

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0709006	(X3) Date Survey Completed 06/14/2022
Name of Provider or Supplier Pchc	Street Address, City, State 376 Main St, Jackman, ME	
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>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 lack of documentation, record review and interview with testing personnel #1 (TP1), the laboratory failed to perform a 6 month calibration verification on the Sysmex XS 1000I for the specialty of hematology. Findings include: 1. Record review on 6/14/2022 of the Sysmex XS 1000I manufacturer's maintenance manual specifies "6 month" calibration as part of the preventive maintenance program. 2. During interview with (TP1) on 6/14/2022 at 10:00 AM, TP1 noted that, the laboratory</p>

missed a 6 month calibration due to a contract renewal oversight. 3. The laboratory performs approximately 305 tests in the specialty of hematology per year.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on documentation and interview with testing personnel #1 (TP1) the technical consultant (TC) failed to document annual competency of testing personnel to assess the knowledge and skills necessary to perform moderate complexity laboratory testing in the specialty of hematology. Findings include: 1. Record review on 6/14/2022 of the CMS form 209 revealed 2 of 2 TP perform moderate complexity testing. 2. During interview with (TP1) on 6/14/2022 at 9:15 AM, TP1 stated: a. Testing personnel are evaluating each other's competencies. b. The staff was unaware that annual competencies fall under the TC's responsibilities. c. The laboratory did not document a 2nd competency for the first year for 1 TP. 3. The laboratory performs approximately 305 tests under the specialty of hematology per year.