Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0395541	01/30/2020
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency test (PT) records and interview with the general supervisor, the laboratory director or a qualified designee did not attest to the routine integration of the immunohematology PT samples into the patient workload using the laboratory's routine methods for six of six immunohematology events in 2018 and 2019. Findings include: 1. Review of American Proficiency Institute (API) immunohematology PT records showed the laboratory director, who is the immunohematology technical supervisor, did not sign six of six immunohematology attestation statements in 2018 and 2019. 2. Interview with the general supervisor on January 29, 2020 at 3:39 PM confirmed the laboratory director or a qualified designee did not sign the immunohematology attestation statements in 2018 and 2019. This is a repeat deficiency previously cited on November 11, 2015 and February 24, 2010.
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 surveyor observation of the microbiology refrigerator, review of quality

	control (QC) records and interview with the general supervisor, the laboratory did not retain quality control and expiration date of the Optochin (P) discs used for patient testing since February 14, 2019. Findings include: 1. Observation of the microbiology refrigerator on January 29, 2020 at 2:00 PM revealed a vial of P discs used for patient testing, Lot# 6309912, opened February 14, 2019. Further observation revealed the expiration date was not readable on the vial. 2. Review of quality control records revealed no documentation of QC retained on the current vial, Lot 6309912, opened February 14, 2019. 3. Interview with the general supervisor on January 29, 2020 at 2: 10 PM confirmed the laboratory had no documentation of the expiration date for the vial of P discs. Further interview confirmed documentation of QC was not available. This is a repeat deficiency previous cited on January 23, 2008.
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 a blood culture report and interview with the general supervisor, the laboratory did not retain any preliminary test results from the culture, including a reported gram stain result. Findings include: 1. Review of the test report for patient one showed the laboratory referred an isolate from a positive blood culture, collected on November 19, 2019 at this facility, to another laboratory for identification and susceptibility testing on November 20, 2019 at 8:58 AM. The report showed testing personnel staff A called a critical test result on November 20, 2019 at 9:11 AM but the report did not identify the test performed at his laboratory or the reported result. 2. Interview with the general supervisor on January 29, 2020 at 12:15 PM revealed testing personnel perform and report a gram stain when a blood culture is positive. Further interview confirmed the report for patient one did not identify the test or the result called by staff A on November 20, 2019 at 9:11 AM. The general supervisor also stated the information system does not retain preliminary reports.
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 review of laboratory procedures and competence evaluation records and interview with the general supervisor, the laboratory did not follow their written policies for training and competence evaluation for one of one new testing personnel. Findings include: 1. The laboratory's procedure "Competency Assessment of Testing Personnel" stated, "Initial training and competency must be documented prior to the reporting of any patient results" and "Whenever a new test method is added or an existing procedure is modified substantially, all testing personnel must demonstrate competency in performing the new (or altered) test procedure." 2.

