Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0911301	01/13/2022
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
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on review of blood bank records, policy and procedure, and interview with Testing Personnel (TP) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and of returned blood or blood products not used for transfusion and failed to perform and document regular alarm inspection checks for 1 of 1 blood bank refrigerator for years 2020 and 2021. Findings: 1. Review of blood bank records lacked documentation of temperatures of blood and blood products upon receipt of new shipments and unused blood or blood products returned to the laboratory for years 2020 and 2021. 2. Review of Policy and Procedure, Storage and Monitoring of Blood lacks temperature requirements for acceptance of blood or returned blood products not used for transfusion. 3. Review of the Policy and Procedure, Blood Bank Refrigerator and Temperature and Alarm System Maintenance showed "D. Quarterly 1. Check audible and remote alarm system for both above and below range limits according to the manufacturer's instructions." 4. Review of the 2020, 2021 documentation for alarm checks revealed the laboratory performed alarm checks on January 2020; May 2020; September 2020; January 2021 and July 2021. 5. Interview with TP #1 on January 12, 2022 at 12:00 PM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and returned blood or blood products not used for transfusion and failed to regularly perform quarterly alarm inspection checks 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 regularly perform instrument comparison for chemistry analyzers VITROS 350 and Abbott iSTAT testing analytes sodium, potassium, chloride, ionized calcium, total CO (2), glucose, blood urea nitrogen (BUN) and creatinine from January 1, 2020 to January 13, 2022 Findings: 1. Interview with TP#1 on January 12, 2022 at 9:50 AM revealed the Abbott iSTAT analyzer was used as a backup system for the VITROS 350. 2. Review of laboratory instrument comparison records for VITROS 350 and Abbott iSTAT revealed the laboratory performed no comparison studies for 2020 and one comparison study out of two for 2021. 3. Interview with TP#1 on January 13, 2022 at 10:00 A.M., confirmed the laboratory failed to regularly perform twice a year instrument comparison between VITROS 350 and Abbott i-STAT testing analytes sodium, potassium, chloride, ionized calcium, total CO (2), glucose, blood urea nitrogen (BUN) and creatinine from January 1, 2020 to January 13, 2022.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with the testing personnel (TP) #1, the laboratory failed to have a mechanism to periodically verify the laboratory information system (LIS) accuracy of its calculated data for LDL Cholesterol and hemoglobin A1C from January 1, 2020 to January 13, 2022. Findings: 1. No documentation was available for review to verify the LIS accuracy of its calculated data for LDL Cholesterol and hemoglobin A1C. 2. Interview with TP#1 on January 13, 2022 at 12:30 P.M., confirmed the laboratory failed to have a mechanism to verify their LIS accuracy of its calculated data for LDL Cholesterol and hemoglobin A1C from January 1, 2020 to January 13, 2022.