

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0663065	(X3) Date Survey Completed 10/21/2022
Name of Provider or Supplier North Shore Childrens Healthcare	Street Address, City, State 3 School Street, Suite 302, Glen Cove, 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 lack of humidity documentation, the laboratory failed to follow manufacturer requirement of hematology analyzer Horiba Micros 60 humidity requirement of 20-80%. Confirmed on an interview with technical supervisor on 10/21 /2022 about 12pm, humidity monitoring and documentation were not performed for 2020 through survey date.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the review of the laboratory's API PT records and an interview with the technical supervisor, the laboratory director failed to ensure that corrective action was performed and documented for the laboratory's unsatisfactory PT performance.
Finding: 1. 2021 first event - WBC Differential 93%, Lymphocytes 80% 2. 2021 second event - MCH 80%