Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0397019	09/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Burnett Medical Center	257 W St George Ave, Grantsburg, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of laboratory records and interview with the general supervisor, the laboratory director did not review and approve the performance specification verification records on the Quidel Solana Group A Strep assay prior to reporting patient results. Findings include: 1. Review of the "Solana Group A Strep Assay" validation form showed the laboratory performed performance specification verification on April 4, 2022. 2. Interview with the general supervisor on September 8, 2022 at 8:20 AM stated the laboratory started patient testing on April 13, 2022. Further interview stated director did not review and approve the performance specification verification records for the Quidel Solana Group A Strep assay until April 26, 2022. 3. Interview with the general supervisor on September 8, 2022 at 8:20 AM confirmed the laboratory director did not review and approve the performance specification verification records on the Quidel Solana Group A Strep assay prior to reporting patient results. Item 2: Based on surveyor review of laboratory records and interview with the general supervisor, the laboratory director did not review and approve the performance specification verification records on the Alcor miniiSED erythrocyte sedimentation rate (ESR) analyzer prior to reporting patient results. Findings include: 1. Review of the "Alcor miniiSED" quality control and maintenance form showed the laboratory started patient testing on the analyzer on July 1, 2021. 2.

	Review of the "Erythrocyte Sedimentation Rate (ESR) Correlation Data Analysis Report" showed the general supervisor, who is not delegated to approve performance specification verification data, signed the analysis on June 29, 2021. Further review showed the laboratory director reviewed and accepted the performance specification verification on January 25, 2022. 3. Interview with the general supervisor on September 7, 2022, at 2:05 PM confirmed the laboratory director did not review and approve the performance specification verification records on the Alcor miniiSED ESR analyzer prior to reporting patient results. This is a previous deficiency from July 18, 2014.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on survey review of coagulation records, observation of the Sysmex CA 600 coagulation analyzer and interview with the general supervisor, the laboratory failed to verify the accuracy of the new lot information used for calculating the International Normalized Ratio (INR). Findings include: 1. Review of the "QA New Lot Innovin Patient Comparison (Normal Range Validation)" records for the Sysmex CA 600 coagulation analyzer showed the current International Sensitivity Index (ISI) for Innovin lot number 549770B is 1.01 and the established Mean Normal Range (MNR) is 10.17 seconds. Further review showed the new lot was implemented on July 13, 2021. 2. Observation of the ISI and MNR data on September 8, 2022, at 12:12 PM revealed the IS value in the Sysmex CA 600 analyzer is 1.01 and the MNR is 9.9 seconds. 3. Interview with the general supervisor on September 8, 2022, at 12:25 PM confirmed the laboratory failed to verify the accuracy of the new lot information used for calculating the International Normalized Ratio (INR) for the Innovin lot in use since July 13, 2021.