Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2115357	04/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Froedtert Community Hospital - New Berlin	4805 S Moorland Rd - Garden Level, New Berlin, 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
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 laboratory records and procedures, and interview with the laboratory director, the laboratory had not performed two levels of quality control (QC) testing each eight hours of patient testing in twelve of twelve months since April 2022 when the laboratory started D-dimer testing on the Fastpath analyzer. Findings include: 1. Review of Pathfast maintenance worksheets showed QC testing was performed once per day for the three tests performed on the test system. 2. Review of the 'Pathfast Instrument Testing (Troponin I, NT-pro-BNP, D-dimer)' procedure showed the procedure required two levels of external QC daily for D-dimer testing. The procedure did not include instructions to perform QC testing every eight hours of patient testing. 3. Interview with the laboratory director on April 20, 2023 at 1:00 PM confirmed the laboratory did not perform QC testing each eight hours of patient testing on the Fastpath D-dimer test since starting testing in April 2022.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)

	The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of test records and interview with the laboratory director, the laboratory did not maintain a record system that identified which testing person performed each hematology test on the Sysmex XN-330 analyzer in 2022 and 2023. Findings include: 1. Review of test records showed no paper records of tests performed on the Sysmex XN-330 hematology analyzer. Review of electronic records showed no record of which person performed the CBC tests on the Sysmex XN-330. The laboratory estimated they tested approximately 6000 samples annually with the Sysmex XN-330. 2. Interview with the laboratory director on April 20, 2023 at 2:00 PM confirmed the laboratory did not maintain a record system that included the identity of the testing person who performed hematology testing on the Sysmex XN-330 analyzer.