Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2163824	05/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ascension Medical Group-Fox Valley Wisconsin, Inc	5045 W Grande Market Drive, Appleton, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical consultant, the hematology procedures did not include calibration or calibration verification procedures for one of one procedure reviewed. Findings include: 1. Review of the "Sysmex XP-300" hematology procedure showed no evidence the laboratory included calibration or calibration verification procedures on the hematology analyzer in their procedure. 2. Interview with the technical consultant on May 2, 2024, at 12:20 PM confirmed the hematology procedures did not include

	calibration or calibration verification procedures for the Sysmex XP-300 hematology analyzer.
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 the Pathfast N-terminal pro b-type natriuretic peptide (NT-proBNP) verification records and interview with the technical consultant, the laboratory did not perform calibration verification analysis that included the minimum and maximum reportable range for one of one analytes. Findings include: 1. Review of the NT-proBNP calibration verification records showed the current reportable range was 15-30,000 picograms/milliliter (pg/mL). Further review showed the range for the calibration verification performed on December 8, 2023, was 152-13,018 pg /mL. 2. Interview with the technical consultant on May 2, 2024, at 12:20 PM confirmed the calibration verification range for NT-proBNP did not cover the reportable range.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on survey review of a patient's Basic Metabolic Panel (BMP) test report and laboratory procedures and interview with the technical consultant, the reference ranges shown on the patient report were not the same as the approved reference ranges for one of eight chemistry analytes reviewed. Findings include: 1. Review of the reference range of the BMP test report from May 2, 2024, in the electronic medical

	record (EMR) for patient 1 (an adult male) showed the following expected ranges: Analyte/Reference range Sodium/137-145 milli moles/Liter (mmol/L) Potassium/3.4-5.1 mmol/L Chloride/98-107 mmol/L Carbon Dioxide-Total/22-32 mmol/L Blood Urea Nitrogen/7-25 milligrams/deciliter (mg/dL) Creatinine/0.66-1.25 mg/dL Calcium /8.4-10.2 mg/dL Glucose/74-106 mg/dL 2. Review of the "Normal Ranges procedure showed the approved reference ranges for an adult male are: Analyte/Reference range Sodium/137-145 milli moles/Liter (mmol/L) Potassium/3.4-5.1 mmol/L Chloride/98-107 mmol/L Carbon Dioxide-Total/22-30 mmol/L Blood Urea Nitrogen/7-25 mg/dL Creatinine/0.66-1.25 mg/dL Calcium/8.4-10.2 mg/dL Glucose/74-106 mg/dL Further review showed the carbon dioxide reference range in the procedure did not match the patient's test report. 3. Interview with the technical consultant on May 2, 2024, at 12: 20 PM confirmed the reference range for carbon dioxide was updated in the EMR and the procedure had not been updated to be consistent with the approved reference ranges.