Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0708598	(X3) Date Survey Completed 12/11/2018
Name of Provider or Supplier Pattner & Grodstein Md Pa	**Street Address, City, State** 177 North Dean St, Englewood, NJ	

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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records, Manufactures Package Insert (MPI) and interview with the Technical Consultant (TC), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Hematology testing performed on the AcT Diff 2 analyzer from on the date of survey. The finding includes: 1. One (Normal level) out of three control levels was being run for QC verification before new QC material was being put into use. 2. The results of normal level QC material was not verified with MPI values. 3. The laboratory did not verify all QC materials used in 2017 and 2018. 4. The TC confirmed on 12/11/18 at 12:00 pm that the assayed values of QC materials were not verified before putting in use.