Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410131	05/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Logan Health Conrad	805 Sunset Blvd, Conrad, 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 review of Immunohematology records, policies, and interview with technical supervisor (TS) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood or blood products and on units reissued from May 17, 2021, to May 17, 2023. Findings: 1. A review of Immunohematology records revealed the laboratory failed to take and document the temperatures of blood or blood products upon receipt of new shipments from May 17, 2021, to May 17, 2023. 2. A review of "Transfusion Service Testing Record" lacked a temperature record for one blood unit not used for transfusion and returned to inventory on 12/01/22. 3. An interview with TS #1 on May 17, 2023 at 11:40 AM, confirmed laboratory staff failed to take the temperature upon receipt of new shipments of blood or blood products and units reissued from May 17, 2021, to May 17, 2023.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, laboratory policies, and an interview with technical supervisor (TS) #1, the laboratory failed to establish, follow, and perform two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to perform external controls at the manufacturer's recommended frequency for mononucleosis (Mono), clostridium difficile (C. diff) toxin A and B, and Helicobacter pylorifrom (H. Pylori) from May 17, 2021, to May 17, 2023. Findings: 1. A review of QC records revealed the laboratory was performing external QC at the frequency of once per lot/shipment for Cardinal Health Mono II rapid test, Tech lab C. DIFFICILE TOX A/B II, and Tech lab H. PYLORI CHEK. 2. No IQCP evaluation containing a risk assessment, a quality control plan, and a quality assessment plan was available for review to support QC practices less stringent than the regulatory control procedure. 3. An interview with the TS #1 on May 17, 2023, at 3:30 PM confirmed the laboratory failed to perform two levels of external QC each day of testing or develop an IQCP for alternative QC practices from May 17, 2021, to May 17, 2023 4. A review of the test volume sheet revealed the laboratory performed 20 H. pylori, 11 Mono(serum) and 20 C. diff toxin A and B tests, from May 17, 2022 to May 17, 2023 (12-month period).
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of chemistry quality control (QC) records and procedures and an interview with the technical supervisor (TS) #1, the laboratory failed to establish acceptable criteria (mean and standard deviation) for new lots of Bio-Rad liquid unassayed Multiqual controls performed on the Siemens Dimension EXL chemistry analyzer from May 17, 2021, to May 17, 2023. Findings: 1. No correlation studies of new lots of Bio-Rad liquid unassayed Multiqual controls were available for review that showed an established mean and standard deviation for each analyte performed on the Siemens Dimension EXL chemistry. 2. The laboratory failed to establish a step-by-step procedure on how to perform and determine the statistical parameters for new lots of unassayed control material. 3. An interview with (TS) #1 on May 17, 2023, at 1:10 PM confirmed the laboratory failed to establish and document acceptable

	statistical parameters for new lots of Bio-Rad liquid unassayed Multiqual controls performed on the Siemens Dimension EXL chemistry analyzer from May 17, 2021, to May 17, 2023
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, review of policies, blood bank alarm records, and interview with the technical supervisor (TS) #1, the laboratory failed to monitor the alarm for one of one freezer and failed to follow their procedure for documentation of one of one alarm check for the blood bank refrigerator from May 17, 2021, to May 17, 2023. Findings: 1. Observed one of one refrigerator and freezer containing blood or blood products stored by the laboratory. 2. No records of alarm checks for the freezer were available for review from May 17, 2021, to May 17, 2023. 3. A review of the alarm check logs for the refrigerator revealed no records were available for year 2021 and the alarm check record in 2022 failed to include the high and low temperature records per the laboratory policy. 4. An interview with TS #1 on May 17, 2023, at 10:45 AM. confirmed the laboratory failed to perform alarm checks for the freezer and failed to follow their procedure for documentation of the refrigerator alarm check from May 17, 2021, to May 17, 2023.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, and interview with technical supervisor (TS) #1, the laboratory failed to assess the blood bank refrigerator and freezer temperature wheels and take corrective action for temperatures outside the acceptable storage limits, and missing off or on dates from May 17, 2021, to May 17, 2023. Findings: 1. A review of blood bank refrigerator and freezer temperature wheels revealed the temperature wheels lacked either off or on dates, corrective action for temperatures outside of the acceptable storage limits, and missing laboratory identification stamp for the following dates: 1/3/22, 1/10/22, 1/17/22, 1/24/22, 2/1/22, 2/14/22, 4/18/22, 4/11/22, 7/4/22, 7/11/22, 7/25/22, 8/8/22, 9/19/22, 10/17/22, 11/28/22, 12/20/22, 1/2/23, 1/9/23, 1/23/23, and 2/13/23. 2. An interview with TS #1 on May 17, 2023, at 11:20 AM, confirmed laboratory staff failed to review the blood bank refrigerator and freezer temperatures wheels for accuracy to include on and off dates, address unacceptable

	temperature spikes and include the laboratory identification from May 17, 2021, to May 17, 2023.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of employees' annual competency files for years 2022 and 2023, the CMS-209 Laboratory Personnel Report, and an interview with the technical supervisor (TS) #1, the technical supervisor failed to perform annual competency assessments for two out of three testing personnel for the year 2022. Findings: 1. A review of annual competency records for the year 2022 lacked annual competencies for two out of three testing personnel (TP-1 and TP-3). 2. A review of the "Lab Medical Director Delegation of Duties" revealed the technical supervisor failed to perform their delegated duty of "Assessing competency of existing employees". 3. Interview with the TS #1 on May 17, 2023, at 9:40 AM, confirmed annual competencies were missed for year 2022 for two out of three testing personnel.