Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409807	05/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sheridan Memorial Hospital Association	440 West Laurel Avenue, Plentywood, MT	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on review of laboratory procedure and interview with technical supervisor (TS) #1, the laboratory failed to record temperature for the Genesis 2002 Plasma Thawing Water Bath. Findings: 1. Review of laboratory procedure for Thawing Fresh Frozen Plasma revealed, "Fresh frozen plasma (FFP) must be thawed with agitation at temperatures between 30 and 37 degrees C and must be infused within 24 hours." 2. No temperature log for the Genesis 2002 Plasma Thawing Water Bath was available for review. 3. Interview with TS #1 on May 12, 2021 at 1:45 PM, confirmed the laboratory failed to document temperatures for Genesis 2002 Plasma Thawing Water Bath.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as

	acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on review of calibration records for the Beckman Coulter AU480 chemistry analyzer and interview with the technical supervisor (TS) #1, the laboratory failed to perform at least a three point (a minimal, mid-point, and maximum) calibration verification every six months for years 2019 and 2020. Findings: 1. Review of 2019 and 2020 calibration records for the Beckman Coulter AU480 chemistry analyzer, revealed the laboratory failed to perform a calibration verification to include, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Interview with the TS #1 on May 12, 2021 at 9:55 AM confirmed the laboratory failed to perform at least a three-point calibration for sodium, potassium, and chloride on the Beckman Coulter AU480 chemistry analyzer every six months.