Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0662099	11/14/2019
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 laboratory records, observation of test equipment, and interview with the technical consultant, the laboratory did not verify the patient normal prothrombin time was accurately entered into the coagulation analyzer for the current lot of RecombiPlasTin reagent that was in use. Findings include: 1. Review of laboratory records showed the laboratory started using the current lot number of RecombiPlasTin 2G reagent August 17, 2018. Further review shows the lab determined the patient normal prothrombin time for this lot number was 11.5 seconds. 2. Observation of the Instrumentation Laboratory ACL TOP 300 coagulation analyzer Materials Setup menu on November 14, 2019 at 10:15 AM shows the patient normal prothrombin time in the analyzer was set at 11.8 seconds. The patient normal prothrombin time is used with the RecombiPlasTin 2G International Sensitivity Index (ISI) to calculate the patient International Normalized Ratio (INR). Patient INR results are reported in the laboratory. 3. Interview with technical consultant A on November 14, 2019 at 10:15 AM confirmed the patient normal prothrombin time entered into the coagulation analyzer and used to calculate patient INR results was not correct. This deficiency (D5411) was previously cited on October 16, 2007, February 9, 2010, October 12, 2011, August 9, 2013, November 12, 2015, and November 9, 2017.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of chemistry maintenance logs and interview with the technical consultant, the laboratory has not performed maintenance on the Cobas 6000 and 501 chemistry analyzers as required. Findings include: 1. Review of the Cobas chemistry maintenance logs "501 Yearly Maintenance Log" and "6000 Yearly Maintenance Log" shows the bimonthly, trimonthly, and every six month maintenance was not performed at the required frequency: Cobas 6000 Analyzer: Bimonthly maintenance performed: April 22, 2019 July 25, 2019 Trimonthly maintenance performed: February 22, 2019 July 25, 2019 Next trimonthly maintenance was due October 2019 and as of the survey date on November 14, 2019 it was not performed. Every six month maintenance performed: April 22, 2019 Next six month maintenance was due October 2019 and as of the survey date on November 14, 2019 it was not performed. Cobas 501 Analyzer Bimonthly maintenance performed: March 12, 2019 July 16, 2019 Trimonthly maintenance performed: March 12, 2019 July 16, 2019 Every six month maintenance performed: October 9, 2018 July 16, 2019 2. Interview with technical consultant A on November 14, 2019 at 1:30 PM confirmed maintenance had not been performed at the required frequency on the Cobas 6000 and 501 chemistry analyzers. This deficiency was previously cited on November 12, 2015.
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 BACT/ALERT blood culture media records, and interview with the technical consultant, the laboratory does not check each batch blood culture media for its ability to support growth, inhibit specified organisms, maintain sterility, or document the physical characteristics of each lot of media. Findings include: 1. Review of BACT/ALERT blood culture media records show no evidence the laboratory documents the media's ability to support growth, inhibit specified organisms, maintain sterility, or document the physical characteristics for each lot of blood culture media used for patient testing. 2. Review of BACT/ALERT blood culture media records show the laboratory retains the Certificates of Conformance for each lot of blood culture media used for patient testing and no further quality control testing is performed. 3. Interview with technical consultant B on November 13, 2019 at 2:50 PM confirmed the laboratory does not perform blood culture media quality control and document the media's ability to support growth, inhibit specified organisms, maintain sterility, or document the physical characteristics for each lot of blood culture media used for patient testing.