Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0662099	11/09/2023
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
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: Item 1 Based on surveyor review of laboratory records and interview with a technical consultant and hematology lead, staff A and staff B, the laboratory did not retain the lot and expiration date for the wash solution on the Mini-iSED for five of five months reviewed in 2023. Findings include: 1. Review of the Mini-iSed quality control log showed no documentation of wash solution lot or expiration date information from May 23, 2023, through November 9, 2023. 2. Interview with the staff A and staff B on November 9, 2023, at 12:40 PM confirmed the laboratory did not retain the lot and expiration dates from the Mini-iSED analyzer. Item 2 Based on surveyor review of laboratory records and interview with the a technical consultant, staff C, the laboratory did not retain the lot and expiration date for the quality control used on the Cepheid Gene Xpert analyzer for four of seven analytes performed on the analyzer. Findings include: 1. Review of the quality control on the Cepheid Gene Xpert showed no documentation of quality control lot or expiration date information in 2022 and 2023. 2. Interview with the staff C on November 8, 2023, at 1:45 PM stated three of the seven analytes used quality control material from plated cultures and the other four analytes used commercial quality control material. Further interview confirmed the laboratory did not retain the lot and expiration dates for the commercial quality control material.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and email interview with a technical consultant, staff A, the laboratory failed to document corrective action for two of four analytes with a 80% score on 2023-Chemistry-Core-Event 1. Findings include: 1. Review of PT records for the first event in 2023 showed the laboratory received a score of 80% for albumin, pro-brain natriuretic peptide (pro-BNP), thyroid stimulating hormone (TSH) and free thyroxine 4 (FT4) analytes. Further review of the PT records showed no documentation of corrective action for TSH and FT4. 2. Email with staff A on November 13, 2023, at 11:55 AM confirmed the laboratory failed to document corrective action when scores were not 100%.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on survey review of chemistry procedures and interview with a technical consultant, staff A, the laboratory director did not approve, sign and date two of two new chemistry analyte procedures prior to patient use. Findings include: 1. Review of chemistry procedures for two new analytes showed the following: Analyte/Start date /Procedure sign date Vitamin D/August 1, 2022/December 19, 2022 Ferritin/August 1, 2022/no evidence the procedure has been signed at time of survey November 9, 2023 2. Interview with the staff A on November 9, 2023, at 9:50 AM confirmed the laboratory director did not approve, sign and date new chemistry analyte procedures prior to patient use.
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 blood bank freezer, review of blood bank freezer temperature log, and interview with a technical consultant, staff A, 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 blood bank freezer for two hundred twenty-two days of two hundred twenty-two days in 2023. Findings include: 1. Observation of Maine Standards Validate calibration verification material used for chemistry analytes in the

	blood bank freezer on November 9, 2023, at 8:43 AM showed the manufacturer required storage at -10 to -25 degrees Celsius (C). Further review showed the reagents had been received into the laboratory in April 2023 and October 2023 and used for calibration verification in those two months. 2. Review of the "Blood Bank Freezer Temperature/Alarm Monitoring Log" from April to November 2023 showed the defined acceptable temperature range for the freezer was -20 to -40 degrees C. Further review showed all temperatures in the chemistry freezer were below -25 C from April 1, 2023 through November 9, 2023. 3. Interview with the staff A on November 9, 2023, at 8:45 AM confirmed the laboratory's acceptable range for the blood bank freezer was not consistent with the manufacturer's acceptable range for the Maine Standards calibration material.
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 laboratory records and interview with a technical consultant, staff A, the laboratory director did not review and approve the performance specification verification records for two of two new chemistry analytes prior to reporting patient results. Findings include: 1. Review of the validation forms for Ferritin and Vitamin D showed the laboratory director signed the performance specification verifications on November 18, 2022. 2. Interview with the Staff A on November 9, 2023, at 9:50 AM stated the laboratory started patient testing for the two analytes on August 1, 2022. Further interview confirmed the laboratory director did not review and approve the performance specification verification records prior to reporting patient results.
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: Item 1 Based on surveyor review of laboratory records and interview with a technical supervisor, staff A, the laboratory had not evaluated and defined the relationship between test systems for hematology differential testing on a twice a year basis for one of two events in 2022. Findings include: 1. Review of laboratory records showed evaluation of test systems between the Sysmex XN550 automated differential and manual differential testing in May 2022 and May 2023. Further review showed no

	additional evaluation in 2022. 2. Interview with staff A on November 9, 2023, at 11: 20 AM confirmed the laboratory had not evaluated and defined the relationship between the test systems for hematology differential testing on a twice a year basis for 2022. Item 2 Based on surveyor review of laboratory records and interview with a technical supervisor, staff A, the laboratory had not evaluated and defined the relationship between test systems for D-Dimer testing on the Biosite triage meters on a twice a year basis for 2022 and 2023. Findings include: 1. Review of laboratory records showed the laboratory had two Biosite triage meters available for D-Dimer patient testing. Further review showed no evaluation of twice yearly comparison testing between the two analyzers. 2. Interview with the staff A on November 9, 2023, at 9:00 AM confirmed the laboratory had not evaluated and defined the relationship between the test systems for the Biosite Triage analyzers on a twice a year basis for 2022 and 2023.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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: Based on survey review of Individualized Quality Control Plan (IQCP) records, laboratory binders and interview with a technical consultant, staff A, the laboratory director had not ensured the IQCP quality assurance plan was maintained for one of seventeen IQCP plans in the laboratory. Findings include: 1. Review of the IQCP binder showed IQCP plans for ROM, Micro ID and AST, Genexpert, Expect crypto and Giardia, EHEC, Leuko EZ, spreg, HIV ab, and Medtox had been reviewed in 2022. No documentation of the IQCP plans for the I-Stat blood gas analyzer or Biosite Triage meter was available. 2. Review of the I-Stat blood gas analyzer binder showed an IQCP plan reviewed in 2022. 3. Review of the Biosite Triage meter binder showed an IQCP plan that had not been reviewed since the last survey on December 16, 2021. 4. Interview with staff A on November 9, 2023, at 9:00 AM confirmed the laboratory director had not ensured the IQCP quality assessment program was maintained on the Biosite Triage meter. This is a repeat deficiency from December 16, 2021.