

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 20D0649494	(X3) Date Survey Completed 02/01/2022
Name of Provider or Supplier Nordx	Street Address, City, State 335 Brighton Avenue, Portland, 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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>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 record review and interview with general supervisor #2 (GS2) the laboratory failed to test College of American Pathologists (CAP) proficiency testing (PT) samples in the same manner as patient samples in the specialty of Hematology. Findings include: 1. Record review on 2/1/2022 of the laboratory's CAP PT attestation sheets revealed: a. New testing personnel #1 (NTP1) and GS2 both signed the attestation sheet as testing personnel for CAP Blood Cell Identification FH9-B 2021. 2. Record review on 2/1/2022 of the laboratory's, 'Proficiency testing in the Clinical lab' policy revealed: a. "With respect to morphological examinations, group review and consensus identifications are permitted only for unknown samples that would ordinarily be reviewed by more than one person in an actual patient sample." 3. Record review on 2/1/2022 of the laboratory's, 'Differential Leukocyte Count Manual Method' policy revealed: a. "Abnormal differential results may require review by the Lead tech, Hematology Specialist or Pathologist." 4. During staff interview with GS2 on 2/1/2022 at 1:00 PM, GS2: a. Stated, "GS2 performed the CAP Blood Cell Identification FH9-B together with NTP1 as part of NTP1's training and competency." b. Confirmed, CAP Blood Cell Identification FH9-B contained both normal and abnormal cells. c. Confirmed, normal cells are not routinely examined by more than</p>

	<p>one TP. 5. The laboratory performs 189 manual Differential Leukocyte Counts annually in the specialty of Hematology.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with general supervisor #1 (GS1) and general supervisor #2 (GS2), the laboratory failed to establish and follow the written procedure to assess the competency of the GS in the specialty of Hematology. Findings include: 1. Review of the laboratory's 2020 and 2021 employee competency records on 2/1/2022 revealed the laboratory did not have competency documentation for the GS1 and GS2 based on his/her CLIA federal regulatory responsibilities. 2. Staff interview on 2/1/2022 at 2:00 PM with GS1 and GS2 confirmed the above findings. 3. The laboratory performs 136,063 tests annually in the specialty of Hematology.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, maintenance record review and interview with general supervisor #1 (GS1) and Roche technical service representative (TSR) the laboratory failed to document routine monthly maintenance and function checks for laboratory equipment in the specialty of Chemistry. Findings include: 1. Record review of the laboratory's Roche e411, 2020 and 2021 maintenance logs on 2/1/2022 revealed the laboratory failed to document the monthly change of the pinch valve tubing for the following: a. Eleven months in 2020 b. Ten months in 2021 2. During interview with the Roche TSR on 2/1/2022 at 2:00 PM, the TSR stated, "If the e411 in reception mode, the pinch valve tubing must be changed monthly." 3. Surveyor observation of the Roche e411 on 2/1/2022 at 2:00 PM revealed the instrument was in reception mode. 4. Staff interview with GS1 on 2/1/2022 at 2:00 PM confirmed the above findings. 5. The laboratory performs 1,057 Troponin tests annually on the Roche e411.</p>