

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2075610	(X3) Date Survey Completed 02/06/2025
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, and interview with the laboratory director (LD), the laboratory failed to test proficiency testing (PT) samples in the same manner as it tests patient samples when analyzing and reporting PT samples for five of five PT events reviewed in the specialty of general immunology in the years of 2023 and 2024. Findings include: 1. Review of laboratory policies and procedures revealed the policy manual titled, "General Policy", which stated: a) Under "III. [Quality Control] QC / [Quality Assurance] QA in the Laboratory": "C. Proficiency Testing 1. Enroll in CLIA-approved PT programs; do PT tests in conjunction with patient testing.", and "5. PT samples must be handled as patient samples" b) Under "V. Patient Identification and Preparation for Specimen Collection": "C. Ensuring accurate identification of patient specimen 5. Specimen should be registered in the [Laboratory Information System] LIS.", and "F. Reporting of Results": "7. Result will be accepted from the LIS" 2. Review of laboratory PT records revealed the test reports for the PT samples performed on the Bio-Rad Bioplex 2200 (Serial Number: 2200-0993) were generated from the Bio-Rad Bioplex 2200 instrument, not the laboratory's LIS (LIMSABC). PT Event: VM-A 2023 VM-C 2023 VM-A 2024 VM-B 2024 VM-C 2024 3. Interview with the LD on</p>

02/06/2025, at 2:10 pm, revealed that the laboratory had not been entering PT samples into the laboratory's LIS prior to running the PT specimens on the Bio-Rad BioPlex 2200 as done with patient specimens.

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 laboratory policies and procedures, laboratory records, and interviews with the laboratory director, the laboratory director a) failed to ensure that the Bio-Rad Bioplex 2200 used for Human Immunodeficiency Virus (HIV) testing provided accurate results, affecting 93 patients (See D6082), and b) failed to ensure proficiency testing (PT) samples were tested in the same manner as patient samples when analyzing and reporting PT samples for six of six PT events in the specialty of diagnostic immunology in the years of 2023 and 2024 (See D6089).

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records, and interviews with the laboratory director (LD), the laboratory director failed to ensure that the Bio-Rad Bioplex 2200 (Serial Number: 2200-0993) used for Human Immunodeficiency Virus (HIV) testing in the specialty of diagnostic immunology provided accurate results, affecting 93 patients from 09/08/2023 through the date of survey, 02/06/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy manual titled, "General Policy", which stated, in the section labelled "XI. Computer Policy Manual": a) Under "[Laboratory Information System] LIS Testing", "Programs shall be adequately tested for proper functioning when first installed and after any modifications, and that the laboratory director or designee has approved the use of all new programs and modifications." b) Under "Interface Result Integrity", "There is a procedure to verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic) Interface validation should include examples of individual results, test packages or panels, abnormal flags, and results with comments/footnotes." 2. Review of laboratory records revealed 93 HIV reactive [positive] patients had been falsely reported as non-reactive [negative] from 09/28/2023 to the date of survey, 02/06/2025. Accession #: Result Reported: Actual Result: 309110117 Non-reactive Reactive 309110115 Non-reactive Reactive 309110107 Non-reactive Reactive 309120566 Non-reactive Reactive 309120561 Non-reactive Reactive 309120556 Non-reactive Reactive 309120557 Non-reactive Reactive 309150345 Non-reactive Reactive 309300065 Non-reactive Reactive 310050147 Non-

reactive Reactive 310040294 Non-reactive Reactive 310050305 Non-reactive
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 reactive Reactive 412230274 Non-reactive Reactive 412260024 Non-reactive
 Reactive 501010012 Non-reactive Reactive 501010029 Non-reactive Reactive
 501010023 Non-reactive Reactive 501040138 Non-reactive Reactive 3. Review of
 laboratory records revealed a letter to ordering providers regarding the false HIV
 reporting which stated, "[The] Laboratory has discovered a workflow issue in its
 serology reporting that has had an impact on, in particular, HIV screening results.
 "The nature of the issue is that the HIV Screen test, "HIV Combo [Antigen] Ag/
 [Antibody] Ab", result is a calculated result based upon the direct instrument results
 for four analytes tested in our serology department. If any one or more of these
 analytes are resulted by the instrument as "Detected" or "Reactive" (Positive) then the
 calculated reportable result should also be "Reactive" (Positive). We have found that,
 since a LIMS system upgrade, this functionality has not been working as it should
 have been." 4. Interview with the LD on 02/06/2025, at 4:45 pm, confirmed the
 laboratory director failed to ensure that the Bio-Rad Bioplex 2200 used for Human
 Immunodeficiency Virus (HIV) testing in the specialty of diagnostic immunology
 provided accurate results, affecting 93 patients from 09/08/2023 through the date of
 survey, 02/06/2025.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, and interview with the laboratory director (LD), the laboratory director failed to ensure proficiency testing (PT) samples were tested in the same manner as patient samples when analyzing and reporting PT samples for six of six PT events reviewed in the specialty of general immunology in the years of 2023 and 2024. See D2006.