

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0410143	<b>(X3) Date Survey Completed</b>  10/05/2022
<b>Name of Provider or Supplier</b>  Logan Health-Cut Bank	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with Testing Supervisor (TS) #1, the laboratory failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Endocrinology (human chorionic gonadotropin (hCG)) for serum specimens from January 1, 2021 to October 5, 2022. Findings: 1. Review of Test Volume Report revealed 48 tests were performed from September 25, 2021 to September 25, 2022 (12 months). 2. Review of 2021 and 2022 American Proficiency Institute (API), testing program records lacked documentation of proficiency testing for serum hCG. 3. Interview on October 5, 2022 at 9:00 AM with the TS#1 confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for serum hCG from January 1, 2021 to October 5, 2022.</p>
<b>D5016</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.1210</p> <p>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.</p>

This CONDITION is not met as evidenced by:  
Based on review of chemistry records, instrument manuals, product inserts, and policies, the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Siemens Dimension EXL 200 analyzer (refer to 5469); failed to perform calibration verification every six months for CG8+ cartridge on the Abbott i-STAT chemistry analyzer (refer to D5535); failed to perform external QC at the frequency required by their i-STAT IQCP and failed to establish a new IQCP for the i-STAT CG8+ cartridge. This is a repeat deficiency (refer to D5537); and failed to establish a written quality assurance (QA) policy to outline an ongoing mechanism to monitor, assess and correct problems in the laboratory. (Refer to 5791)

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on record review, product inserts and interview with the Technical Supervisor (TS) #1, the laboratory failed to ensure reagents were not used past their expiration date for Triage D-Dimer test device and quality control (QC) material used to check CoaguChek XS PT Test strips. Findings: 1. Review of the Triage D-Dimer worksheet revealed the laboratory used expired cartridges to test patients: One patient on 2/19/22 with Kit Lot# T12249 Exp Date 2/15/22, and eight patients tested from 4/25/2022 to 5/31/2022 with Kit Lot# T12489N Exp Date: 4/20/22. 2. Review of Quidel Triage D-Dimer Test Product Insert revealed, the laboratory failed to follow manufacturer's instructions that state, "Do not use the kit beyond the expiration date printed on the outside of the box" 3. Review of "Protime/INR CoagChek XS PT Test" worksheet revealed the laboratory failed to ensure QC material Lot# 53179200 was not used past the expiration date of 2/28/22 when used to perform quality check for Protime/INR Strip Lott# 58078514 on 7/2/22. 4. Interview on October 5, 2022, at 1:30 PM with the TS #1, confirmed the laboratory failed to ensure Triage D-Dimer cartridges used for patient testing and QC reagent used to check CoaguChek XS PT Test strips were not used past their expiration date.

