

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0663065	(X3) Date Survey Completed 12/17/2019
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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of hematology calibration records and interview with the clinical consultant/laboratory supervisor, calibration of the hematology analyzer was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzers. FINDINGS: The laboratory's calibration policy and the manufacturer of the Horiba ABX Micros 60 hematology analyzer require analyzer calibration every six months. The documentation of the hematology analyzer calibration available for review was for calibrations performed on 3/6/17 and 6/27/17. The analyzer was therefore out of calibration from 12/28/17 through this survey date. Approximately 2000 patient specimens were tested and reported for hematology during the time period when analyzer was out of calibration. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON JUNE 9, 2017.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a surveyor findings and interview with the clinical consultant/laboratory supervisor, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. maintained the plan of correction from the survey conducted on June 9, 2017; and, 2. maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on a surveyor review of the laboratory Quality Assessment (QA) policy and interview with the clinical consultant/laboratory supervisor, the laboratory director failed to ensure that the general laboratory system QA reviews were performed and documented at least two times per year in calendar year 2018 and up to survey date, as required by their QA policy. Refer to D5437