Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0158554	05/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
North Shore Hematology-Oncology Associates Pc	365 East Main Street, Patchogue, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, humidity logs, and interview with the Quality Assurance Associate (QAA), the laboratory failed to monitor and document humidity ranges. FINDINGS: 1. There was no documentation of humidity ranges from July 2022 through the date of survey. 2. This was contrary to instructions indicated in the current, approved standard operating procedures. 3. Confirmed findings by interview with QAA on May 3, 2024, at approximately 11:00 A.M.
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 a review of the laboratory's policy and procedure manual and interview with the QAA, the laboratory failed to draft, approve written procedures for urine microscopy, bleeding time, and Sysmex XN-1000 hematology analyzer complete blood count (CBC) testing. FINDINGS: 1. The current, approved standard operating procedures did not include written instructions for urine microscopy, Sysmex XN-100 hematology analyzer CBC, and bleeding time performance. 2. Confirmed findings by interview with QAA on May 3, 2024, at approximately 11:30 A.M.