

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D0978594	<b>(X3) Date Survey Completed</b> 11/08/2022
<b>Name of Provider or Supplier</b> Bellin Health Brillion	<b>Street Address, City, State</b> 235 East Ryan Street, Brillion, WI	
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>D6072</b>	<p><b>TESTING PERSONNEL RESPONSIBILITIES</b> CFR(s): 493.1425(b)(3)</p> <p>Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and records and interview with the technical consultants, testing personnel did not follow quality control procedures when sodium controls required corrective action from January 25 through 31, 2022 and 22 of 49 patient samples tested had abnormal high sodium results reported. Findings include: 1. Review of the 'Quality Control Program' procedure showed, "If corrective action is taken for more than 3 days in a row, service must be called." 2. Review of the 'Laboratory Corrective Action Log' for January 25 through 31, 2022 showed testing personnel documented sodium control results for both control levels were above the acceptable range and required repeat testing and corrective actions on January 25, 26, 27, 28, and 31 (laboratory was not open on January 29 or 30) before the control results were both acceptable. The log showed personnel first contacted service on January 31, 2022. 3. Review of patient results from January 25 through 31, 2022 showed 48 of 49 results were above the midpoint (140.5 mmol/L (millimoles per liter)) of the normal range (136-145 mmol/L) and twenty-two patients had abnormal high sodium results reported (results above the normal range). Date / total patients tested / number of abnormal high results January 25 / six / three January 26 / seven / four January 27 / thirteen / seven January 28 / fifteen / five January 31 / eight / three 4. Interview with the technical consultants (staff A and B) on November 8, 2022 at 12:30 PM confirmed the testing personnel (staff C) did not follow the quality control program procedures when they did not contact service until the fifth day they took corrective actions to bring sodium control results into the acceptable range.</p>