Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0879413	10/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Logan Health Primary Care Eureka	304 Osloski Road, Eureka, 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
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 one of seventeen testing personnel (TP #1), the laboratory failed to perform two levels of external quality controls at the frequency and type as dictated by their policies for Troponin and CHEM 8+ cartridges performed on the Abbott i-STAT from January 1, 2022, to October 4, 2023. Findings: 1. A review of patient results reports dated 06/03/2022, 09/02/2022, and 06/12/2023 for CHEM 8+ (sodium, potassium, chloride, ionized calcium, total carbon dioxide, glucose, urea nitrogen (BUN), creatinine, hematocrit and anion gap) and for Troponin dated 06/06/2022, 09 /02/2022 and 06/12/2023 revealed no external QC was performed. 2. A review of QC records revealed the laboratory failed to perform Troponin external QC for six out of 12 months for year 2022; and failed to perform CHEM 8+ external QC for five out of 12 months for the year 2022. 3. A review of Policy No. POC. 144 revealed the laboratory failed to follow its policy to perform "Troponin and beta-hCG cartridges require two different levels of QC (low, mid or high) run monthly" and "Chem 8+ cartridge requires two levels of liquid QC (low, mid and high) run monthly." 4. A review of QC records revealed the laboratory failed to follow their procedures and perform the manufacturer's external liquid QC as dictated by their Policy No. POC.

	144 for materials used, "i-STAT controls storage and type specific to each cartridge type." for the month of June for years 2022 and 2023. 5. An interview with the TP #1 on October 4, 2023, at 11:45 AM confirmed the laboratory failed to perform two levels of external QC for the Abbott i-STAT Troponin and CHEM 8+ cartridges at the frequency and type dictated by their policies from January 1, 2022, to October 4, 2023.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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--When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (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, calibration verification records, policies, and an interview with one of seventeen testing personnel (TP #1), the laboratory failed to use a different calibration verification lot number as external control than the lot number used to calibrate their i-STAT instruments for each month of June for years 2022 and 2023. Findings: 1. A review of QC records revealed the laboratory used calibration material lot# 22059 as external QC for Abbott i-STAT cartridges Troponin and CHEM 8+ (sodium, potassium, chloride, ionized calcium, total carbon dioxide, glucose, urea nitrogen (BUN), creatinine, hematocrit and anion gap) for the month of June for years 2022 and 2023. (Cross Refer D5445) 2. A review of the calibration verification records for the Abbott i-STAT revealed the calibration material's lot #22059 was used to perform the calibration in June of 2022 and June of 2023. 3. Interview with TP#1 on October 4, 2023, at 12:00PM, confirmed the (one of two) technical consultant (TC #2) used the calibration verification lot #22059 as the external quality control for the month of June for years 2022 and 2023.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Based on review of quality control (QC) records, policies, and interview with one of seventeen testing personnel (TP #1), the laboratory failed to perform corrective action for each instance of missed external quality control checks to verify the patients tested and results reported with the Abbott i-STAT Troponin and CHEM 8+ cartridges were not adversely affected from October 4, 2021, to October 4, 2023. Findings: 1. No corrective action documents for Abbott i-STAT Troponin and CHEM 8+ for the missed monthly external quality control checks were available for review. (Cross

	Refer D5445) 2. No evaluation of patients test results to ensure patients were not adversely affected since the last acceptable external quality control were available for review. 3. A review of the "Quality Management Policy, Point of Care" signed by the laboratory director revealed the policy failed to define corrective action for missed external quality controls. 4. Interview with TP #1 on October 4, 2023, at 12:00PM, stated the laboratory does not have access to their quality control or patient testing raw data analyzed on the Abbott i-STAT to perform corrective actions for missed QC from October 4, 2021, to October 4, 2023.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on review of employees' competency files, CMS-209 Laboratory Personnel Report, policies and interview with one of seventeen testing personnel (TP #1), the technical consultant failed to perform a six-month evaluation for three of three new testing personnel (TP) performing moderate-level diagnostic tests on the Abbott i-STAT analyzer from July 1, 2022, to October 4, 2023. Findings: 1. A review of employees' competency evaluations for three new employees (TP #10, TP #13, and TP #14) lacked documentation of six-month competency to include the six regulatory requirements for assessment of competency at the time of the survey. 2. A review of the "Quality Management Policy, Point of Care" signed by the laboratory director revealed the technical consultant failed to follow their procedures as stated, "CLIA regulations are followed concerning competency and training frequency; initial training, 6 month evaluation followed by yearly competency evaluation after." 3. Interview with the TP#1 on October 4, 2023, at 9:15 AM, confirmed (one of two) technical consultant (TC #2) was responsible for competency evaluations and could not locate a six-month evaluation for three of three new testing personnel from July 1, 2022, to October 4, 2023.