

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0985294	(X3) Date Survey Completed 09/18/2019
Name of Provider or Supplier Labcorp Kansas, Inc - Main Lab	Street Address, City, State 2916 E Central Ave, Wichita, KS	
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	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of instrument type and test settings, reagent package insert, and interview, the laboratory failed to follow manufacturer's instruction for the ISI setting in prothrombin time testing. Findings include: 1. Prothrombin time testing is performed on the ACL TOP 300 using RecombiPlasTin2G reagent. 2. ACL TOP 300 instrument setting for prothrombin time testing showed lot #N0588147, ISI set to 1.020, and last modification date/time as 09/02/2018 11:45:17. 3. RecombiPlasTin2G reagent package insert for lot #N0588147 defines the ISI at 0.98 for ACL TOP Series instruments. 4. Interview with GS #1 September 18, 2019 at 10:50 AM confirmed the laboratory failed to follow manufacturer's instruction for the ISI setting in prothrombin time testing.</p>