

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2311658	(X3) Date Survey Completed 09/23/2025
Name of Provider or Supplier North Shore Hematology Oncology Assoc Pc	Street Address, City, State 159 Barnegat Road , Suite 101, Poughkeepsie, 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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature records, Standard Operating Procedures (SOPs), lack of corrective action records, as well as interviews with the Technical Consultant (TC) and Quality Assurance Associate (QAA), the laboratory failed to perform and document corrective action for test systems that did not meet the laboratory's established performance specifications. FINDINGS: 1. Ambient room temperatures documented on the "Room/Humidity Temperature Chart" deviated from the specified range of 18C - 25 C for six days: September 19, 2024, 25.3C; November 6, 2024, 26.3 C; November 7, 2024, 25.1C; January 3, 2025, 17.5C; February 6, 2025, 17.3C; and February 24, 2025, 17.4C. 2. There was no documentation of corrective action performance for the respective out-of-range ambient room temperatures. 3. This is contrary to instructions included in the current, approved SOPs. 4. The TC and QAA confirmed the findings on September 23, 2025, at approximately 10:45 A.M.</p>