

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2091427	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier Well Key Health, Pllc	Street Address, City, State 6606 Clinton Hwy, Knoxville, TN	
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
D0000	A revisit survey was conducted on May 29, 2019 (Well Key) laboratory for all previous deficiencies cited on May 16, 2019. All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with all regulations surveyed.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the maintenance schedule for the Sysmex XP-300 and interview confirmation with the Technical Consultant, the laboratory failed to document weekly maintenance three out of four weeks in April 2019. Findings include: 1. Three out of four weeks weekly maintenance for the Sysmex XP 300 was not documented during April 2019. 2. The Technical Consultant confirmed at 10:00 AM on May 16, 2019 three out of four weeks weekly maintenance for the Sysmex XP 300 was not documented during April 2019.</p>