Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0395541	02/24/2022
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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. 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 general supervisor, the laboratory did not retain immunohematology PT records for the second event in 2020. Findings include: 1. Review of WSLH PT records for 2020 showed no evidence of testing records, signed attestation statements, PT result scores from the provider, documentation of result review and investigation for all immunohematology scores of 80% for the second event in 2020. 2. Interview with the general supervisor on February 23, 2022 at 11:45 AM confirmed the laboratory did not have immunohematology PT testing records, documentation of results review and investigation for scores of 80% for the second event in 2020.
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on surveyor review of blood culture reports and interview with the general supervisor, the laboratory did not retain any preliminary test results from the culture, including the gram stain result. Findings include: 1. Review of the test report for

	patient 1 showed the laboratory referred an isolate from a positive blood culture, collected on February 11, 2022 at this facility, to a reference laboratory for identification and susceptibility testing on February 13, 2022. The report showed testing personnel, staff A, called a critical test result on February 13, 2022 at 3:58 AM but the report did not identify the test performed at this laboratory or the reported result. 2. Interview with the general supervisor on February 23, 2022 at 1:35 PM revealed testing personnel perform and report a gram stain when a blood culture is positive. Further interview confirmed the report for patient 1 did not identify the test or the results called by staff A on February 13, 2022 at 3:58 AM and the system does not retain preliminary reports. This is a repeat deficiency from January 30, 2020.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor observation of laboratory equipment, review of laboratory procedures and training and competency evaluations and interview with the general supervisor, the laboratory did not follow their written policies for training and competency evaluation for two analyzers on four of four current staff members. Findings include: 1. Observation of laboratory equipment on February 23, 2022 at 8: 40 AM revealed two new analyzers: a. Beckman Coulter DxH520 back up hematology analyzer b. Werfen GEM Premier 4000 blood gas analyzer 2. Review of the "Competency Assessment of Testing Personnel" procedure stated "Newly hired personnel or current staff member who is learning a procedure for the first time must demonstrate competency in accordance to the following schedule": a. "Initial training and competency must be documented prior to reporting of any patient results." b. "Six months following the initial competency assessment." 3. Review of training and competency evaluation records showed no evidence of initial training and competency for the DxH 520 backup hematology analyzer for four of four current staff members. Further review showed no evidence of six month competency for the GEM Premier 4000 blood gas analyzer for four of four current staff members. 4. Interview with the general supervisor on February 23, 2022 at 11:00 AM confirmed the laboratory did not follow their written policies for training and competency evaluation for two analyzers on four of four current staff members. This is a repeat deficiency from January 9, 2014 and January 30, 2020.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) 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). 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 general supervisor, the laboratory did not evaluate the accuracy for "Not scored-insufficient peer group" for twenty-five of thirty mean platelet volume (MPV) results and twenty-five of thirty nucleated red blood cell (NRBC) results in 2020 and 2021. Findings include: 1. Review of WSLH PT records showed the laboratory did not evaluate the accuracy of the following PT results in 2020 and 2021. a. 2020-HemeReg1: Five of five "Not scored-insufficient peer group" "MPV" results and five of five "Not scored-insufficient peer group" "NRBC" results. b. 2020-HemeReg2: Five of five "Not scored-insufficient peer group" "MPV" results and five of five "Not scored-insufficient peer group" "NRBC" results. c. 2020-HemeReg3: Five of five "Not scored-insufficient peer group" "MPV" results and five of five "Not scored-insufficient peer group" "NRBC" results. d. 2021-HemeReg1: Five of five "Not scored-insufficient peer group" "MPV" results and five of five "Not scored-insufficient peer group" "NRBC" results. e. 2021-HemeReg3: Five of five "Not scored-insufficient peer group" "MPV" results and five of five "Not scored-insufficient peer group" "NRBC" results. Further review showed the laboratory did evaluate the accuracy for five of five "Not scored-insufficient peer group" "MPV" results and five of five "Not scored-insufficient peer group" "NRBC" results for 2021-HemeReg2. 2. Interview with the general supervisor on February 23, 2022 at 10:10 AM confirmed the laboratory did not evaluate the accuracy for "Not scored-insufficient peer group" for twenty-five of thirty mean platelet volume (MPV) results and twenty-five of thirty nucleated red blood cell (NRBC) results in 2020 and 2021.
