Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0904018	(X3) Date Survey Completed 12/10/2018
Name of Provider or Supplier Saint Francis Clinic Cape Girardeau Kingshighway	**Street Address, City, State** 1702 North Kingshighway, Cape Girardeau, 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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, manufacturer's inserts and November and December quality control (QC) documentation and interview with the technical consultant, the laboratory failed to perform a positive and negative control for four of four days of testing for moderately complex human chorionic gonadotropin(HCG) kit testing. Findings: 1. Review of manufacturer's insert and laboratory procedures for HCG kit testing showed the laboratory allowed usage of serum. This changed the kits from waived complexity to moderate complexity. 2. Review of the November and December QC documentation revealed the laboratory failed to perform a positive and negative qualitative control four of four days of testing for serum HCG. 3. Interview with the technical consultant on December 10, 2018 at 11:00 AM confirmed, the laboratory did not test a positive and negative control each day of testing.