Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410131	11/14/2023
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
D0000	Based on an unannounced complaint survey conducted on November 14, 2023, deficiencies were cited for Logan Health Conrad, in Conrad, MT.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of chemistry records, patient results reports, product inserts and procedures, the laboratory failed to verify the precision overtime for the VITROS Chemistry Analyzer and the reference intervals (normal values) for analytes high-density lipoprotein and C-reactive protein (Cross refer D5421); failed to establish a procedure for the Ortho VITROS signed by the laboratory director (Cross Refer D5403); failed to establish acceptable QC statistical parameters for each analyte tested on the Ortho VITROS chemistry analyzer prior to patient testing (Cross Refer D5469); and failed to meet the chemistry quality control (QC) acceptability criteria for triglyceride and amylase assays prior to reporting patient test results (Cross Refer D5481).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, procedure review and interview with the testing personnel (TP#1) the laboratory failed to establish a procedure for the Ortho VITROS signed by the laboratory director to include the reference ranges (normal values) appropriate for the laboratory's patient population and the number, type and frequency of quality controls to be used from September 20, 2023, to November 14, 2023. Findings: 1 Observed on November 14, 2023, at 9:15 AM one of one Ortho VITROS chemistry system in use in the laboratory. 2. No procedure manual for the Ortho VITROS chemistry analyzer signed by the laboratory director was available for review. 3. A review of "Hi Line Quality Control Policy" lacked the number, type, and frequency of quality controls and the reference intervals of each analyte performed on the Ortho VITROS chemistry analyzer. 4. Interview with the TP #1 on November 14, 2023, at 11:00 AM confirmed the laboratory did not have chemistry procedures for the Ortho VITROS signed by the laboratory director.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the VITROS System Verification records and an interview with technical supervisor (TS #1), the laboratory failed to verify the precision of the VITROS to assess the day-to-day and, run-to-run variance and the reference intervals (normal values) for analytes high-density lipoprotein (HDL) and C-reactive protein (CRP) are appropriate for the laboratory's patient population prior to approval by the laboratory director on September 28, 2023. Findings: 1. A review of the VITROS System Verification records revealed the laboratory failed to have 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. A review of Verification of Reference Interval records revealed the laboratory failed to provide a passing reference interval for analyte HDL that is appropriate for the laboratory's patient population. 3. No verification record for

	analyte CRP reference intervals was available for review. 4. An interview with TS #1 on November 14, 2023, at 12:45 PM confirmed the lack of information and would submit additional information by email.
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 a review of quality control (QC) records, procedures, product inserts, and interview with technical supervisor (TS #1), the laboratory failed to establish and verify the mean and standard deviation of their quality control materials performed on the Ortho VITROS chemistry analyzer prior to patient testing from September 20, 2023, to November 14, 2023 Findings: 1. A review of VITROS instructions for use for CRP Performance Verifier I and II, Chemistry Performance Verifier I and II, Liquid Performance Verifier I and II revealed the laboratory failed to follow the manufacturer's instructions to "establish its own analyte-specific mean". 2. No verification studies to support the instruments mean and standard deviation for the VITROS CRP Performance Verifier I and II, Chemistry Performance Verifier I and II, Liquid Performance Verifier I and II controls performed on the Ortho VITROS chemistry analyzer prior to starting patient testing were available to review. 3. No studies to establish the mean and standard deviation for Bio-Rad Liquid Unassayed Multiqual Levels 1, and 3 controls performed on the Ortho VITROS chemistry analyzer prior to starting patient testing were available to review. 4. An interview with TS#1 on November 14, 2023, at 12:50 PM confirmed the laboratory failed to have studies to establish the mean and standard deviation for the Unassayed Multiqual Levels 1, and 3 controls and studies to support the mean and standard deviations used for CRP Performance Verifier I and II, Chemistry Performance Verifier I and II, Liquid Performance Verifier I and II controls prior to patient testing.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor (TS #1), the

	laboratory failed to meet the chemistry quality control (QC) acceptability criteria for triglyceride and amylase assays prior to reporting nine of nine patient test results on October 10, 2023. Findings: 1. A review of Mulitqual QC levels 1, and 3 quality control records from October 10, 2023, revealed the laboratory failed to verify that the triglyceride chemistry QC met the acceptability requirements before reporting eight of eight patient test results. 2. A review of performance verifiers I and II quality control records from October 10, 2023, revealed the laboratory failed to verify that the amylase chemistry QC met the acceptability requirements before reporting one of one patient test result. 3. Interview with the TP #1 on November 14, 2023, at 1:15 PM confirmed the laboratory failed to perform an acceptable chemistry QC for triglyceride and amylase prior to reporting patient test results.