Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0129195	10/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
North Shore Hematology Oncology Associates Pc	945 5th Avenue, Office 6, New York, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a lack of laboratory quality control (QC) records and an interview with the laboratory testing person, the laboratory failed to test QC material for the Siemens' 10 SG Urine reagent strip and the Even Care glucometer. Findings Include: It was confirmed by the laboratory testing person on October 17, 2019, at approximately 12: 30 pm that the laboratory failed to follow the manufacturer's instruction for: 1) Siemens' 10 SG Urine reagent strips which state QC is to be performed when a new bottle is opened; 2) Even Care glucometer, controls are to be tested once a week. Approximately 50 patient tests were performed for urinalysis, glucose testing and results reported.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS

	may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor's review of the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the laboratory testing person, the laboratory failed to successfully participate in a PT program approved by the Center for Medicare and Medicaid Services (CMS) for Cell Identification (Cell I.D.) /White Blood Cell (WBC) Differential. The following scores were assigned: 2018 second event = 47% 2018 third event = 47% This is considered an unsuccessful PT performance. Refer to D2130.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the testing person, the laboratory failed to participate and perform successfully in a PT program approved by CMS, for the following test analytes: 2019 1st event Hemoglobin = 60% 2019 2nd event Erythrocyte count = 60% Hematocrit = 60% Platelet count = 60% This is considered unsatisfactory PT performance.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on the surveyor's review of proficiency testing (PT) records from the American Preficiency Institute (API) program and an interview with the laboratory testing person, the laboratory failed to achieve a satisfactory performance for the following analyte: Cell Identification/White Blood Cell Differential. The following scores were assigned: Cell Identification/White Blood Cell Differential 2018 second event = 47% 2018 third event = 47% This is considered unsuccessful PT performance.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves

	a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor's review of records and an interview with the laboratory testing person, the laboratory failed to monitor and evaluate the overall quality system and prevent problems from occurring for the following: 1. Ensure that personnel competency is performed for all 6 components. Refer to D5209 2. Ensure that all PT results for less than 100% are evaluated. Refer to D5211 3. Ensure that the laboratory perform their monthly QA reviews. Refer to D5291
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 surveyor's review of the laboratory policies/procedures, no competency record and an interview with the laboratory testing person, the laboratory failed to follow their laboratory's policies and procedures for assessing personnel competency. Finding Include: It was confirmed by the laboratory testing person on October 17, 2019, at approximately 10:45 am that the laboratory failed to follow and assess the testing person on six (6) of the laboratory's six (6) criteria's for 2017 and 2018: 1) Direct observation of routine test performance, patient preparation, specimen handling, processing & testing; 2) Monitoring, recording, and reporting of test results; 3) Review of intermediate test results worksheet, QC records, PT results, and preventive maintenance; 4) Direct observation of performance of instruments maintenance and function checks; 5) Assessment of test performance; 6) Assessment of problem-solving skills.
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 a review of the American Proficiency Institute (API) proficiency test (PT) reports and an interview with the laboratory testing person, the laboratory did not evaluate, perform and document remedial action for the PT scores less than 100%. Findings Include: It was confirmed by the laboratory testing person on October 17, 2019, at approximately 12:15 pm, that the laboratory failed to evaluate the following PT results: 2019 1st event RBC = 80% Platelet = 80% 2019 2nd event Granulocytes = 80% Lymphocytes = 80%
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's Quality Assessment (QA) policies and procedures and confirmed in an interview with the laboratory testing person on October 17, 2019, at approximately the time 1:15 am, the laboratory failed to follow their established QA policy and perform their monthly QA review since September 2017.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's procedure manual and an interview with the laboratory testing person, the laboratory failed to have a procedure manual that is comprehensive, up-to-date, and accurate. FINDINGS: The procedure manual did not include the following procedures: 1. Verification of new lots of controls (a lot to lot verification); 2. The interval in which the laboratory's QA review would be performed; 3. Peripheral blood smear, slide staining, smear examination for the manual differential; 4. The interval in which the Microscope will be serviced; 5. Remediation for proficiency testing failures and grades less than 100%.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on surveyor's findings and an interview with the current technical consultant, the laboratory director failed to provide overall management of the laboratory. Refer to D6089, D6094, and D6128
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of API PT test reports and confirmed in an interview with the testing person, the laboratory director failed to ensure that the laboratory successfully performed and participate in a CMS-approved PT program for the less than 100% PT score and White Blood Cell Differential (WBCD). Refer to: 2121 and D2130 The following scores were assigned: 2019 1st event Hemoglobin = 60% 2019 2nd event Erythrocyte count = 60% Hematocrit = 60% Platelet count = 60% This is considered unsatisfactory PT performance. Cell Identification/White Blood Cell Differential 2018 second event = 47% 2018 third event = 47% This is considered an unsuccessful PT performance.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review oflaboratory procedures, and an interview with the laboratory testing person, the director failed to ensure that the laboratory's QA program was maintained for all areas of laboratory testing. Refer to: D5211, D5291 and D5403,
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a lack of competency records and an interview with the laboratory testing person, the director, acting as the technical consultant, failed to ensure that annual

	competency for the laboratory testing person was not performed. The last employee competency record available for review was performed on July 29, 2016. Refer to D5209