

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0158571	(X3) Date Survey Completed 07/05/2021
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	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>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)</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT data reports and PT records from the American Proficiency Institute (API) PT program, the laboratory failed to maintain the accuracy for the following non-regulated analyte's C-peptide, Testosterone, 25-OH-Vitamin D, Folate and Vitamin B-12.</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent</p>

with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:

Based on PT desk review of the CMS PT data reports and PT records from API PT program, the laboratory failed to participate successfully in proficiency testing for the speciality Endocrinology and the test analyte's Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH) and Triiodothyronine (T3). The following scores were assigned: 2021 first event = 0% [failure to participate] 2021 second event = 0% [failure to participate] This is considered unsuccessful PT performance. Refer to D2107 and D2108.

D2107

ENDOCRINOLOGY

CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on PT desk review of the CMS PT data reports and PT records from API PT program, the laboratory failed to participate successfully in proficiency testing for the test analyte's Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH) and Triiodothyronine (T3). The following scores were assigned: 2021 first event = 0% [failure to participate] 2021 second event = 0% [failure to participate] This is considered unsuccessful PT performance.

D2108

ENDOCRINOLOGY

CFR(s): 493.843(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on PT desk review of the CMS PT data reports and PT records from API PT program, the laboratory failed to participate successfully in proficiency testing for the speciality Endocrinology. The following scores were assigned: 2021 first event = 0% [failure to participate] 2021 second event = 0% [failure to participate] This is considered unsuccessful PT performance.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on PT desk review of the CMS PT and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the test speciality Endocrinology and the test analyte's Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH) and Triiodothyronine (T3). Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on PT desk review of the CMS PT and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the test speciality Endocrinology and the test analyte's Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH) and Triiodothyronine (T3). The following scores were assigned: 2021 first event = 0% [failure to participate] 2021 second event = 0% [failure to participate] This is considered unsuccessful PT performance.