Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0708598	05/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pattner & Grodstein Md Pa	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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), patient work records and interview with the Technical Consultant (TC), the laboratory failed to follow their PM policy for "Act Diff #2 Flags and Codes" for Hematology tests ran on the Beckman Coulter AcT diff 2 from 1/7/21 to the date of survey. The finding includes: 1) The PM stated "X flag indicates that one of the multiple Alert criteria was not met. 1. Thoroughly mix and rerun the sample. 2. If the flag does not repeat report result. 3. If flag repeats, clean the aperture as instructed in zapping the aperture. 4. If after cleaning, problem persists contact your Beckman Coulter Representative". a) Patient number 25071 run on 1/7/21 with "X" flagged results was not rerun. b) Patient number 111350 run on 4/6/21 with "X" flagged results was not rerun. c) Patient number 52458 run on 4/6/21 with "X" flagged results was not rerun. d) Patient number 23951 run on 4/30/21 with "X" flagged results was not rerun. e) Patient number 50062 run on 3/18/21 with "X" flagged results was not rerun. f) Patient number 331369 run on 3/31/21 with "X" flagged results was not rerun. 2) The TC confirmed on 5/11/21 at 2:05 pm the above mentioned procedure was not followed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration Verification (CV) records and interview with the Technical Consultant (TC), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Testing on the Beckman Coulter AcT diff 2 analyzer in the calendar years 2019 and 2020. The finding includes: 1. The laboratory last performed CV 8/21/18, but there was no documented evidence CV was after that. 2. The TC confirmed on 5/11/21 at 2:30 am CV was not performed every six months.
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, Manufacturers 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 Beckman Coulter AcT Diff 2 analyzer from 12 /11/18 to the date of survey. The TC confirmed on 5/11/21 at 1:45 pm that the assayed values of QC materials were not verified before putting in use.