Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0392724	06/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Edgerton Hospital & Health Services	11101 N Sherman Rd, Edgerton, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of Unity Interlaboratory Quality Assurance Program (IQAP) reports and immunoassay analyzer information and interview with the chemistry lead, staff B, the laboratory did not retain the quality control (QC) information when the QC range was updated for troponin analyte for one of one event reviewed. Findings include: 1. Review of Unity IQAP reports showed the laboratory reviewed and updated the QC range for the troponin analyte after receipt of the IQAP peer group data. 2. Review of the Abbott i1000 immunoassay analyzer showed the updated quality control range had changed all previous data to the new QC range. Further review showed no indication of the previous QC range or the time and date the change was made. 3. Interview with staff B on June 8, 2023, at 9:30 AM confirmed the laboratory did not retain QC range information when the troponin QC range was updated.
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 records and interview with the laboratory manager and microbiology lead, staff A and staff C, the laboratory does not have an acceptable target range listed for the PROMPT verification procedure to ensure corrective action when the verification fails to meet the laboratory's criteria for acceptability for one of one procedure reviewed. Findings include: 1. Review of the "Verification of Prompt" procedure showed the target range for the verification is 5 x 10? colony forming units per milliliter (CFU/ml). Further review showed the unacceptable verification is "anything not close is not acceptable" with no range to show what is considered close to 5 x 10? CFU/ml. 2. Review of the Beckman Coulter "Colony Count Procedure to Determine Inoculum Density" stated "laboratories are encouraged to perform colony counts on inoculum suspensions at least quarterly to ensure the final concentration routinely obtained closely approximates 5 x 10? CFU /ml". Further review showed no indication of range for this target. 3. Review of the "Verification of Prompt Log Sheet" showed the target range is "approximately 5 x 10? CFU/ml" with no range listed as to acceptability of verification. Further review showed values between 5 x 10? CFU/ml and 13 x 10 CFU/ml. 4. Interview with staff A and staff C on June 8, 2023, at 11:30 AM confirmed the laboratory does not have an acceptable target range listed for the PROMPT verification procedure to ensure corrective action when the verification fails to meet the laboratory's criteria for acceptability.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation of the chemistry freezer, review of chemistry freezer temperature log, and interview with the laboratory manager and chemistry lead, staff A and staff B, the laboratory did not define an acceptable temperature range that was consistent with the manufacturer's acceptable range for the Maine Standards calibration verification material stored in the chemistry freezer for ten of ten days in between reagent receipt in the laboratory on May 11, 2023 and calibration verification

	testing on May 20, 2023. Findings include: 1. Observation of Maine Standards Validate calibration verification material in the chemistry freezer on June 8, 2023, at 9: 00 AM showed the manufacturer required storage at -10 to -25 degrees Celsius (C). Further review showed the reagents had been received into the laboratory on May 11, 2023 and opened for use on May 20, 2023. 2. Review of the temperature logs for May 2023 showed the defined acceptable temperature range for the chemistry freezer was less than or equal to -18 degrees C. Further review showed all temperatures in the chemistry freezer were below -25 C from May 11, 2023 and May 20, 2023. 3. Interview with the staff A and staff B on June 8, 2023, at 9:03 AM confirmed the laboratory's acceptable range for the chemistry freezer was not consistent with the manufacturer's acceptable range for the Maine Standards calibration material.