Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0911301	09/16/2025
Name of Provider or Supplier	**Street Address, City, State**	
Pioneer Medical Center	301 West 7th Ave, Big Timber, 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	An announced CLIA recertification survey was conducted at Pioneer Medical Center on September 16, 2025, by the Montana CLIA Program. The laboratory was surveyed under 42 CFR Part 493 CLIA regulations and was found to be in compliance with condition-level requirements. However, the following standard-level deficiencies were identified during the survey.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on a review of patient test records, the laboratory's electronic records system, and an interview with Testing Personnel (TP) #1, the laboratory failed to retain two years of patient testing data for 53 out of 69 patients across three out of three testing systems between April 12, 2024, and December 8, 2024. Findings: 1. A review of the patient results report (accession number 24-156-2680) for Troponin I testing performed on June 4, 2024, revealed that the laboratory was unable to produce the associated patient testing records (ISTAT chemistry printout or transcribed data) at the time of the survey. 2. A comparison of the "ISTAT TROPONIN" logs with the laboratory's electronic records for the number of patients tested from 4/12/24 to 6/16 /24 revealed 46 out of 56 patient testing events with no raw data records. 3. A review of the patient test report (accession number 24-234-3517) for H. pylori Ab IgG testing performed on August 21, 2024, revealed that the laboratory was unable to produce the associated patient testing records (transcribed data) for the Consult H. pylori test at the time of the survey. 4. A comparison of the "HPYLORI" logs with the laboratory's electronic records for the number of patients tested from 5/30/24 to 10/18/24 revealed

	two out of six patient transcribed records were not found. 5. A review of the patient test report (accession number 24-287-0816) for Pregnancy Urine (Human Chorionic Gonadotropin, HCG) testing performed on October 13, 2024, revealed that the laboratory was unable to produce the associated patient testing record (transcribed data) for the Osom HCG Combo test at the time of the survey. 6. A comparison of the "HCG" logs with the laboratory's electronic records for the number of patients tested for either urine or serum pregnancy testing from 9/10/24 to 12/08/24 revealed five out of seven patient transcribed records were not found. 7. An interview with TP #1 on September 16, 2025, at 2:17 PM confirmed that the laboratory failed to retain two years of patient testing records for Troponin, H. pylori, and Human Chorionic Gonadotropin (HCG) pregnancy testing for 53 out of 69 patients tested between April 12, 2024, and December 8, 2024.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on a review of patient test records, quality control (QC) logs, the laboratory's electronic records system, and an interview with Testing Personnel (TP) #1, the laboratory failed to provide the quality control records for 29 out of 34 days on which Troponin tests were performed on patient samples between April 12, 2024, and June 16, 2024. Findings: 1. A review of the patient results report (accession number 24-156-2680) for Troponin I testing performed on June 4, 2024, and the associated testing records revealed that the laboratory lacked documentation of two levels of quality control (Level 1 and Level 3) performed on the ISTAT analyzer for the day of patient testing. 2. A record comparison of the "ISTAT TROPONIN" logs with the laboratory's electronic records system for the period from April 12, 2024, to June 16, 2024, revealed that the laboratory failed to provide documentation of two levels of QC for 29 out of 34 days on which patient testing was performed. The following dates were affected: April 15, 2024; April 16, 2024; April 18, 2024; April 23, 2024; April 24, 2024; April 25, 2024; April 30, 2024; May 1, 2024; May 3, 2024; May 5, 2024; May 6, 2024; May 8, 2024; May 9, 2024; May 11, 2024; May 13, 2024; May 15, 2024; May 16, 2024; May 21, 2024; May 22, 2024; May 23, 2024; May 24, 2024; May 27, 2024; May 28, 2024; May 30, 2024; May 31, 2024; June 4, 2024; June 8, 2024; June 10, 2024; and June 11, 2024. 3. An interview with TP #1 on September 16, 2025, at 2:10 PM confirmed the absence of Troponin QC records for 29 out of 34 days on which tests were performed on patient samples between April 12, 2024, and June 16, 2024.