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 the manufacturer's requirements and chemistry freezer temperature log, and interview with the general supervisor, the laboratory did not define an acceptable temperature range that was consistent with the manufacturer's acceptable range for the MAS Diabetes quality control material stored in the freezer. Findings include: 1. Review of the manufacturer's package reqrirements for the MAS Diabetes quality control showed the manufacturer's required storage at -15 to -25 Celsius (C). 2. Observation of MAS Diabetes quality control in the chemistry freezer on February 23, 2022 at 3:22 PM showed the manufacturer required storage at -15 to -25 Celsius (C). 3. Review of the temperature logs for December 2021 and January 2022 showed the defined acceptable temperature range for the chemistry freezer was -20 to -35 C. Forty-four of forty-nine days showed recorded temperatures were colder than -25 C. 4. Interview with the general supervisor on February 23, 2022 at 3:27 PM confirmed the laboratory's acceptable range for the chemistry freezer was not consistent with the manufacturer's acceptable range for the MAS Diabetes quality control material stored. This is a repeat deficiency from January 30, 2020.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of microbiology culture media and interview with the general supervisor, the laboratory had sixteen of sixteen expired macconkey agar plates available for use for patient testing in the laboratory. Findings include: 1. Observation of the microbiology culture set up area on February 23, 2022 at 1:50 PM revealed five of five macconkey agar plates had expired on February 16, 2022. Further observation in the microbiology refrigerator revealed ten of ten macconkey agar plates had expired on February 16, 2022. There were no unexpired macconkey agar plates in the laboratory. 2. Observation of the microbiology incubator on February 23, 2022 at 1:52 PM revealed a blood culture proficiency test culture set up on a macconkey agar plate which expired on February 16, 2022. 3. Interview with the general supervisor on February 23, 2022 at 1:52 PM confirmed sixteen of sixteen macconkey agar plates expired on February 16, 2022 and were available for patient testing in the laboratory. This is a repeat deficiency from February 24, 2010.
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 two analytes on the Siemens Dimension EXL chemistry analyzer in 2021. Finding include: 1. Review of calibration verification records showed calibration verification performed on the following analytes: a. Calcium: October 2020 and June

	2021. Further review showed no additional documentation of calibration verification between those dates. b. Triglyceride: October 2020 and March 2021. Further review showed no additional documentation of calibration verification between those dates. 2. Interview with the general supervisor on February 24, 2022 at 9:00 AM confirmed the laboratory did not perform calibration verification every six month for two analytes on the Siemens Dimension EXL chemistry analyzer in 2021. This is a repeat deficiency from November 4, 2011 and January 30, 2022.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the general supervisor, the laboratory had not evaluated and defined the relationship between test systems from three of three primary and backup analyzers on a twice a year basis. Findings include: 1. Review of laboratory records showed no evidence of evaluation of the relationship between test systems for the following: a. Coagulation analyzers: Siemens CA660 and CA620 both perform protime and partial thromboplastin time (PTT) testing. b. Hematology analyzers: Beckman Coulter DxH600 and DxH520 both perform complete blood count (CBC) testing. c. Blood gas analyzers: Werfen GEM Premier 4000 and Abbott I-Stat analyzers both perform arterial blood gas (ABG) testing. 2. Interview with the general supervisor on February 24, 2022 at 10:35 AM confirmed the laboratory had not evaluated and defined the relationship between the test systems from three of three primary and backup analyzers on a twice a year basis.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) procedures and interview with the general supervisor, the technical consultant did not review and evaluate the microbiology QC program to ensure the program was maintained to assure acceptable levels of test performance. Findings include: 1. Review of gram stain QC records showed no evidence of technical consultant review of the weekly gram stain QC from May 25, 2021 through February 22, 2022. Further review showed QC was not performed for nine of forty weeks during that timeframe. 2. Review of blood culture media QC records showed no evidence of technical consultant review of the new lot blood culture media QC from March 4, 2021 through January 22, 2022. 3. Interview with the general supervisor on February 23, 2022 at 1:38 PM confirmed the technical

