Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394498	(X3) Date Survey Completed 09/26/2023
Name of Provider or Supplier Bellin Health Marinette Laboratory	**Street Address, City, State** 2820 Roosevelt Road, Marinette, 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
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of Individualized Quality Control Plan (IQCP) documents and interview with the laboratory team facilitator, the laboratory director did not ensure completion of the quality assessment evaluation of the IQCP for the Triage analyzer in one of the last two years. Findings include: 1. Review of IQCP documentation for the Triage analyzer revealed a quality assessment evaluation for the Triage IQCP from 2021. No records were available showing the laboratory completed a quality assessment of the Triage analyzer IQCP in 2022. 2. Interview with the laboratory team facilitator (staff A) on September 26, 2023, at 1:30 PM confirmed the director did not ensure completion of the quality assurance evaluation of the IQCP for the Triage analyzer in 2022.