

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0663065	(X3) Date Survey Completed 01/21/2025
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of analyzer calibration records, Standard Operating Procedure (SOPs), as well as interview with the Technical Supervisor (TS), the laboratory failed to perform and document patient specimen processing analyzer calibration verification. FINDINGS: 1. The only Horiba ABX Micros 60 analyzer calibration documentation for 2023 was performed May 12, 2023. 2. This is contrary to instructions included in the current, approved SOPs which require twice per year analyzer calibration performance. 3. The TS confirmed the findings on January 21, 2025, at approximately 12:00 P.M.</p>

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on review of SOPs as well as interview with the TS, the laboratory failed to establish or verify the criteria for acceptability of all control materials. FINDINGS: 1. The current, approved SOPs for external Quality Control (QC) did not include instructions for new lot number validation and guidelines to verify control results correlated with established limits. 2. The TS confirmed the findings on January 21, 2025, at approximately 11:30 A.M.