Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0691046	11/03/2023
Name of Provider or Supplier	**Street Address, City, State**	
Chi St Francis Health	2400 St Francis Drive, Breckenridge, MN	

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
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document alarm system function checks for the blood storage refrigerator, five of eight times in 2022 and 2023. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory on at 12:45 p.m. on November 2, 2023. 2. A designated Helmer refrigerator used to store blood products, with a temperature alarm system, was observed in the laboratory during the tour. 3. Quarterly blood storage alarm check requirements were established in the Blood Bank Fridge Alarm Protocol 24hr Temp Monitor System procedure located in the white three ring Blood Bank Procedure Manual. 4. Blood storage alarm check records for 2022 and 2023 were reviewed the day of survey. Records found the laboratory performed the required blood storage alarm checks on the following dates: -January 31, 2022 -October 31, 2022 -January 18, 2023 The laboratory did not have records for five of the eight required alarm checks in 2022 and 2023. 5. The laboratory performed approximately 500 Immunohematology results annually as indicated on the Form CMS-116 provided by the laboratory on date of survey. 6. In an interview at 10:45 a. m. on November 3, 2023, GS1 confirmed the above finding, stating that BioMed had failed to continue to perform the checks when a transition of staff occurred. .

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to evaluate the relationship between test results obtained from two identical Toxicology analyzers at least twice annually in 2021 through 2023. Findings are as follows: 1. The laboratory performed Toxicology testing, which falls under the specialty of Chemistry, as confirmed by General Supervisor 1 (GS1) during a tour of the laboratory at 12:45 p.m. on November 2, 2023. 2. Two identical MedTox Profile V test systems were observed as present and available for use during the tour. Both test systems were used for urine drugs of abuse testing. 3. A twice annual comparison requirement for test results obtained from multiple instruments was not established in the laboratory's Correlation Policy, approved by the Laboratory Director on January 21, 2023. 4. Comparison of the test results obtained from both MedTox Profile V test systems was not found during review of laboratory records for the period reviewed; November 2021 through October 2023. The laboratory was unable to provide documentation of the comparisons upon request. 5. In an interview at 4:10 p.m. on November 2, 2023, General Supervisor 5 (GS5) confirmed the laboratory does not currently correlate the two identical MedTox Profile instruments. .