

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2075610	(X3) Date Survey Completed 05/01/2023
Name of Provider or Supplier N T L Laboratory	Street Address, City, State 8833 Gross Point Rd - Suite 308, Skokie, IL	
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
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 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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CASPER Report 0155D and interview with a American Association of Bioanalysts (AAB) representative the laboratory failed to successfully participate in proficiency testing (PT) for the endocrinology analyte total thyroxine (TT4) during events three of 2022 and one of 2023. See D2107.</p>
D2107	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of CASPER Report 0155D and interview with a American Association of Bioanalysts (AAB) representative; the laboratory failed to successfully participate in proficiency testing (PT) for the endocrinology analyte total thyroxine (TT4) during events three of 2022 and one of 2023. Findings include: 1. Review of the CASPER Report 0155D ran on 5-1-2023 identified the initial unsuccessful PT performance for the endocrinology analyte TT4. ENDOCRINOLOGY TT4 - EVENT-3, 2022 = 60% - Unsatisfactory TT4 - EVENT-1, 2023 = 0% - Unsatisfactory 2. A phone interview with the AAB PT representative on 05/01/2023, at 12:48 pm, confirmed the unsuccessful PT performance for TT4 during events three of 2022 and one of 2023.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the CASPER Report 0155D and interview with a American Association of Bioanalysts (AAB) representative the laboratory director failed to meet the requirements of this condition. The laboratory director failed to ensure test methods were performed as required to provide accurate and reliable results for the endocrinology analyte total thyroxine (TT4) in 2022 through 2023. See D6087.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of the CASPER Report 0155D and interview with a American Association of Bioanalysts (AAB) representative the laboratory director failed to ensure test methods were performed as required to provide accurate and reliable results for the endocrinology analyte total thyroxine (TT4) in 2022 through 2023. Findings Include: 1. The laboratory failed to ensure successful participation in proficiency testing for the endocrinology analyte TT4 during event three of 2022 and event one of 2023. See D2107.