Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410143	05/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Logan Health-Cut Bank	802 2nd Street Se, Cut Bank, 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
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: . Based on observation, record review of Blood Bank, and interview with Technical Supervisor (TS)#1, the laboratory failed to document temperature of blood products upon receipt of new shipment and release of units to be transfused for years 2019 and 2020. Findings: 1. Review of Blood Bank records lacked documentation temperature checks upon receipt and release of blood components for years 2019 and 2020. 2. Observation of shipping containers revealed the lack of thermometers to monitor blood or blood components temperatures during shipment and upon receipt of units. 3. Review of American Red Cross Hospital Partner Resource Guide revealed (page 17), "If products are received out of shipping temperature range or are packed incorrectly, notify Red Cross Customer Service. These products will be managed based on the non-conformance." 4. Interview with TS#1 on April 19, 2021 at 10:30 AM, confirmed the laboratory failed to document visual inspection and record the temperature of blood products upon receipt of new shipment and release of units to be transfused for years 2019 and 2020.
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 the calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes of sodium, potassium, and chloride, 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. Findings: 1. Review of 2019 and 2020 calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Interview with the TS #1 on May 19, 2021 at 9:30 AM confirmed the laboratory failed to perform at least a three-point calibration for sodium, potassium, and chloride on the Siemens Dimension EXL 200 chemistry analyzer every six months.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: D5537 Based on record review EG7+ cartridge for blood gas analysis, Abbott i-STAT 1 Procedure Manual, and interview with Technical Supervisor (TS) #1, the laboratory failed to test a control each 8 hours of patient testing. Findings: 1. Review of QC records for EG7+ cartridge for blood gas analysis lacked one control material each 8 hours of patient testing. 2. Review of Abbott i-STAT Procedure Manual revealed the manufacture's Monitoring of Quality Control as follows: Daily Procedures: Handheld Verification: The internal electronic simulation is automatically programmed to run every 8 hours of use. Monthly Procedures: Periodic Procedures for Cartridges: For acceptance of newly received cartridge lots, check the Temperature Monitor and perform integrity testing. Integrity Testing: From each lot of blood gas/chemistry cartridges received, use a representational number of cartridges to analyze i-STAT Level 1 and 3 Controls 3. No Individualized Quality Control Plan (IQCP) procedure

	was available for review. 4. Interview with TS#1 on May 19, 2021 at 11:50 AM confirmed the laboratory failed to run a control each 8 hours of patient testing on the blood gas analyzer since the EG7+ cartridge was implemented in January of 2021 or have an IQCP for alternative QC practices.