

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2311652	(X3) Date Survey Completed 09/24/2025
Name of Provider or Supplier North Shore Hematology Oncology Assoc Pc	Street Address, City, State 400 Westage Business Center Drive Ste. 103, Fishkill, 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 temperature documented on the "Room/Humidity Temperature Chart" deviated from the specified range of 18C - 25 C for November 1, 2024, 37.7C. 2. There was no documentation of corrective action performance for the respective out-of-range ambient room temperature. 3. This is contrary to instructions included in the current, approved SOPs. 4. The TC and QAA confirmed the findings on September 24, 2025, at approximately 10:30 A.M.</p>
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p>

(k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on review of patient records, Electronic Medical Records (EMRs), SOPs, Quality Assurance (QA) policy, as well as interviews with the TC and QAA, the laboratory failed to issue corrected reports and promptly notify the authorized person ordering tests, or individual using the test results of reporting errors. FINDINGS: 1. Patient TK's EMR reported urinalysis results did not match the corresponding Siemens Clinitek Status+ analyzer printed urinalysis results for August 29, 2024. a. Glucose analyte EMR result: Negative; Analyzer Result: 100. b. Protein analyte EMR result: 100; Analyzer Result: Trace. 2. There was no documentation of corrected patient report. 3. This is contrary to instructions included in the current, approved SOPs and QA policy. 4. The TC and QAA confirmed the findings on September 24, 2025, at approximately 1:30 P.M.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of patient logs, EMRs, SOPs, QA, as well as interviews with the TC and QAA, the laboratory failed to follow documented policies and procedures for an ongoing mechanism to monitor, assess and, when indicated correct problems identified in the postanalytic systems. Refer to 5821.