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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D1085214 | (X3) Date Survey Completed 04/01/2025 |
| Name of Provider or Supplier Cancer Team At Bellin Health,The | Street Address, City, State 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 |
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| D5785 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer environmental specifications for the Atellica chemistry analyzer and laboratory records and interview with the Technical Consultant, the laboratory recorded relative humidity readings below the manufacturer's specified range on 36 of 41 days in February and March 2025 without documenting any corrective actions taken. 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. Interview with the Technical Consultant on April 1, 2025, at 2:30 PM confirmed the recorded humidity readings were not within the manufacturer's specified range for relative humidity and confirmed testing personnel did not document corrective actions taken.</p> |