Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0395541	11/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Marshfield Medical Center-Neillsville	N3708 River Ave, Neillsville, 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 verification documentation and procedures for the Osmo1 analyzer and interview with the technical consultant, the laboratory procedure for osmolality testing identified two of two interfering substances that were not concordant with those identified in the verification documentation. Findings include: 1. Review of the verification documentation for the Osmo1 analyzer showed hemolysis interfered and lipemia did not interfere with the test performance. 2. Review of the laboratory procedure for the Osmo1 analyzer showed hemolysis did not interfere and lipemia interfered with test performance. 3. Interview with the technical

	consultant on November 16, 2023, at 9:10 AM confirmed the verification documentation and the procedure for the Osmo1 analyzer did not consistently identify the substances that interfered with the test performance.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer instructions, observation of supplies in the laboratory, and interview with a technical supervisor, the laboratory did not label one of one Remel Gram Iodine bottle in use with the prepared and expiration date. Findings include: 1. Review of the Remel Gram Iodine manufacturer's instructions showed Gram Iodine concentrate is added to diluent to prepare the working Iodine solution. The instructions also state, "Use Gram Iodine within 3 months after reconstitution". 2. Observation of gram stain reagents in use in the laboratory on November 15, 2023 at 2:10 PM showed the bottle of Gram Iodine solution was not labeled with a prepared date or three month diluted expiration date. 3. Interview with a technical supervisor (staff A) on November 15, 2023 at 2:10 PM confirmed the laboratory did not have records to show when testing personnel diluted the Gram Iodine solution and confirmed the bottle did not show the prepared or expiration date for the diluted iodine solution.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory Individualized Quality Control Plans (IQCP) and interview with the technical consultant, the laboratory did not define in their IQCPs the number or type of external quality control (QC) samples required for four of four analyzers. Findings include: 1. Review of IQCP documentation for four analyzers (Biofire, GeneXpert, Medtox Scan, and GEM Premier) showed the laboratory had not defined the number or type of external QC samples required prior

	to patient testing. 2. Interview with the technical consultant on November 15, 2023 at 12:45 PM confirmed the laboratory had not defined the number and type of controls required for external quality control testing in the IQCP documentation.