

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0920451	<b>(X3) Date Survey Completed</b>  09/09/2020
<b>Name of Provider or Supplier</b>  Bellin Hfmc Howard	<b>Street Address, City, State</b>  2714 Riverview Dr, Green Bay, 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>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 surveyor review of the chemistry procedures and interview with the technical consultant, the chemistry procedures did not include reference intervals for testing performed on the Siemens EXL 200 chemistry analyzer. Findings include: 1. Review of the chemistry procedures showed no evidence the laboratory included patient reference intervals in their procedure for testing performed on the Siemens EXL 200 chemistry analyzer. 2. Interview with the Technical Consultant on</p>

September 9, 2020 at 10:55 AM, confirmed that patient reference intervals were not included in the chemistry procedures. This is a repeat deficiency from February 8, 2012.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor review of competency assessment records and interview with the technical consultant, the technical consultant's evaluation of competency for two of two testing personnel was not specific to the Bellin HFMC Howard location in 2018 and 2019. Findings include: 1. Review of competency assessment records of 2018 and 2019 showed no evaluation of competency specific for the Bellin HFMC Howard location for Staff A and B. 2. Interview with the technical consultant on September 9, 2020 at 9:35 AM, confirmed the technical consultant's evaluation of the testing personnel competency was not specific to the testing location.