Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0662099	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Vernon Memorial Hospital Inc	507 S Main St, Viroqua, 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
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 the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (Form CMS-209), personnel records, and laboratory procedures, and interview with the Technical Supervisor (Staff A), the laboratory did not establish procedures for evaluation of two of two staff members with delegated technical consultant, technical supervisor, or general supervisor responsibilities. Finding include: 1. Review of the Form CMS-209 the laboratory provided for this survey showed the Laboratory Director delegated technical consultant, technical supervisor and general supervisor responsibilities to Staff A and technical supervisor responsibilities to Staff B. 2. Review of personnel records showed no competence evaluation of the technical consultant, technical supervisor, or general supervisor responsibilities for Staff A and B. 3. Review of the laboratory procedure, "CLIA Delegation for Competency and Proficiency Attestation", effective September 30, 2024, showed no requirement for evaluation of the technical consultant, technical supervisor, and general supervisor responsibilities. 4. Interview with Staff A on November 13, 2025, at 3:20 PM confirmed the laboratory had not established procedures to assess the technical consultant, technical supervisor, and general supervisor competence and had not defined the frequency of evaluation for these positions.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the Technical Consultant (Staff A), the laboratory did not verify the accuracy of sperm motility tests twice annually in two of the last two years. Findings include: 1. Review of PT records from 2024 and 2025 showed no evidence the laboratory enrolled in PT for sperm motility evaluation. Printed test reports from the electronic medical record included with the PT records showed the laboratory reports an evaluation of sperm motility with their post-vasectomy semen analysis test. 2. Interview with Staff A on November 13, 2025, at 3:40 PM confirmed testing personnel report sperm motility as part of the post-vasectomy semen analysis procedure and confirmed the laboratory had not enrolled in a PT program to verify the accuracy of sperm motility evaluations. Further interview confirmed the laboratory did not utilize another method to verify the accuracy of this test twice annually. This is a repeat deficiency, D5217 was previously cited on December 16, 2021.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 records and procedures, and interview with Testing Personnel (Staff C), the laboratory used a prewarming technique on two of 122 days reviewed without a written procedure for the process. Findings include: 1. Review of blood banking logs, "Ortho Workstation IDMTS Gel Worksheet", from September through December 2024 showed the laboratory performed crossmatch testing for blood transfusion compatibility on specimens from Patient 1 on October 22 and 23, 2024. The entry for testing on October 22, 2024, included, "patient plasma warmed and respun to make compatible". The entry on October 23, 2024, included the statement, "patient plasma warmed and respun to make Xmatch compatible". 2. Review of laboratory procedures showed no evidence of a procedure with step-by-

	step instructions for prewarming plasma for compatibility testing. 3. Interview with Staff C on November 13, 2025, at 12:05 PM confirmed the laboratory did not have a procedure for prewarming compatibility tests.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of crossover studies performed for International Normalized Ratio (INR) calculations performed with prothrombin time results from the ACL Top 300 analyzer, observation of the ACL Top 300 analyzer, and interviews with Testing Personnel (Staff C) and the Technical Consultant (Staff A), the laboratory did not ensure the mean normal prothrombin time result was accurately entered into the analyzer when the laboratory started use of the current lot number of Recombiplastin for prothrombin time tests. The analyzer used the incorrect mean value to calculate patient INR results for 76 of 76 days since the laboratory started using Recombiplastin reagent lot N159343. Findings include: 1. Review of the laboratory's crossover studies for Prothrombin Time Recombiplastin reagent lot N159343 showed the mean patient normal prothrombin time was 11.7 seconds with this reagent lot. 2. Observation of the ACL Top 300 analyzer on November 13, 2025, at 3:30 PM revealed the mean normal prothrombin time value personnel entered in the analyzer for INR calculations for lot N159343 was 11.2 seconds. 3. Interview with Staff C on November 13, 2025, at 3:35 PM confirmed personnel entered an incorrect mean normal prothrombin time in the analyzer resulting in inaccurate INR calculations for tests performed with lot N159343. Email interview with Staff A on November 25, 2025 at 8:55 AM revealed the laboratory first used lot number N159343 for patient testing on August 29, 2025. This is a repeat deficiency previously cited on November 14, 2019.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 procedures, observation in the laboratory, and interview with Testing Personnel (Staff D), the laboratory did not monitor and document the percentage of carbon dioxide (CO2) in the CO2 incubator for two of the last two years. Findings include: 1. Review of the procedure, "User Quality Assurance

