

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  20D0087881	<b>(X3) Date Survey Completed</b>  10/26/2022
<b>Name of Provider or Supplier</b>  Nordx	<b>Street Address, City, State</b>  329 Maine Street, Brunswick, ME	
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>D5891</b>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, it was determined that the reference range for chemistry on the laboratory's final patient test report did not correlate with the reference ranges in the laboratory's procedure manual. Findings include: 1. Comparison of final patient test report's chemistry reference range for patient #1 (male) with the laboratory's procedure for chemistry policy manual on 10/26/2022 revealed 10 of 10 reference ranges did not match. 2. Staff interview with the technical consultant on 10/26/2022 at 10:00AM confirmed the findings above. 3. The laboratory performs 33,674 tests annually in the specialty of chemistry.</p>
<b>D6031</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with laboratory manager, the</p>

laboratory director (LD) failed to ensure that an approved procedure manual was available to testing personnel under the specialty of Chemistry. Findings include: 1. Record review of the laboratory online testing manual on 10/26/2022 revealed no signature of approval by the current LD. 3. Interview with the laboratory technical consultant on 10/26/2022 at 9:00am confirmed the above findings. 4. The laboratory performs 33,364 tests annually in the specialty of Chemistry.