Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1085214	06/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cancer Team At Bellin Health,The	1580 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
D6010	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer's environmental specifications for the Atellica chemistry analyzer and laboratory records and evidence provided in the laboratory's plan of correction received in response to the survey completed on April 1, 2025 (Event UO1S), the laboratory director did not ensure the environmental conditions of the laboratory were appropriate for the operation of the Attelica chemistry analyzer during February and March of 2025. Findings include: 1. Review of the 'Atellica Analyzer Environmental Specifications' showed the manufacturer required a laboratory ambient relative humidity of 20 - 80%, noncondensing. 2. Review of the laboratory temperature and humidity logs from February and March 2025 showed the documented relative humidity readings for each day of testing. The log showed the acceptable humidity reading was 20 - 80%. Summarized records for February and March 2025 follow: February / March Number of recordings: 20 / 21 Number of days at 20%: 3 / 2 Number of days at 16%: 17 / 19 3. Review of verification records showed the laboratory performed verification testing in January 2025 and began patient testing with the analyzer on February 17, 2025. 4. Review of two letters provided by the laboratory from Siemens Healthineers, both dated May 6, 2025, confirmed the manufacturer supported environmental humidity range was 20 - 80%, non-condensing. The letters stated the specifications provided are the ranges the company determined they can ensure reliable performance of the analyzer and stated the laboratory may wish to consider options to help reduce any fluctuations in laboratory humidity. 5. Review of the evidence received on May 19, 2025, for the plan of correction signed by the laboratory director on April 10, 2025, did not show the laboratory director had performed an internal study with accompanying data to

	establish a range (suitable for their laboratory) that shows the instrument can operate outside of specified environmental requirements, or that the laboratory explored the use of humidifiers or dehumidifiers for the laboratory area.