Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0160423	(X3) Date Survey Completed 11/06/2024
Name of Provider or Supplier North Shore Hematology Oncology Associates	**Street Address, City, State** 750 Old Country Rd, Suite A And Suite B, Riverhead, 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
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 review of the laboratory's standard operating procedure (SOPs) as well as interview with the Quality Assurance (QA) personnel, the laboratory failed to draft, approve SOPs for all patient specimen testing and analyzer maintenance performed in the laboratory. FINDINGS: 1. The current, approved SOPs did not include instructions for: a. i-STAT analyzer calibration and verification performance. b. Siemens Hematek 3000 automated slide stainer system. 2. QA personnel confirmed the findings on November 6, 2024, at approximately 12:30 P.M.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observations, review of the SOPs, as well as interview with the QA personnel, the laboratory failed to comply with the Hematek slide stainer maintenance log. FINDINGS: 1. The surveyor's observations confirmed on November 6, 2024, at approximately 12:00 P.M: a. The Hematek pump tubing was not changed after third stain pack install. b. There was no documentation of Hematek pump tubing install on the maintenance log sheet after fourth stain pack receipt on September 11, 2024. 2. These are contrary to instructions indicated in the Hematek slide stainer maintenance log. 3. QA personnel confirmed the findings on November 6, 2024, at approximately 12:00 P.M.