Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0387141	09/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Monroe County Hospital	6580 165th Street, Albia, IA	

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 review of d-dimer quality control (QC) records, the annual laboratory test list, the Quality Control Policy and confirmed by the general supervisor, identifier #1, at 12:25 pm on 9/17/2024, the laboratory failed to perform two levels of d-dimer controls each eight hours of operation for one out one day of patient testing on 5/8 /2024. The findings include: 1. The annual laboratory test list revealed the laboratory performed d-dimer testing on the Biomeriuex Vidas 3 test system. 2. The Quality Control Policy stated for the Biomeriuex Vidas 3, "Two levels of control material will be performed day of use. QC only needs to be performed once every 24 hours." 3. On 5/8/2024 the laboratory performed two levels of d-dimer QC at 6:52 am. 4. On 5/8 /2024 patient identifier #1 had a d-dimer performed at 18:12 pm. 5. The general supervisor confirmed the laboratory performed two levels of QC only once per day for d-dimer testing. 6. The laboratory failed to perform d-dimer QC every 8 hours of patient testing.