

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0934129	(X3) Date Survey Completed 07/22/2022
Name of Provider or Supplier North Shore Hematology Oncology Associates Pc	Street Address, City, State 640 County Road 39, Southampton, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the review of humidity log, the laboratory failed to maintain manufacturer humidity requirement of 30-85% for Sysmex Poch 100i. Findings: 1. Following months humidity fell below 30% a. 2020 - January, February, March, December b. 2021 - January, February, and March c. 2022 - January, February, March, May, June 2. Confirmed on an interview with Quality Assessment (QA) Coordinator on 7/20 /2022 about 12:30pm.</p>
D6020	<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 the quality control program is 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 Assessment (QA) review for year 2020 through survey date, the laboratory director failed to maintain the quality of laboratory services, including the identification of failures in quality as they occur. Refer: D5413