Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	43D0041615	08/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bowdle Hospital	8001 West Fifth St, Bowdle, SD	

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
D0000	A recertification survey for compliance with 42 CFR Part 493, Requirements for Laboratories, was conducted on 8/22/25. The Bowdle Hospital laboratory was found not in compliance with these requirements: D5400 and D5555.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with the laboratory supervisor, the laboratory failed to ensure the continuous monitoring of the internal temperature of the blood bank refrigerator for six of twelve weeks (5/26/25 through 8/18/25) reviewed. Continuous monitoring of the blood bank refrigerator internal temperature was necessary to ensure the blood products stored within the refrigerator were continuously stored at a safe temperature (1-6 Celsius) prior to transfusion to a patient. Findings include: 1. Review on 8/22/25 at 12:20 of the blood bank refrigerator continuous temperature recording charts revealed nine occasions where the recording pen left the temperature recording chart and did not return for an extended length of time. During these time periods, there had been no documentation of the internal temperature of the blood bank refrigerator to ensure the blood had been stored at a safe temperature (1-6 Celsius). Refer to D5555.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)

(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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.

This STANDARD is not met as evidenced by:
Based on observation, review of maintenance records, and interview with laboratory staff, the laboratory failed to ensure the internal temperature of the blood bank refrigerator had been continuously monitored for six of twelve weeks (5/26/25 through 8/18/25) reviewed. Continuous monitoring of the blood bank refrigerator internal temperature was necessary to ensure the blood products had been stored at a safe temperature (1-6 Celsius) prior to transfusion to a patient. Findings include: 1. Observation on 8/22/25 at 12:15 p.m. of the laboratory's blood bank refrigerator revealed: a. The laboratory stored blood products for potential transfusion to patients in the refrigerator. b. There had been several units of blood stored in the refrigerator, including a unit tagged for transfusion to a patient. c. The refrigerator had contained a thermometer which would be manually read and the internal temperature documented on a daily basis by laboratory staff. d. The refrigerator had contained a second temperature probe connected to a continuous temperature recording unit mounted on the wall above the blood bank refrigerator. *The temperature recording chart unit consisted of a preprinted paper chart that rotated at a consistent speed and a pen that recorded the continuous internal temperature of the blood bank refrigerator on the preprinted chart. *The chart would continuously record the internal blood bank refrigerator temperature for a period of seven days. *Changes in the internal temperature would be indicated by spikes on the temperature chart. *If the internal blood bank temperature exceeded the safe storage temperature range (1-6 Celsius), an alarm would sound in the laboratory and a page would be sent to the laboratory staffs' telephones. *Every seven days the temperature chart would be replaced by laboratory staff. Review on 8/22/25 at 12:20 p.m. of the blood bank refrigerator continuous recording charts revealed: a. At approximately 4:30 a.m. on 6/9/25, the recording pen moved off of the recording chart. The temperature chart had been replaced at approximately 6:00 a.m. that same day. *There had been no record of the internal temperature of the blood bank refrigerator during that approximately 1.5 hour time period. *Laboratory staff had documented "no alarm" on the temperature recording chart. *There had been no documentation for the cause of the temperature recording malfunction. b. At approximately 1:30 a.m. on 6/20/25, the recording pen moved off of the recording chart. The temperature chart had been replaced at approximately 7:00 a.m. on 6/23/25. *There had been no record of the internal temperature of the blood bank refrigerator during that approximately 53 hour time period. *There had been no documentation on the temperature chart regarding the reason for the temperature recording malfunction. *There had been no documentation as to whether the blood bank alarm had sounded during that time period. c. At approximately 2:00 a.m. on 7/1 /25, the recording pen moved off of the recording chart. The pen returned to the chart approximately 15 minutes later indicating the blood bank refrigerator was again at a safe temperature. *Laboratory staff had documented 'power outage" on the chart as the reason for the malfunction. *Laboratory staff had documented "no alarm" on the temperature recording chart. d. At approximately 5:00 p.m. on 7/6/25, the recording pen moved off of the recording chart. The temperature chart had been replaced at approximately 7:00 a.m. on 7/7/25. *There had been no record of the internal temperature of the blood bank refrigerator during that approximately 14 hour time