	Review of training and competence evaluation records for testing personnel staff B showed no evidence of initial training and competency for the hematology analyzer (UniCel DxH 600), or three chemistry analyzers (Dimension EXL 200, MedtoxScan Profile-V, and STAT-Site M Beta-Hydroxybutyrate Analyzer). 3. Interview with the general supervisor on January 29, 2020 at 8:45 AM confirmed records were not available to show the laboratory trained and evaluated competence of staff B for the MedtoxScan Profile-V or for the new UniCel DxH 600, Dimension EXL, or the STAT-Site M Beta-Hydroxybutyrate Analyzer. This is a repeat deficiency previously cited on January 9, 2014.
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 general supervisor, the Cepheid GeneXpert and Ortho MTS (Micro Typing System) Gel Workstation procedures did not specify the external quality control (QC) procedures required for testing. Findings include: 1. The "Cepheid Strep A Test" procedure for the Cepheid GeneXpert includes the following requirement for external QC, "External controls should be used in accordance with local, state, and federal accrediting organizations' requirements, as applicable." Review of the laboratory's procedure for Clostridium difficile on the GeneXpert revealed the procedure included the same statement. The laboratory did not define the frequency for testing external QC in either procedure. 2. Review of the laboratory's QC procedure for the Ortho MTS Gel Workstation showed the procedure did not specify the frequency of external QC testing. Review of immunohematology procedures for individual tests showed the laboratory recommends QC testing each day of use. 3. Interview with the general supervisor on January 29, 2020 at 10:35 AM and 2:40 PM confirmed the laboratory's procedures did not specify the required frequency for testing external QC materials.
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 review of temperature records and the manufacturer's manual for the Erythrocyte Sedimentation Rate (ESR) analyzer, and interview with the general supervisor, the laboratory defined operating temperature range is not consistent with the manufacturer's instructions. 1. Review of temperature records for January 2020 showed the laboratory defined zero to forty degrees Celsius (C) as the acceptable laboratory room temperature. 2. Review of the manufacturer's instruction manual for the ESR analyzer, the ESR STAT PLUS, shows the manufacturer's defined operating temperature range is eighteen to twenty-five degrees C. 3. Interview with the general supervisor on January 30, 2020 at 1:00 PM confirmed the laboratory defined room temperature range is not consistent with the manufacturer's requirements.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of validation records for the Cepheid GeneXpert Streptococcus Group A and Clostridium difficile test systems and interview with the general supervisor, the records did not show the laboratory completed validation of the test systems before reporting patient test results in November 2019. Findings include: 1. Review of validation records for the Cepheid GeneXpert Streptococcus Group A test system showed no evidence the laboratory director reviewed or approved the validation studies. 2. Review of validation records for the Cepheid GeneXpert Clostridium difficile test system showed no evidence the laboratory reviewed the data obtained to evaluate the accuracy and showed no testing to evaluate precision of the test system. Further review showed no evidence the laboratory director approved the validation studies. 3. Interview with the general supervisor on January 29, 2020 at 10:20 AM confirmed records for the evaluation of the Cepheid GeneXpert Streptococcus Group A and Clostridium difficile test systems were incomplete and did not show the laboratory director approved the test systems before use in November 2019 for patient testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces

	a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records from 2019 and January 2020 for the i-STAT blood analyzer and interview with the general supervisor, the laboratory did not establish performance specifications for the G3+ (blue) cartridges after receiving notification dated January 2020 from the manufacturer that Abbott had not fully characterized the performance of the cartridges. Findings include: 1. Review of i-STAT blood analyzer records showed the laboratory had used the G3+ blood gas cartridges in 2019 and January 2020. There is no evidence the laboratory evaluated or established performance specifications after receiving notification from the manufacturer dated January 2020 that the performance of the i-STAT G3+ (BLUE) cartridge had not been fully characterized by Abbott. 2. Interview with the general supervisor on January 30, 2020 at 11:00 AM confirmed the laboratory used the blue G3+ cartridges for patient testing, that they had received notification from the manufacturer that the G3+ cartridges were not fully characterized by Abbott, and that they had not done testing to establish performance specifications for the cartridges prior to continued use.
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 Vidas 3 procalcitonin assay from May 2018 through September 2019. Findings include: 1. Review of calibration verification records showed calibration verification for the Vidas 3 procalcitonin assay on May 20, 2018, January 21, 2019 and September 7, 2019. 2. Interview with the general supervisor on January 30, 2020 at 9:50 AM confirmed the laboratory did not perform calibration verification every six months on the Vidas 3 procalcitonin assay from May 2018 through September 2019. This is a repeat deficiency previously cited on November 4, 2011.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Item 1: Based on surveyor comparison of quality control (QC) and patient test records from January 16 through 29, 2020, and interview with the general supervisor, the laboratory had not tested positive and negative QC materials on six days when the laboratory performed patient testing with the Cepheid GeneXpert Streptococcus Group A test and the Cepheid GeneXpert Clostridium difficile test. Findings include: 1. Comparison of QC records with patient testing records from January 16 through 29, 2020 showed the laboratory performed patient Cepheid GeneXpert Streptococcus Group A tests on the following patient samples on January 23, 24, 28, and 29. January 23, 2020, Patients two and three January 24, 2020, Patient four January 28, 2020, Patients five through ten January 29, 2020, Patient eleven No records were available to show external QC materials were tested on January 23, 24, or 28. The laboratory had not tested external controls on January 29 prior to the patient test. 2. Comparison of Cepheid GeneXpert Clostridium difficile QC and patient testing records from January 2020 showed the laboratory performed patient testing on January 17 and 22, when no external QC materials were tested. 3. Interview with the general supervisor on January 29, 2020 at 10:40 AM confirmed the laboratory had performed a patient Clostridium difficile test earlier in the day without testing QC material first. Further interview confirmed the laboratory did not test QC materials each day they tested patient samples for Streptococcus Group A or Clostridium difficile, and revealed the laboratory had not developed an IQCP (Individualized Quality Control Plan) for these test systems. 42427 Item 2: Based on surveyor review of quality control and patient test records from January 2020, and interview with the general supervisor, the laboratory had not tested a positive and negative control material once each day of patient testing with the Ortho Diagnostics Micro Typing Systems (MTS) gel system. Findings include: 1. Review of quality control records for 2019 showed the laboratory performed quality control testing for the MTS gel system on January 19, 2019 and January 21, 2019. Further review revealed the laboratory did not perform quality control on January 20, 2019. 2. Review of patient test records for this system showed testing personnel performed testing on Patient twelve and Patient thirteen on January 20, 2019, when no quality controls were tested. 3. Interview with the general supervisor on January 29, 2020 at 2:40 PM confirmed the laboratory did not test quality control each day of patient testing for the MTS gel system.

