Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0879413	10/20/2021
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) records, laboratory policy and interview with Testing Personnel (TP #1), the laboratory failed to review and evaluate the results obtained on proficiency testing performed for years 2020 and 2021. Findings: 1. Review of Quality Management Policy, Point of Care revealed, "7) Review- a) Clinics maintain QC records in a well-organized system that permits regular review by appropriate personnel such Medical Director or Designee." 2. API's Performance Review and Correction Action sheet states, "After reviewing the evaluation reports, complete the information below and retain this form along with enclosed reports for your records." Includes a "Reviewed by" signature line for the Lab Director or designee and date. 3. API's Performance Review and Correction Action sheets lacked documentation of review by the laboratory director for 2020 Immunology/Immunohematology, 2020 Microbiology, 2020 Hematology /Coagulation, 2020 Chemistry - Miscellaneous, 2020 Chemistry Core, 2021 Immunology/Immunohematology, 2021 Microbiology, 2021 Hematology /Coagulation, 2021 Chemistry - Miscellaneous, and 2021 Chemistry Core 4. Interview with TP #1 on October 20, 2021 at 2:00 PM, confirmed the laboratory failed to review and evaluate the results obtained on proficiency testing performed for years 2020 and 2021.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or

	instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel (TP) #1, the laboratory failed to perform instrument comparison for two out of two Abbott iSTAT analyzers performing cardiac troponin with the cTnI cartridge twice a year for 2020 and 2021. Findings: 1. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies between the two Abbott iSTAT analyzers for analyte troponin for 2020 and 2021. 2. Interview with TP #1 on October 20, 2021 at 11:15 AM confirmed the laboratory failed to perform twice a year instrument comparison for two of two Abbott iSTAT analyzers for 2020 and 2021.
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC) #1, the laboratory allowed unqualified testing personnel without an applicable state license to perform moderate complexity testing performed on the Abbott i-STAT from 2/28 /2020 to 10/02/2021. Findings: 1. A review on October 20, 2021 of the CMS-209 form filled out by the laboratory included 1 out of 18 testing personnel (TP) #18 listed as testing personnel. A review of the credentials lacked an applicable state license. 2. A review of 2020 and 2021 competency evaluations included TP#18 assessed as competent on the moderate complexity i-STAT analyzer for the CHEM 8+ cartridge for analytes sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit, total carbon dioxide. 3. Interview with TC #1 on October 20, 2021 at 1:40 PM confirmed TP #18 performed and reported patent results for Abbott i-STAT between 2/28/2020 to 10/20/2021. 4. Interview with TP#1 on October 20, 2021 at 1:41 PM confirmed TP #18 lacked an applicable state license and was unqualified to perform moderate complexity testing.