period. *There had been no documentation on the temperature chart regarding the reason for the temperature recording malfunction. *Laboratory staff had documented "no alarm" on the temperature recording chart. e. At approximately 11:30 p.m. on 7/26 /25, the recording pen moved off of the recording chart. The temperature chart had been replaced at approximately 7:00 a.m. on 7/28/25. *There had been no record of the internal temperature of the blood bank refrigerator during that approximately 31.5 hour time period. *There had been no documentation on the temperature chart regarding the reason for the temperature recording malfunction. *There had been no documentation as to whether the blood bank alarm had sounded during that time period. f. At approximately 4:30 p.m. on 7/28/25, the recording pen moved off of the recording chart. The pen returned to the chart at approximately 7:00 a.m. on 7/29/25 indicating the blood bank refrigerator was again at a safe temperature. *There had been no record of the internal temperature of the blood bank refrigerator during that approximately 14.5 hour time period. *Laboratory staff had documented 'power outage" on the chart as the reason for the malfunction. *There had been no documentation as to whether the blood bank alarm had sounded during that time period. g. At approximately 8:00 p.m. on 7/29/25, the recording pen moved off of the recording chart. The pen returned to the chart at approximately 12:15 a.m. on 7/30/25 indicating the blood bank refrigerator was again at a safe temperature. *There had been no record of the internal temperature of the blood bank refrigerator during that approximately 4.25 hour time period. *Laboratory staff had documented 'power outage" on the chart as the reason for the malfunction. *There had been no documentation as to whether the blood bank alarm had sounded during that time period. h. At approximately 11:45 p.m. on 8/3/25, the recording pen moved off of the recording chart. The temperature chart had been replaced at approximately 7:00 a.m. on 8/4/25. *There had been no record of the internal temperature of the blood bank refrigerator during that approximately 7 hour time period. *There had been no documentation on the temperature chart regarding the reason for the temperature recording malfunction. *There had been no documentation as to whether the blood bank alarm had sounded during that time period. i. At approximately 5:30 a.m. on 8/15 /25, the recording pen moved off of the recording chart. The temperature chart had been replaced at approximately 7:00 a.m. on 8/18/25. *There had been no record of the internal temperature of the blood bank refrigerator during that approximately 73.5 hour time period. *Laboratory staff had documented 'power outage" on the chart as the reason for the malfunction. *There had been no documentation as to whether the blood bank alarm had sounded during that time period. Review of the blood bank refrigerator maintenance records revealed: *The laboratory staff checked the thermometer in the blood bank refrigerator and documented the temperature on a daily basis during the time period reviewed (5/26/25 through 8/18/25). *The blood bank refrigerator had an alarm that sounded and paged laboratory staff if the safe storage temperature was exceeded. *The blood bank alarm had been tested for high alarm activation at 5.5 degrees and low alarm activation at 1.5 degrees Celsius on a quarterly basis in 2024 and to date in 2025 by technical consultant B. There had been documentation that nursing staff responded to the alarm activation tests by contacting the laboratory staff. Interview with laboratory supervisor A on 8/22/25 at 12:25 p.m. revealed: *She confirmed the blood bank refrigerator had been used to store blood units for patient transfusion. *She confirmed the blood bank refrigerator had been connected to emergency power and had an alarm back up. *She confirmed it would take a minute or two for the emergency generator to start and provide emergency power to the blood bank refrigerator in the case of a power outage. *She confirmed she had been aware of the issue with the blood bank temperature monitoring charts failing to continuously document the internal blood bank refrigerator temperature. *She had been aware that there had been a large number of power outages over the

	last several months. When the power failed, the blood bank temperature recording pen would move off the chart due to the lack of power. It would take less than a minute for the generator to activate providing emergency power. Once the power returned the pen would attempt to return to the temperature chart, but would get caught on the edge of the paper. *If staff were present at the time of the power outage, they would reset the recording chart pen manually. *Staff did not regularly check the blood bank recording chart on a daily basis. *Staff were present in the laboratory only from approximately 6:00 a.m. until 5:30- 6:00 p.m.. Staff would then be "on-call" until the next morning. * She thought that if there had been a temperature issue the alarm would have sounded in the laboratory and the laboratory staff would have received a page on their telephone that the safe temperature had been exceeded. Nursing staff would have heard the alarm sounding in the laboratory and would have notified the on-call laboratory staff member. *She confirmed that the blood bank alarm had not sounded when there had been a power outage and the temperature chart showed the temperature spikes caused by the pen leaving the temperature chart. *She confirmed that there had been no way to verify the internal temperature of the blood bank refrigerator during the time periods when the recording pen was off the chart. *She did not know if the blood bank temperature recording unit had a back up power source to prevent the loss of power during the frequent power outages experienced by the hospital. Interview with technical consultant B, via telephone on 8/26/25 at 11:00 a.m., revealed: *He had not been aware of the issue with the blood bank continuous temperature monitoring charts. *He had not reviewed the blood bank temperature recording charts as that had not been a part of the documentation he was required to review on his quarterly visits.