Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D1063761	(X3) Date Survey Completed 07/09/2018
Name of Provider or Supplier Laboratory Corporation Of America	**Street Address, City, State** 1068 West Main St, Waterbury, CT	

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
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, the laboratory failed to document centrifuge function checks every 6 months to ensure platelet poor plasma (PPP) is obtained. Findings include: 1. Record review of the laboratory's "Measurement of the Platelet Count of Platelet Poor Plasma" procedure on 7/9/18 revealed: a) "For all centrifuges used to prepare PPP, this procedure is performed at least annually, after modification of the centrifuge, and before a new centrifuge is placed into service." b) Clinical Laboratories Standards Institute (CLSI) H21-A5 Vol 28 No. 5 is listed in the reference section. 2. Record review of the Dade Innovin Package insert on 7/9/18 revealed the following statement under the Specimen Collection and Preparation heading, "Please refer to CLSI document H21-A5 for detailed information on sample preparation and storage. 3. Staff interview with the laboratory director on 7/9/18 at 11: 30 AM, confirmed PPP performance is not checked every 6 months. *Repeat Deficiency