Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0997447	(X3) Date Survey Completed 01/26/2018
Name of Provider or Supplier Mckay-Dee Surgery Center	**Street Address, City, State** 3895 S Harrison Blvd, Suite 200, Ogden, UT	

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
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on patient test records review, quality control records review and interview with staff, the laboratory failed to ensure quality control was performed prior to testing patient samples after a complete change of reagents (new iSTAT lot number of test cartridges) for 1 of 9 lot number changes reviewed for prothrombin time (PT) testing and International Normalized Ratio (INR) calculation results reporting. Findings include: 1. Patient test records review for patient 1208415040 tested on 09/04/2017 documented PT/INR was reported using i STAT test cartridge lot number 354S17125117. 2. Quality control (QC) records review failed to include documentation the laboratory performed quality control for lot number 354S17125117 prior to testing patient 1208415040 on 09/04/2017. The QC for lot number 354S17125117 was performed on 09/11/2017. 3. In an interview conducted on 01/26/2018 at approximately !0 :45 A.M. the staff confirmed QC was performed after patient testing for lot number 354S17125117.