Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2081491	10/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Endocrinology Consultants, Pc	221 Engle Street, 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), Operators Manual (OM) and interview with the Technical Consultant (TC), the laboratory failed to follow the OM for calibrating the Abbott Cell-Dyn Emerald analyzer from March 2021 to the date of the survey. The findings include: 1. The OM stated under "Pre-Calibration Procedure Checklist" to "Verify Instrument precision by running a fresh, normal whole blood specimen ten times into the PRECISION file." 2. The laboratory did not perform the aforementioned procedure when calibrating the Abbot Cell-Dyn Emerald. 3. The TC confirmed 10/7/21 at 10:30 am that the laboratory did not follow the PM.
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 and interview with the Technical Consultant (TC), the laboratory failed to verify QC material before use for Chemistry, Endocrinology and Immunology tests performed on the Abbott Alinity analyzer from March 2021 to the date of survey. The findings include: 1. The laboratory failed to verify the following QC material: a) Alinity Intact PTH Controls. b) Alinity Folate controls. c) Alinity C-Peptide Controls. b) Alinity SHBG controls. d) Biorad liquichek urine chemistry controls. e) Biorad liquichek specialty immunoassay controls. 2. There was no documented evidence to show the above QC material was verified. 3. The TC confirmed on 10/7/21 at 11:15 am that the assayed values of QC material were not verified before putting in use.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Technical Consultant (TC), the laboratory failed to follow their procedure for "Auto-Calculation Check" to verify the accuracy of calculations performed by the Laboratory Information System (LIS) from 10/29/18 to the date of survey. The findings include: 1. The procedure "Auto-Calculation Check" stated "Obtain 5 printouts of results that have been calculated by the LIS and verify their accuracy by manually calculating them" 2. There was no documented evidence that the above procedure was performed. 3. The TC confirmed on 10/7/21 at 2:00 pm that the laboratory did not follow the procedure mentioned above.