

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0395058	(X3) Date Survey Completed 10/18/2022
Name of Provider or Supplier Bellin Health Generations - Development Drive	Street Address, City, State 2641 Development Dr, Green Bay, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on survey review of laboratory records and the ASPEN WEB Clinical Laboratory Improvement Amendments (CLIA) database and interview with the technical consultant, the laboratory did not ensure compliance with regulations at 493.51, Notification Requirements for Laboratories Issued a Certificate of Compliance and did not notify Health and Human Services (HHS) or its designee within thirty days of any change in director. Findings include: 1. Review of the laboratory procedure binder showed the following: Staff A: Laboratory Director, Effective: 2022-Present Staff B: Laboratory Director, Effective: 2021-2022 (Interim) Staff C: Laboratory Director, Effective: 2017-2021 Further review showed Staff A delegated the technical consultant duties in February 2022 and Staff B delegated the technical consultant duties on January 4, 2022. 2. Review of the ASPEN WEB CLIA database showed Staff A as the current laboratory director effective February 17, 2022, and staff C as the previous laboratory director. Further review showed no notification that staff B had served as the laboratory director for this location. 3. Interview with the technical consultant on October 18, 2022, at 10:40 AM revealed staff C had resigned from the location in December 2021 and staff B took over as laboratory director from</p>

December 2021 through February 17, 2022, and staff A became the laboratory director on February 17, 2022. Further interview confirmed, the laboratory did not ensure compliance with regulations at 493.51, Notification Requirements for Laboratories Issued a Certificate of Compliance and did not notify Health and Human Services (HHS) or its designee within thirty days of any change in director.