

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2075610	(X3) Date Survey Completed 12/05/2023
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 an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and interview with the AAB-MLE PT program representative confirmed the laboratory's initial unsuccessful PT performance for the hematology analyte cell identification/white blood cell differential (See D2130) for two of three PT events in 2023 (events one & three).</p>
D2130	HEMATOLOGY

CFR(s): 493.851(f)

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

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and interview with the AAB-MLE PT program representative found the laboratory failed to achieve satisfactory performance for the hematology analyte cell identification/white blood cell differential for two of three PT events in 2023 (events one & three). Findings Include: 1. Review of the CASPER Report 0155D, generated on 12-05-2023, and the AAB-MLE PT records found the laboratory received the following unsatisfactory analyte scores: Cell Identification/White Blood Cell Differential EVENT 1, 2023 0% Unsatisfactory EVENT 3, 2023 40% Unsatisfactory 2. A phone interview with the AAB-MLE PT representative on 12-05-2023 at 2:26 PM, confirmed the laboratory failed to submit results for event one of 2023 and scored a 40% for event three of 2023. The AAB-MLE representative indicated the laboratory reported absolute numbers for event three of 2023 and not percentages for white blood cell differential.

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 an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and interview with the AAB-MLE PT program representative found 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 hematology analyte cell identification /white blood cell differential in 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 an off-site desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, American Association of Bioanalysts-Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records, and interview with the AAB-MLE PT program representative

found the laboratory director failed to ensure laboratory personnel were performing test methods ss required to provide accurate and reliable results for the hematology analyte cell identification/white blood cell differential in 2023. See D2130.