

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2231456	<b>(X3) Date Survey Completed</b>  02/05/2025
<b>Name of Provider or Supplier</b>  North Shore Hematology Oncology Associates Pc	<b>Street Address, City, State</b>  501 Hawkins Ave, Lake Ronkonkoma, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) Proficiency Testing (PT) summary reports as well as interview with the Quality Assurance Coordinator (QAC), the Laboratory Director (LD) failed to document review and date of review for the CAP PT summary reports. FINDINGS: 1. There was no documented CAP hematology PT summary report LD review and date of review for the third event of 2023 as well as the third event of 2024. 2. There was no documented CAP urine analysis PT summary report LD review and date of review for the second event of 2023 as well as the second event of 2024. 3. QAC confirmed the findings on February 5, 2025, at approximately 12:00 P.M.</p>
<b>D5439</b>	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number</p>

changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of Sysmex XN-450 analyzer Calibration Verification (CV) certificates as well as interview with the QAC, the laboratory failed to perform and document corrective action to assure results are within acceptable CV limits.

FINDINGS: 1. The Sysmex XN-450 analyzer SN#12648 CV certificate Control Level two, Lot #32091402, Expiration: November 7, 2023, Red Blood Cell (RBC) upper mean limit indicated was 4.433. However, the documented laboratory CV RBC mean was 4.450. 2. There was no documentation of subsequent corrective action performance. 3. QAC confirmed the findings on February 5, 2025, at approximately 12:00 P.M.