Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2081491	04/16/2025
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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) (a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specifications (PS) for the Abott Emereald Cell Dyn and interview with the Technical Consultant (TC), the laboratory failed to retain instrument raw data reports used to verify normal population reference ranges for complete blood count (CBC) tests from 4/19/23 to 4/16/25. The findings include: 1. The laboratory failed to retain the instrument raw data reports used to verify the normal population reference ranges for CBC tests. 2. The TC confirmed on 4/16/25 at 2:00 pm, the intrument raw data reports were not available for review.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Technical Consultant (TC), the laboratory failed to perform and document two levels of external controls on each day of patient testing for Folate, and Microalbumin run on the Abbott Alinity alayzer from 6/1/21 to 4/16/25. The findings include: 1. The laboratory did not select control material that correlated with the abnormal patient range. 2. The Patient Range (PR) for Folate was 7.0-31.4 ng/ml. a) The high QC mean

	was 15.0 ng/ml 3. The TC confirmed on 4/16/25 at 12:20 pm that laboratory did not select control material that correlated with the abnormal patient range for the above mentioned analyte.