Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410131	01/26/2024
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
D0000	Based on a remote complaint survey conducted on January 26, 2024, deficiencies were cited for Logan Health Conrad located in Conrad, MT.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on record review, laboratory policies, and an interview with technical supervisor (TS) #1, the laboratory failed to provide a written or electronic request for patient testing from an authorized person for ten out of eleven patients tested on the GeneXpert and two out of two patients tested on the i-STAT from December 30, 2023, through January 02, 2024. Findings: 1. An interview with TS#1, February 8, 2024, at 7:42 AM, confirmed the "Lab Specimen Log For Collection 12/27/23 Thru 01 /03/24" (an electronic health report (Meditech) query which contains patients demographics, test orders and test results) "included all orders regardless of status" for patients tested from December 27, 2023, through January 03, 2024. 2. A review of GeneXpert patient data tested from December 28, 2023, to January 02, 2024 revealed ten out of eleven patients failed to be listed on the "Lab Specimen Log For Collection 12/27/23 Thru 01/03/24". 3. A review of i-STAT patient data tested from December 30, 2023, to December 31, 2023, revealed two out of two patients failed to be listed on the "Lab Specimen Log For Collection 12/27/23 Thru 01/03/24". 4. A review of "Specimen Ordering and Collection" revealed laboratory staff failed to ensure an order for the laboratory tests performed on the i-STAT and GeneXpert was provided and to enter all laboratory requests into the computer from December 30, 2023, through January 02, 2024. .
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 record review, laboratory policies, and an interview with technical supervisor (TS) #1, the laboratory failed to perform quality control at the frequency dictated by the policies for i-STAT Troponin I and B-Type Natriuretic Peptide cartridges used to perform patient testing on two out of two patients tested on December 30, 2023, and December 31, 2023. Findings: 1. A review of "i-STAT Troponin I (cTnI)" and "i-STAT BNP (B-Type Natriuretic Peptide)" policies revealed laboratory staff failed to follow their policies to perform and document "Two levels of external liquid controls (Level 1 and 3) to be run monthly" for two out of two patients (MD2642 and MD0326) tested on December 30, 2023, and December 31, 2023. 2. A review of QC records lacked monthly external QC (Level 1 and 3) for i-STAT CTNI and BNP cartridges for the month of December 2023. 3. An interview with TS #1 on January 26, 2024, at 1:05 PM confirmed the laboratory staff failed to perform quality control at the frequency dictated by the policies for i-STAT CTNI and BNP cartridges used to perform patient testing on December 30, 2023, and December 31, 2023. .
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: Based on record review, laboratory policies, i-STAT Individualized Quality Control Plans (IQCP), and an interview with technical supervisor (TS) #1, the laboratory failed to perform and document a low and high quality control (QC) for each day i-STAT CG8+ and CG4+ cartridges were used to perform patient testing on two of two patients tested on December 30, 2023, and December 31, 2023. Findings: 1. A review of "i-Stat CG8+ Cartridge (Blood Gas)" and "i-Stat CG4+ Cartridge" policies revealed laboratory staff failed to perform and document external control levels 1 and 3 "every 24 hours when running patient samples". 2. A review of QC records lacked two levels of external QC for each day i-STAT CG8+ and CG4+ cartridges were used to test two of two patients (MD2642 and MD0326) on December 30, 2023, and December 31, 2023. 3. A review of i-STAT QC records from January 13, 2023, to December 31, 2023, lacked identification of which i-STAT cartridge was used, cartridge lot number, QC lot number, date prepared, expiration date, and the actual test measurements or reaction. 4. An interview with TS #1 on January 26, 2024, at 1:05 PM confirmed the laboratory staff failed to perform quality control at the frequency dictated by the

	policies for the i-STAT CG8+ and CG4+ cartridges used to perform patient testing on December 30, 2023, and December 31, 2023. .
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the i-STAT verification records, and an interview with technical supervisor (TS) #1, the technical supervisor failed to verify the performance of CG8+, the precision of CG4+, and the reference intervals (normal values) for the laboratory's patient population for analytes: Glucose, Sodium, Potassium, Ionized Calcium, Hemoglobin, Hematocrit, pH, PO2, PCO2, TCO2, HCO3, Base Excess, O2 saturation, Lactate, cardiac troponin I and B-type Natriuretic Peptide performed on the i-STAT prior to approval by the laboratory director from September 28, 2023, to January 26, 2024 Findings: 1. A review of the i-STAT CG4+ precision study lacked more than two days of data to assess the repeatability of day-to-day and run-to-run variance prior to starting patient testing. 2. The technical supervisor failed verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population for analytes tested on the i-STAT: Glucose, Sodium, Potassium, Ionized Calcium, Hemoglobin, Hematocrit, pH, PO2, PCO2, TCO2, HCO3, Base Excess, O2 saturation, Lactate, cardiac troponin I and B-type Natriuretic Peptide. 3. The technical supervisor failed to verify the performance specifications of the i-STAT CG8+ cartridge. 4. Interview with TS #1 on January 26, 2024, at 1:30 PM, confirmed the technical supervisor failed to verify the performance specifications for the CG8+ cartridge, lacked multiple days of precisions studies for CG4+ and verify the reference ranges for four of four i-STAT cartridges prior to approval by the laboratory director from September 28, 2023, to January 26, 2024. .
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 record review, the CMS-209 Laboratory Personnel Report (CLIA) form, policies, and interview with technical supervisor (TS) #1, two out of ten testing personnel lacked orientation, training, and competency assessment with the six required procedures and were unqualified to perform moderate-level diagnostic testing on the i-STAT for two out of two patients tested on December 30, 2023, and December 31, 2023. Findings: 1. A review of laboratory training records for TP09 and TP10 lacked an orientation checklist and training records signed off by the "Hi Line Supervisor" per their "Orientation and Training" policy. 2. A review of laboratory

	training records for the i-STAT revealed TP09 and TP10 lacked competency assessments to include the six required procedures per their "Competency Assessment" policy. 3. An interview with TS #1 on January 26, 2024, at 1:00 PM confirmed the lack of orientation, training, and i-STAT competency assessment for two out of ten testing personnel prior to performing patient testing on December 30, 2023, and December 31, 2023.