

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D2071112	<b>(X3) Date Survey Completed</b>  01/26/2018
<b>Name of Provider or Supplier</b>  Mckay Dee Anticoagulation Clinic	<b>Street Address, City, State</b>  4421 Harrison Blvd Suite A-12, Ogden, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5461</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(6)(g)</p> <p>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.</p> <p>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 8 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 1200449166 tested on 02/16 /2016 documented PT/INR was reported using i STAT test cartridge lot number 334B15317016 . 2. Quality control (QC) records review failed to include documentation the laboratory performed quality control for lot number 334B15317016 prior to testing patient on 02/16/2016. The QC for lot number 334B15317016 was performed on 02/23/2016. 3. In an interview conducted on 01/26 /2018 at approximately 10 :45 A.M. the staff confirmed QC was performed after patient testing for lot number 334B15317016.</p>