 26 B, Stony Brook, 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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a surveyor review of hematology calibration records and an interview with the laboratory supervisor and the practice administrator, calibration of the hematology analyzer was not performed at the frequencies required by the manufacturer of the POCH 100i hematology analyzer in calendar year 2018. FINDINGS: 1. The laboratory has two hematology analyzers, Sysmex XS1000i and POCH 100i. The manufacturer of the hematology analyzers and the laboratory's calibration policy require analyzers calibration every six months. 2. The only documentation for the POCH 100i analyzer calibration available for review was for calibration performed in August 2017 during the validation study. The POCH 100i hematology analyzer was therefore out of calibration from February 2018 through the survey date. 3. Approximately 200 patient specimens were tested and reported for hematology during the above time frame when the POCH 100i analyzer was out of calibration. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON JANUARY 27, 2017.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a surveyor review of randomly selected test reports and an interview with the laboratory supervisor and the practice administrator, the laboratory failed to document complete test results for Prothrombin Time and International Normalized Ratio (PT/INR) in the patients electronic medical records. Findings: It was confirmed by the laboratory supervisor and the practice administrator, on August 15, 2018 at approximately 1:30 PM, that the laboratory failed to follow the laboratory's test report policy which requires documenting the PT and INR test results in the electronic medical records. The laboratory only documented the INR results and failed to document PT test results for approximately 44 patients from January 2017 through April 2017.
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 surveyor findings and interview with the laboratory supervisor and the practice administrator, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on 1/27/17; 2. Maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021.
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 laboratory records and confirmed in an interview with the laboratory supervisor and the practice administrator on August 15, 2018 at approximately 1:30 PM, the laboratory director failed to ensure that the QA program for hematology testing was maintained to ensure quality laboratory services. Refer to D5437, D5805 PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON JANUARY 27, 2017.