

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0911771	(X3) Date Survey Completed 03/10/2026
Name of Provider or Supplier Nordx	Street Address, City, State 301a Us Route 1, Scarborough, ME	
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
D0000	A federal surveyor from the Centers for Medicare & Medicaid Services (CMS) Division of Clinical Laboratory Improvement & Quality (DCLIQ) Survey Branch conducted an announced CLIA validation survey at NORDX on March 10, 2026. The laboratory was surveyed under 42 CFR Part 493, CLIA regulations, and found to be in compliance with condition-level CLIA requirements. The following standard-level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, the lack of humidity monitoring, and an interview with the laboratory director (LD), the laboratory failed to monitor and document humidity in the laboratory for 2 of 2 years (March 10, 2024, to March 10, 2026). Findings: 1. Review of the following instrument manufacturer's instructions on March 10, 2026, revealed the following manufacturer humidity requirements: a. Navios Flow Cytometer Instructions for Use, Ambient Temperature and humidity, stated, "Keep the humidity between 30% and 85%..." b. Luminex FLEXMAP 3D User Manual, Environmental conditions stated, "Shipping and operating relative humidity: 20% to 80%, non-condensing." c. Luminex 200 User manual, Environmental conditions stated, "Shipping and operating relative humidity:</p>

20% to 80%, non-condensing." d. QuantStudio 6 RT-PCR System User Guide, Environmental requirements stated, "Operating 15%-80% (non-condensing)." e. EZ1 Advanced XL User Manual, operating conditions stated, "Relative Humidity 15-75% (noncondensing)." 2. The laboratory was unable to provide documentation of monitored humidity in the laboratory where the above instruments were operating from March 10, 2024, to March 10, 2026. 3. On March 10, 2026, at 10:00 am, the LD confirmed the laboratory failed to document humidity.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on a review of personnel competency assessment records and an interview with the laboratory director (LD), the technical supervisor (TS) failed to evaluate 1 out of 3 testing personnel (TP) semiannually during their first year of histocompatibility testing. Findings: 1. Review of laboratory personnel records revealed that 1 out of 3 TP (TP#2) was hired and trained in March 2024. The TS performed TP#2's next competency assessment on December 15, 2025. 2. The laboratory was asked to provide documentation of the semiannual competency assessment during TP#2's first year of histocompatibility testing. No documentation was provided. 3. On March 10, 2026, at 9:15 am, the LD confirmed the above findings.