Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385663	02/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Stewart Memorial Community Hospital	1301 West Main Street, Lake City, IA	

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 review of the blood bank procedures and temperature logs and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 12:12 pm on 2/29/2024, the laboratory failed to perform quarterly alarm checks for three out of four quarters from 1/1/2023 - 12/31/2023. The findings include: 1. The Blood Bank Alarm Check procedure states alarm checks will be performed quarterly. 2. The laboratory performed an alarm check on 6/13/2023. 3. The laboratory did not perform any other alarm checks in 2023.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory temperature logs and the blood bank refrigerator

	temperature wheel and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at 12:12 pm on 2/29/2024, the laboratory failed to correct problems identified with the blood bank refrigerator monitoring system for seven out of seven days from 12/24/2023 - 12/31/2023. The findings include: 1. The laboratory manually documented the following temperatures in Celsius (C) for the blood bank refrigerator: *12/24/23 Upper = 3.2 and Lower = 3.8 *12/25/23 Upper = 3. 2 and Lower = 3.7 *12/26/23 Upper = 3.1 and Lower = 3.7 *12/27/23 Upper = 3.2 and Lower = 3.8 *12/28/23 Upper = 3.2 and Lower = 3.7 *12/29/23 Upper = 3.2 and Lower = 3.7 *12/30/23 Upper = 3.2 and Lower = 3.7 *12/31/23 Upper = 3.2 and Lower = 3.7 2. The blood bank temperature wheel documented the temperature for the above dates as somewhere between 1 degree C and 4 degrees C. The temperature wheel recorded a thick line between 1 degree C and 4 degrees C, it did not record the exact temperatures. 3. At the time of the survey, the laboratory did not have documentation of corrective action for the inconsistent blood bank temperature wheel recordings.