**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, manufacturer's inserts, test volume sheet, and interview with the technical supervisor (TS) #1, the laboratory failed to establish acceptable criteria (statistical parameters/standard deviation) for assayed controls. Seven of seven selected chemistry analytes performed on the Siemens Dimension EXL 200 analyzer failed to have acceptable standard deviation (SD) and ranges for either QC level 1 or level 3 for Bio-Rad Multiquel. Findings: 1. Review of Bio-Rad Multiquel level 1 QC mean and SD in the Siemens Dimension EXL 200 showed the following data: Alcohol (ethanol)-lot #45911 with a mean of 20 mg/dL and a SD of 4.0 Chloride-lot #45911 with a mean of 74.5 mEq/L and SD of 3.25 Sodium -lot #45911 with a mean of 117 mEq/L and a SD of 4.5 Triglycerides lot #45911 with a mean of 90.0 mg/dL and a SD of 9.0 Cholesterol lot #45911 a with mean of 110.0 mg/dL and a SD of 12.0 HDL lot #45911 with a mean of 26.0 mg/dL and a SD of 3.6 2. Review of Bio-Rad Multiquel level 1 QC package inserts showed: Alcohol (ethanol)--lot #45913 with a range of 13.8-25.6 mg/dL and a mean of 19.7 mg /dL Chloride-lot #45911 with a range of 72.7 - 81.3 mEq/L and a mean of 77.0 mEq/L Sodium -Lot #45911 with a range of 109 -127 mEq/L and a mean of 118 mEq/L Triglycerides lot #45911 with a range of 73.5 - 91.6 mg/dL and a mean of 82.6 mg/dL Cholesterol lot #45911 with a range of 94.7 - 115 mg/dL and a mean of 105 mg/dL HDL lot #45911 with a range of 24.6 - 32.4 mg/dL and a mean of 28.5 mg/dL 3. Review of Bio-Rad Multiquel level 3 QC mean and SD in the Siemens Dimension EXL 200 showed the following data: Alcohol (ethanol)-lot #45913 with a mean of 186 mg/dL and a SD of 37.5 Chloride-lot #45913 with a mean of 116.5 mEq/L and SD of 5.75 Potassium-lot #45913 with a mean of 8.04 mEq/L and a SD of 0.38 Sodium -lot #45913 with a mean of 160 mEq/L and a SD of 8.0 Triglycerides lot #45913 with a mean of 212.0 mg/dL and a SD of 42.0 Cholesterol lot #45913 with a mean of 261.0 mg/dL and a SD of 26.0 HDL lot #45913 with a mean of 62.0 mg/dL and a SD of 8.5 4. Review of Bio-Rad Multiquel level 3 QC package inserts showed: Alcohol (ethanol)-lot #45913 with a range of 164 - 216 mg/dL and a mean of 190 mg /dL Chloride-lot #45913 with a range of 118 - 129 mEq/L and a mean of 123 mEq/L Potassium-lot #45913 with a range of 7.53 - 8.24 mEq/L and a mean of 7.88 mEq/L Sodium -lot #45913 with a range of 149 -165 mEq/L and a mean of 157 mEq/L Triglycerides lot #45913 with a range of 198 - 223 mg/dL and a mean of 211 mg/dL Cholesterol lot #45913 with a range of 248 - 285 mg/dL and a mean of 266 mg/dL HDL lot #45913 with a range of 54.0 - 71.5 mg/dL and a mean of 62.8 mg/dL 5. Review of test volume sheet recording the last 12 months of patients' results showed 95 alcohol results, 2418 chloride, potassium, and sodium results, 540 HDL, cholesterol and triglycerides results were reported from 9/25/2021 to 9/25/2022. 4. Interview with TS#1 on October 5, 2022 at 2:10 PM confirmed the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Siemens Dimension EXL 200 analyzer.

**D5535**

**ROUTINE CHEMISTRY**  
CFR(s): 493.1267(a)(d)

For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
 Based on review of blood gas calibration records for the Abbott i-STAT, Individualized Quality Control Plan (IQCP) and interview with Technical Supervisor (TS) #1, the laboratory failed to follow their procedures and perform at least three-point (a minimal, mid-point, and maximum) calibration verification every six months from January 1, 2021 to October 5, 2022. Findings: 1. Review of blood gas "IQCP Written for Abbott I-STAT Cartridge EG 7+" revealed the laboratory failed to perform calibration verification as stated, "Per CLIA recommendations, we will perform a 3 level calibration verification." 2. No calibration verification records were available for review at the time of the survey for i-STAT CG8+ cartridge for analytes: sodium, potassium, ionized calcium, glucose, hematocrit, pH, oxygen partial pressure, and carbon dioxide partial pressure. 3. No specific IQCP or procedure was available for review for the Abbott I-STAT CG8+ Cartridge. 4. Interview with the TS #1 on October 5, 2022, at 3:00 PM, confirmed the laboratory failed to perform at least a three-point calibration verification for the CG8+ cartridge performed on the i-STAT analyzer every six months from January 1, 2021 to October 5, 2022.