	consultant did not review and evaluate the microbiology QC program to ensure the program was maintained to assure acceptable levels of test performance.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory procedures, quality control (QC) records and interview with the general supervisor, testing personnel did not perform and document quality control for the gram stain test weekly according to the procedure for nine of forty weeks between May 25, 2021 and February 22, 2022. Findings include: 1. Review of the "Gram Stain-Regional Center Labs" procedure revealed "QC is performed weekly and on each new lot or shipment in accordance with the current CLSI standards". 2. Review of the "Weekly Gram Stain Quality Control-Regional Center" log from May 25, 2021 through February 22, 2022 showed no documentation of gram stain QC for nine of forty weeks. 3. Interview with the general supervisor on February 23, 2022 at 1:38 PM confirmed testing personnel did not perform and document quality control for the gram stain test weekly according to the procedure for nine of forty weeks between May 25, 2021 and February 22, 2022. Item 2: Based on surveyor review of the Cepheid Gene Xpert Individualized Quality Control Plan (IQCP), quality control (QC) logs and patient records and interview with the general supervisor, testing personnel did not perform and document quality control per the IQCP plan for two analytes performed on the Cepheid Gene Xpert analyzer. Findings include: 1. Review of the Cepheid Gene Xpert IQCP for Streptococcus A (Strep A) and Chlamydia trachomatis/Neisseria gonorrhea (CT/NG) tests QC is to be performed every 30 days and with each new lot or shipment. 2. Review of the Cepheid Gene Xpert QC logs showed: a. Strep A QC performed June 11, 2021 and July 26, 2021 with no documentation of additional QC run between those dates. b. CT /NG QC performed July 28, 2021 and September 9, 2021 with no documentation of additional QC run between those dates. c. CT/NG QC performed November 10, 2021 and December 31, 2021 with no documentation of additional QC run between those dates. 3. Review of patient records showed: a. Strep A testing on fourteen patients was performed between July 11, 2021 and July 26, 2021. b. CT/NG testing on two patients was performed between August 28, 2021 and September 9, 2021. c. CT/NG testing on two patients was performed between December 10, 2021 and December 31, 2021. 4. Interview with the general supervisor on February 23, 2022 at 3:05 PM confirmed testing personnel did not perform and document quality control per the IQCP plan for two analytes performed on the Cepheid Gene Xpert analyzer.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	Based on surveyor review of previous cited deficiencies and plans of correction, the laboratory director has not provided overall management and direction in accordance with 143.1455 of this subpart. Findings include: 1. Corrective actions taken to correct previously cited deficiencies have not been maintained resulting in repeat deficiencies. See D6079.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor comparison of citations identified during the January 29-20, 2020 survey with previous Centers for Medicare and Medicaid Services (CMS) Form 2567, Statement of Deficiencies and Plan of Correction and review of laboratory records, the laboratory has not maintained previous corrective actions to assure compliance with applicable regulations. Findings include: 1. The following citations are repeat deficiencies from prior surveys: D3041 493.1105(a)(6) Retention Requirements: previously cited on January 30, 2020 D5209 493.1235 Personnel Competency Assessment Policies: previously cited on January 19, 2014 and January 30, 2020. D5413 439.1252(b) Test Systems, Equipment, Instruments, Reagent: previously cited on January 30, 2020. D5417 493.1252(d) Test Systems, Equipment, Instruments, Reagent: previously cited on February 24, 2010 D5439 493.1255(b) Calibration and Calibration Verification: previously cited on November 4, 2011 and January 30, 2020. 2. Interview with the general supervisor on February 24, 2022 at 2:30 PM confirmed the corrective actions needed to maintain compliance were not maintained.