

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0160423	(X3) Date Survey Completed 11/30/2022
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of the College of American Pathology Proficiency Test (CAP PT) records and an interview with the testing personnel, the laboratory failed to rotate proficiency testing for hematology between the five-testing person 2021 first event through survey date. FINDINGS: 1. PT attestation form for 2021 first event through survey date had same testing person signature. 2. Confirmed in an interview with general supervisor on 11/30/2022 about 11:30am</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 review of the iSTAT policy and procedure manual, the laboratory failed to establish a written standard Operations Procedure (SOP) manual laboratory for new lot control/new cartridge validation. FINDINGS: 1. Procedure for validation of new control and cartridge lot number was not available. 2. Confirmed in an interview with general supervisor on 11/30/2022 about 12pm.