

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D1093324	<b>(X3) Date Survey Completed</b>  03/17/2021
<b>Name of Provider or Supplier</b>  Bellin Health Fmc Bellevue	<b>Street Address, City, State</b>  3263 Eaton Rd, 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>D5425</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(3)</p> <p>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) for the TRIAGE troponin test and interview with the technical consultant, the IQCP showed no evidence the laboratory used data collected in this laboratory by its own personnel to support the frequency of external control testing. Findings include: 1. Review of the IQCP for the TRIAGE troponin test signed by the laboratory director on May 22, 2019 failed to show the laboratory used internally collected data to determine the frequency of external quality control testing described in the IQCP. 2. Interview with the technical consultant on March 17, 2021 at 12:30 PM confirmed the laboratory could not show the laboratory developed the IQCP using in-house data, established by the laboratory in its own environment and by its own personnel, to support the frequency of external control testing.</p>