Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0158571	(X3) Date Survey Completed 09/22/2022
Name of Provider or Supplier Endocrine Associates Of Long Island Pc	**Street Address, City, State** 732 Smithtown Bypass, Suite 103, Smithtown, NY	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) Proficiency Testing (PT) records for 2020 through survey date, the laboratory failed to enroll PT program for COVID-19 Spike Abs. Confirmed on an interview with testing person on 9/22/2022 about 12pm.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of the Quality Control (QC) records, the laboratory failed to provide/maintain QC assay sheets for Abbott Cell-Dyn Emerald hematology analyzer for past two years. Confirmed in an interview with testing personnel on 9/22/2022 about 11am.
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 review of the laboratory's Quality Control (QC) records, the laboratory failed to perform a verification of current lot number to new lot number of the hematology analyzer Abbott Cell-Dyne Emerald. FINDINGS: 1. The new QC lot to lot validation documentations of hematology analyzer were not available upon request during the survey since the hematology analyzer implementation date to survey date. 2. The testing personnel confirmed during interview on 9/22/2022 at 11:30 am, the new lot to lot validation of QC material for hematology analyzer was not performed.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of laboratory's Quality Control records, and Proficiency Testing records, the laboratory director failed to maintain and assure the quality of laboratory services provided. Refer D5469, D3031, D2000