D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of quality control records in microbiology and interview with the general supervisor, the laboratory had not performed required quality control testing for blood culture media, and had not developed an Individualized Quality Control Plan (IQCP). Findings include: 1. Review of quality control records showed the laboratory had not checked each batch of blood culture media for its ability to support growth. 2. Interview with the general supervisor on January 30, 2020 at 8:07 AM confirmed the laboratory had not performed required quality control testing on blood culture media and had not developed an IQCP. This is a repeat deficiency previously cited on January 24, 2006 and January 4, 2018.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of Symex CA-600 coagulation analyzer printouts from January 3 through January 8, 2020 and interview with the general supervisor, the laboratory did not perform quality control (QC) each eight hours of operation on the coagulation analyzer on one of six days. Findings include: 1. Review of Sysmex CA-600 printouts from January 3 through January 8, 2020 revealed the laboratory did not perform QC each eight hours of operation for one of six days on the following: January 3, 2020: The laboratory performed QC at 5:05 AM and 2:11 PM. The laboratory tested Patient fourteen at 1:33 PM. The laboratory tested Patient fifteen at 1: 43 PM. 2. Interview with the general supervisor on January 30, 2020 at 11:00 AM confirmed the laboratory did not perform quality control each eight hours of operation prior to patient testing on the Sysmex CA-600 coagulation analyzer for one of six days from January 3 through January 8, 2020.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that

	perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory, review of instrument records and interview with the general supervisor, the laboratory had not maintained records of corrective action when equipment or test systems are not performing as expected. Findings include: 1. Observation of the laboratory on January 29, 2020 at 8:10 AM revealed the Beckman Coulter DXH600 hematology analyzer was not operational and testing personnel had called service. Further observation on January 30, 2020 at 8:15 AM revealed the Siemens EXL 200 chemistry analyzer was not operational and testing personnel had called service. 2. Review of the instrument records showed no mechanism for documentation or evaluation of corrective actions when an analyzer is not functioning as expected. Further review showed testing personnel did not document corrective action steps for the Beckman Coulter DXH600 hematology analyzer or the Siemens EXL 200 chemistry analyzer when the analyzers were not functioning as expected. 3. Interview with the general supervisor on January 30, 2020 at 12:03 PM confirmed the laboratory does not document corrective actions when equipment or test systems do not meet the laboratory's established performance expectations.