

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0907183	(X3) Date Survey Completed 07/02/2025
Name of Provider or Supplier Bellin Hfmc Ashwaubenon	Street Address, City, State 1630 Commanche Ave, 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
D3029	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the Technical Consultant, the laboratory did not retain the risk assessment, including data to support their risk assessment decisions, for one of one Individualized Quality Control Plan (IQCP) in use in the laboratory for the Biosite Triage D-Dimer test system. Findings include: 1. Review of laboratory procedures and IQCP documentation showed no evidence of the risk assessment and data used to support the risk assessment decisions for the Biosite Triage D-Dimer test system at this laboratory. 2. Interview with the Technical Consultant on July 2, 2025, at 11:45 AM, confirmed the laboratory used an IQCP to reduce the frequency of external quality control testing. An email communication on July 7, 2025, at 9:13 AM, confirmed the laboratory could not find and had not retained the risk assessment and data for the Biosite Triage D-dimer IQCP for this laboratory.</p>