

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0159503	(X3) Date Survey Completed 05/11/2022
Name of Provider or Supplier North Shore Hematology Oncology Associates Pc	Street Address, City, State 5316 Nesconset Hwy, Port Jefferson Station, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of validation records of Sysmex XN-450, the laboratory failed to perform complete method validation when analyzer was moved to new location in April 2021 prior to patient testing. Findings: 1. Complete Method Validation documentation not available for review at the time of the survey. 2. Approximately 30,000 patients were tested and reported since April 2021. 3. Confirmed on an interview with technical consultant on 5/11/2022 about 11am.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:

Based on the review of Quality Assurance records and interview with technical consultant, the laboratory director failed to maintain quality of laboratory service provided. Refer to D5421