

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0990994	(X3) Date Survey Completed 07/14/2021
Name of Provider or Supplier A2cl-Aurora Baycare Medical Center - Kaukauna	Street Address, City, State 1500 Arbor Way, Kaukauna, WI	
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 laboratory procedures and records and interview with the technical consultant, the laboratory did not ensure biannual calibration of the Sysmex hematology analyzer after the last calibration on September 14, 2020 as required by the laboratory's procedure. Findings include: 1. Review of the 'SYSMEX XNL-450 / 550 OPERATING PROCEDURE', document number 62487, showed the laboratory's calibration requirement identified in 'Section VI. Calibration' was as follows: "Calibration is performed bi-annually by Sysmex either on site or remotely." 2. Review of calibration records for the laboratory's Sysmex XNL hematology analyzer showed Sysmex last calibrated the analyzer on September 14, 2020. No additional calibration records were available between September 14, 2020 and July 14, 2021. 3. Interview with the technical consultant (Staff A) on July 14, 2021 at 2:30 PM confirmed no records were available documenting calibration of the analyzer biannually after September 14, 2020 as required by the laboratory's procedure.</p>