	Procedure for Culture Media", showed the procedure required incubation of chocolate agar media plates with 5-7% CO2. 2. Observations of the CO2 incubator on November 12, 2025, at 3:15 PM and on November 13, 2025, at 8:45 AM showed the CO2 concentration in the incubator was 7.5% on both occasions. Media plates in the incubator included chocolate agar plates. 3. Interview with Staff D on November 13, 2025, at 8:45 AM confirmed the laboratory did not monitor and document the incubator CO2 concentration to ensure accurate and reliable test system results. This is a repeat deficiency, D5413 was previously cited on November 9, 2023.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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: Item 1: Based on surveyor review of laboratory records and interview with the General Supervisor (Staff A), the laboratory used expired microbiology reagents in two of the last two years. Findings include: 1a. Review of the "Beta-Lactamase QC Log" showed lot number 3629053 expired on February 17, 2024. The log showed personnel performed testing with expired reagent on February 26 and 28, and March 1, 2024. 1b. Further review of the Beta-Lactamase log showed lot number 3715583 expired on August 27, 2024. The log showed personnel performed testing with the expired reagent on September 14, 2024. 1c. Review of the "Bacitracin QC Log" showed lot number 6135976 expired "7/25". The log showed personnel performed testing with the expired reagent on August 4, 2025. 2. Interview with Staff A on November 13, 2025, at 10:05 AM confirmed personnel documented the use of expired Beta-lactamase and Bacitracin reagents for testing in 2024 and 2025. Item 2: Based on surveyor observation of phlebotomy collection trays and interview with the General Supervisor (Staff A), one blood culture bottle on a phlebotomist's collection tray was expired but available for use in blood culture collection. Findings include: 1. Observation of phlebotomy collection trays on November 12, 2025, at 3:30 PM revealed a blood culture bottle, lot number 0004062730, expiration date October 22, 2025, available for use. 2. Interview with Staff A on November 13, 2025, at 8:15 AM confirmed the blood culture bottle was expired and could have been used for collection.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Technical Supervisor (Staff A), the laboratory did not document acceptable staining characteristics of the stain used for manual hematology differential counts each day of use for the last two of two years. Findings include: 1. Review of hematology maintenance and quality control records from 2024 and 2025 showed no evidence

	personnel documented evaluation of the quality of the hematology differential stains each day of use. 2. Interview with Staff A on November 13, 2025, at 4:45 PM confirmed the laboratory had not documented acceptable staining characteristics of the hematology stain in the last two years.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory procedures and quality control (QC) records, observation in the laboratory, and interview with Testing Personnel (Staff D), the Laboratory Director did not ensure the laboratory maintained the individualized quality control plan (IQCP) for the GeneXpert Group B Streptococcus (Xpert GBS) test. One of two cartridge lots available for use in the laboratory at the time of the survey had not been quality control tested since September 26, 2025, eighteen days past the monthly quality control requirement in the IQCP. Findings include: 1. Review of the IQCP for the Xpert GBS test showed the IQCP required testing of external positive and negative controls monthly and with each new shipment and/or lot number of reagent cartridges. 2. Review of the "Cepheid QC Log, Test: Strep B" showed testing personnel performed QC testing for lot number 1001477751 on September 26, 2025. The next QC record showed personnel tested lot 1001491199 on October 27, 2025. The record showed no additional testing of lot 1001477751. 3. Observation of available Xpert GBS test cartridges in the laboratory on November 12, 2025 at 3:30 PM showed two open boxes of cartridges. Lot 1001477751 had two cartridges available for testing, lot 1001491199 had eight cartridges available. 4. Interview with Staff D on November 13, 2025, at 8:30 AM confirmed the two cartridges of lot 1001477751 were available for patient testing and confirmed the laboratory had not performed monthly quality control testing for that lot of cartridges as required in the IQCP. Item 2: Based on surveyor review of procedures, laboratory records, individualized quality control plans, and interview with the General Supervisor (Staff A), the Laboratory Director did not ensure discontinuation of the IQCP for seven of seven months after the laboratory retired the ImmunoCard STAT EHEC procedure. Findings include: 1. Review of the "ImmunoCard STAT EHEC" Standard Operating Procedure showed the procedure was retired on March 31, 2025. 2. Review of the "STAT EHEC (shigatoxin) Monthly QC" log showed the laboratory last documented quality control testing on April 1, 2025. The log also included a comment, "Discontinued 4-1-25". 3. Review of the IQCP for the "Test System: ImmunoCard STAT! EHEC" showed Staff A completed the annual quality review of the IQCP on May 29, 2025, and the Laboratory Director authorized the IQCP for continued use at the Vernon Health Hospital Laboratory. 4. Interview with Staff A on November 13, 2025, at 10:30 AM confirmed the laboratory had not discontinued the ImmunoCard STAT! EHEC IQCP when they discontinued the test system.