**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:  
 This is a repeat deficiency. Based on review of quality control (QC) records, Individualized Quality Control Plan (IQCP) for blood gas and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform external QC at the frequency prescribed by their IQCP and also failed to establish a new IQCP for the CG8+ i-STAT cartridge from May 27, 2021 to October 5, 2022. Findings: 1. Review of blood gas QC records for Abbott i-STAT CG8+ cartridge for quantification of sodium, potassium, ionized Calcium, glucose, hematocrit, pH, oxygen partial pressure, and carbon dioxide partial pressure lacked monthly external QC for January, February, April, May, August, September, and December of 2021 and, May, June, July, August, and September of 2022. 2. Review of "IQCP Written for Abbott I-STAT Cartridge EG 7+" dated May 27, 2021, revealed the laboratory failed to perform external QC as stated, " ...testing external quality control material for each shipment of a new kit lot number and monthly. The external QC will consist of I-Stat Tri Controls level 1 and 3." 3. No IQCP, risk assessment, verification or procedure was available to review at the time of the survey for the moderate complexity i-STAT CG8+ cartridge. 4. Interview with TS#1 on October 5, 2022 at 2:45 PM confirmed the laboratory failed to follow and perform external QC at the required frequency and failed to establish a new IQCP for the CG8+ i-STAT cartridge from May 27, 2021 to October 5, 2022.

**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 review of policies, records of blood bank alarm checks, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform and document quarterly alarm inspection checks for one of one blood bank refrigerator and freezer from January 1, 2021 to October 5, 2022. Findings: 1. Review of policy " Blood Bank Alarm Fridge " revealed the laboratory failed to perform alarm tests as stated, "2. Quarterly, both high and low limits must be checked." 2. Review of "Blood Bank Alarm Quarterly Alarm Check" log revealed the laboratory failed to perform alarms checks for the first, third and fourth quarter of 2021 and the third quarter check for 2022. 3. An interview with TS #1 October 5, 2022, at 1:15 PM. confirmed the laboratory failed to perform alarm checks at the frequency dictated by their policies from January 1, 2021 to October 5, 2022.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of records, policy, and interview with Technical Supervisor (TS) #1, the laboratory failed to establish a written quality assurance (QA) policy to outline an ongoing mechanism to monitor, assess and correct problems in the laboratory from January 1, 2021 to October 5, 2022. Findings: 1. The laboratory lacked a policy for quality assurance to cover the laboratory's preanalytical, analytical and post analytical systems. 2. Review of blood gas "IQCP Written for Abbott I-STAT Cartridge EG 7+" revealed the laboratory failed to perform "Monthly QC review by NRMC manager." and "Documentation of the kit log sheets will be filed for any review as needed." Records of monthly QC checks were not available for review. 3. Review of Triage D-Dimer, Triage BNP, Protime/INR CoaguChek XS PT Test worksheets and Siemens Dimension EXL 200 the quality control (QC) records lacked review for quality assessment. 4. Interview with TS #1 on October 5, 2022, at 5:00PM, confirmed the laboratory failed to have a written QA policy and perform quality assessments from January 1, 2021 to October 5, 2022.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on record review, policies, Individual Quality Control Plan (IQCP), and interview with the technical supervisor (TS) #1, the laboratory director (LD)# 1, failed to prevent a repeat deficiency and failed to establish a quality assessment program for chemistry, hematology, immunohematology, and the general laboratory to be effectively monitored by laboratory staff from January 1, 2021, to October 5, 2022. Findings: 1. The laboratory director failed to establish a quality assessment program to monitor errors in the laboratory (refer to 5791, D5417, D5445, D5469, and D5535). 2. The laboratory director failed to prevent a repeat deficiency to ensure staff perform external QC at the frequency required by their blood gas i-STAT IQCP and failed to establish a new IQCP for the i-STAT CG8+ cartridge (refer to D5537). 3. The laboratory director failed to perform a quality assessment check of the Blood Bank Alarm Quarterly Alarm Check worksheets, temperature logs, Transfusion Service Testing Records, and emergency release documents from January 1, 2021, to October 5, 2022 (refer to D5555). 4. Interview with the TS #1 on October 5, 2022, at 5:00 PM confirmed the laboratory director (LD)#1 failed to establish and maintain quality assessment program to monitor the pre-analytical, analytical and post-analytical processes of the laboratory and prevent a repeat deficiency from January 1, 2021 to October 4, 2022.