

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  30D0652852	<b>(X3) Date Survey Completed</b>  07/14/2021
<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>D5403</b>	<p>PROCEDURE MANUAL 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) 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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's (lab) procedure manual for routine chemistry and toxicology testing failed to include control procedures that outline step by step instruction to establish statistical parameters for use as criteria for acceptability of unassayed control material and the procedure for blood gas analytes failed to include reference intervals. Findings include: 1) Review on 7/14/2021 of the lab's "Quality Control - Chemistry" procedure (in effect March 2019) revealed the lab's acceptable criteria for routine chemistry and toxicology quality control (QC) material was +/- 2 standard deviations (SD). Further review of this procedure revealed</p>

Westgard rules could be used to accept a QC result outside 2 SD if no other Westgard rules had been violated. The lab could not provide at the time of the survey, reference material for Westgard rules and how and when to use them. The procedure manual did not include step by step instruction to establish, and use, criteria for acceptability of QC material. 2) Review on 7/14/2021 of the lab's "parallel testing" of new QC material revealed the lab had performed procedures to establish statistical parameters in accordance with 493.1256(d)(10) for the current and previous lot numbers of QC material. 3) Review on 7/14/2021 of the lab's criteria of acceptability for QC material revealed the lab was not using the statistical parameters established from the parallel testing. 4) The lab was not able to provide the surveyor, at the time of the survey on 7/14/2021, a procedure manual that included the reference intervals for arterial and venous blood gases on cord blood specimens. 5) Interview on 7/14/2021 at 11:30 a.m. with the General Supervisor confirmed the above findings and revealed the QC material for routine chemistry and toxicology testing is unassayed.