

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0388478	(X3) Date Survey Completed 09/01/2021
Name of Provider or Supplier A2c1 Aurora Health Center - Menomonee Falls	Street Address, City, State N84 W16889 Menomonee Ave, Menomonee Falls, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with the technical consultant, the laboratory did not evaluate the accuracy for twenty-five of twenty-five "Not scored-insufficient peer group" "Hematolgy-Comprehensive-AF5" PT results for 2020. Findings include: 1. Review of Wisconsin State Laboratory of Hygiene (WSLH) PT records showed the laboratory did not evaluate the accuracy of the following "Hematology-Comprehensive-AF5" PT results in 2020. a. 2020-HemeReg1: Five of five "Not scored-insufficient peer group" "Monocyte %" results. b. 2020-HemeReg2: Five of five "Not scored-insufficient peer group" "Lymphocytes%" results, five of five "Not scored-insufficient peer group" "Basophils%" results. c. 2020-HemeReg3: Five of five "Not scored-insufficient peer group" "Lymphocytes%" results, five of five "Not scored-insufficient peer group" "Basophils%" results 2. Interview with the technical consultant on September 1, 2021 at 9:35 AM confirmed the laboratory did not evaluate the accuracy for twenty-five of twenty-five "Not scored-insufficient peer group" "Hematolgy-Comprehensive-AF5" PT results for 2020.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and records and interview with the general supervisor, testing personnel did not follow the laboratory's procedure for "Bi-Annual Automated and Manual Differential Comparisons" for hematology differentials in 2020 and 2021. Findings include: 1. Review of the "Bi-Annual Automated and Manual Differential Comparisons" procedure revealed comparisons between automated and manual differential "must be performed at a minimum of twice per year". 2. Review of hematology records showed differential method comparison performed February 28, 2020. Further review showed no additional method comparison in 2020 or 2021. 3. Interview with the general supervisor on September 1, 2021 at 1:30 PM confirmed the testing personnel did not follow the laboratory's procedure "Bi-Annual Automated and Manual Differential Comparisons" for hematology differentials in 2020 and 2021.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:

Based on surveyor review of calibration verification records and interview with the general supervisor, the laboratory did not perform calibration verification every six months for the Siemens Xpand chemistry analyzer in 2021. Findings include: 1. Review of calibration verification records showed calibration verification performed on February 13, 2020 and September 1, 2020 for electrolytes, calcium and aspartate aminotransferase (AST). Further review showed no documentation of calibration verification for the Siemens Xpand chemistry analyzer in 2021. 2. Interview with the general supervisor on September 1, 2021 at 12:10 PM confirmed the laboratory did

not perform calibration verification every six months for the Siemens Xpand chemistry analyzer in 2021.