Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0317513	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
S E Lackey Memorial Hospital	330 N Broad St, Forest, MS	

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 review of manufacturer's instructions for the Sysmex CA-660 coagulation system, documentation of establishment of the geometric mean of the normal patient reference range, and interview on 7/13/22 at 10:00 a.m. with Testing Personnel #2, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to follow manufacturer's instructions for INR (International Normalized Ratio) calculations for Dade Innovin Prothrombin time (PT) reagent Lot #549780, put in use for patient PT testing on 5/5/21. The laboratory's annual volume for patient PT testing is 859, according to Testing Personnel #1/General Supervisor. Findings include: Manufacturer's instructions for the Sysmex CA-660 coagulation system state to calculate the mean normal Prothrombin time (MNPT) for new lots of reagent by testing twenty normal individuals - 10 males and 10 females - and use the geometric mean of the MNPT for International Normalized Ratio (INR) calculations. Review of documentation of establishment of the geometric mean of the normal patient reference range revealed twenty normal individuals were not used in the calculation of the geometric mean of 10.5 entered in the Sysmex CA-660 coagulation system on 5/5/21. In an interview on 7/13/22 at 10:00 a.m., Testing Personnel #2 confirmed that samples from twenty normal individuals were not used to calculate the MNPT for Dade Innovin PT reagent Lot #549780, put in use for patient PT testing on 5/5/21. The laboratory's annual volume for patient PT testing is 859, according to Testing Personnel #1/General Supervisor.