Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441828	07/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Madison Medical Center	611 West Main, Fredericktown, MO	

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
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 review of the performance verification procedures for the Gem 4000 Premier Plus blood gas analyzer and interview with the general supervisor, the laboratory failed to verify reference intervals (normal values). Findings: 1. Review of the verification procedures for the Gem 400 Premier Plus blood gas analyzer for pH, pCO2 and PO2 showed no verification of normal values. 2. Interview with the general supervisor on July 26, 2022 at 11:30 AM confirmed the laboratory failed to ensure the verification procedures for normal values for the Gem 4000 Premier plus blood gas analyzer were appropriate for the laboratory's patient population.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of Vidas 3 chemistry analyzer quality control (QC) and interview with the general supervisor, the laboratory failed to perform two control materials of different concentrations each day of procalcitonin (PCT) patient testing for 9 of 30 days and D-dimer patient testing for 2 of 30 days. Findings: 1. Review of Vidas 3 chemistry analyzer PCT patient testing in June 2022 showed QC was not performed on June 3, 7, 8,15, 19, 21, 23, 27 and 30. During these dates 13 patients were performed. 2. Review of Vidas 3 chemistry analyzer D-dimer patient testing in June 2022 showed QC was not performed on June 3 and 19. During these dates two patients were performed. 3. Interview with the general supervisor on July 26, 2022 at 11:30 AM confirmed the laboratory failed to perform two control materials of different concentrations each day of patient testing for PCT and D-dimer.
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 review of laboratory procedures, Sysmex CA-600 analyzer quality control (QC), patient results and interview with the general supervisor (GS), the laboratory failed to include two levels of control material each 8 hours of operation for prothrombin time (PT) and partial thromboplastin time (PTT) for 24 of 31 testing days in June and to date July 26, 2022. Findings: 1. Review of laboratory procedure "Quality Assessment Policies- Quality Control" states, "Quality Control Frequency - Coagulation 2 levels/8 hr". 2. Review of Sysmex CA-600 analyzer QC for June and July showed QC was not performed every 8 hours on June 26, June 28, June 29, June 30, July 1, July 2, July 3, July 4, July 5, July 6, July 7, July 8, July 9, July 10, July 11, July 15, July 16, July 17, July 19, July 20, July 21, July 22, July 23, and July 24. 3. Review of patient results showed two patient PT results were released without QC being performed on July 11, 2022. 4. Interview with the GS on July 26, 2022 at 11:30 AM confirmed the laboratory failed to perform two levels of PT and PTT QC each 8 hours of operation.