

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 30D0652852	<b>(X3) Date Survey Completed</b> 07/21/2023
<b>Name of Provider or Supplier</b> Nordx	<b>Street Address, City, State</b> 3073 White Mountain Hwy, North Conway, NH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain manual cell count test records for at least 2 years in 2021, 2022, and 2023. Findings include: 1. Review on 7/21/2023 of manual cell counts in July revealed 1 cell count reported in the laboratory's information system (LIS). The laboratory was not able to provide a copy of the corresponding worksheet used for the patient's manual cell count or for the quality control testing. 2. Interview on 7/21/2023 at 8:15 a.m. with a Lead Technologist and the Hematology Technical Supervisor revealed that after the results on the worksheet are reviewed the cell count worksheets and control sheets are discarded. 3. The laboratory performed 60 cell counts annually; a combination of both automated cell counts and manual.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)</p>

The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory's procedure manual for the blood gas analyzer failed to include reportable ranges. Findings include: 1. Review on 7/21.2023 of the laboratory's procedures titled "Radiometer ABL90 Instrument Operation" effective 7/18/23 and "ABL90 Blood Gas and Oximetry Analysis" effective 7/19/23 revealed no reportable ranges for the laboratory's two Radiometer ABL90Flex analyzers. 2. Interview on 7/21/2023 at 9:30 a.m. with the Chemistry Technical Consultant confirmed the reportable ranges were not stated in the procedures.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for 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 record review and staff interview, the Technical Supervisor failed to perform semiannual competency assessments on 4 of 4 new testing personnel in 2021 and 2022. Findings: 1. Review on 7/20/2023 of 6 new personnel records revealed 2 of 6 were still in training. Further review revealed 4 of 6 had been trained in 2021 and 2022 and performing high and/or moderate complexity testing for a year; these 4 testing personnel did not have semiannual competency assessments within their first year of performing high and moderate complexity testing. 2. Interview on 7/20/2023 at 11:15 a.m. with the Technical Supervisor confirmed 4 of 4 testing personnel reviewed and performing testing for at least 1 year did not have semi annual competency assessments.