

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0911301	(X3) Date Survey Completed 10/26/2023
Name of Provider or Supplier Pioneer Medical Center	Street Address, City, State 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
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on record review, policy and procedure review, and an interview with testing personnel (TP #1), the laboratory failed to provide a continual temperature monitored blood bank refrigerator with a functioning alarm system for storage of blood products from January 23, 2023 to October 26, 2023 (Cross refer D3007); failed to establish proper blood storage temperatures and document visual inspections as required by the laboratory policy and procedures for emergency release of blood units for transfusion (Cross refer D3021); failed to establish a procedure to prevent, identify, investigate and report transfusion reactions (Cross refer D3025); and failed to retain emergency release documents for three of three blood units and crossmatch document for one of one blood unit. (Cross refer D3035).</p>
D3007	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p>

This STANDARD is not met as evidenced by:

Based on observation, a review of policies and procedures and an interview with testing personnel (TP #1) the laboratory failed to provide a continual temperature monitored blood bank refrigerator with a functioning alarm system required by their policies and procedures to maintain blood units for emergency release from January 23, 2023, to October 26, 2023. Findings: 1. Observed on October 26, 2023, at 9:50 AM one blood bank refrigerator located in the laboratory with no alarm system. 2. A review of temperature logs revealed the laboratory lacked alarm checks from October 20, 2022, to October 26, 2023, and lacked temperature wheels for continual monitoring of temperature from January 23, 2023, to August 17, 2023. 3. A review of Storage and Monitoring of Blood revealed the laboratory failed to follow their procedure to keep blood for transfusion as stated, "in the temperature monitored and alarmed Blood Bank refrigerator located in the laboratory". 4. An interview with TP #1 on October 26, 2023, at 10:30 AM confirmed the blood bank refrigerator was not functional from January 23, 2023, to August 17, 2023. and the alarm system had not been connected.

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:

REPEAT DEFICIENCY Based on record review, policy and procedure review, and interview with testing personnel (TP #1), the laboratory failed to have a procedure to maintain blood units for transfusion between 1 to 6 C to prevent the deterioration of the blood product, to have a corrective action for blood units that fall outside the temperature storage requirements, to take the temperature every four hours as required by their policy and procedure for alternative storage of blood units, and to document visual inspection of blood units from January 6, 2023, to October 26, 2023. Findings: 1. A review of the Storage and Monitoring of Blood procedure lacked the required temperature to store blood or blood products continuously at 1 to 6 C and lacked corrective action to take when blood units fall outside the required temperature range. 2. A review of the Storage and Monitoring of Blood procedure revealed the laboratory failed to perform temperature checks every four hours for alternative storage of blood units as stated, "The units will be placed in the blood shipping box provided by the Vitalant... The temperature will be monitored every 4 hours and documented." and "The temperature of the alternative refrigerator will be monitored every 4 hours while the blood is being stored and will be documented." 3. A review of blood bank monitoring temperatures lacked temperature records every four hours from January 6, 2023, to August 17, 2023. 4. No corrective action was taken for blood units when daily storage temperatures and Blood Bank Unit Log temperatures were greater than 6 C for the following dates: 05/26/2023 (6.5 C); 07/05/2023 (6.6 C); 07/18/2023 (6.4 C); 08/01/2023 (6.12 C); 08/10/2023 (6.19 C); 08/14/2023 (9.6 C); 08/15/2023 (6.2 C); and for units W04242311362000 and W0422311503900 on 7/31/23 (7.9 C). 5. A review of the Storage and Monitoring of Blood procedure revealed the laboratory failed to perform and document visual inspections as stated, "Examine blood units

daily (including weekends) for signs of hemolysis or contamination." 6. No records of visual inspections of blood units performed daily and prior to release or when blood units are returned were available from January 2, 2023, to October 26, 2023. 7. An interview with TP #1 on October 26, 2023, at 10:32 AM confirmed the laboratory was using an alternative method to store blood units from January 23, 2023, to August 17, 2023.

D3025

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(d)

Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policy and procedure, and interview with testing personnel (TP #1), the laboratory failed to establish a procedure to prevent, identify, investigate and report transfusion reactions from October 26, 2021, to October 26, 2023. Findings: 1. The laboratory lacked a procedure to prevent, identify, investigate, and report blood transfusion reactions from October 26, 2021, to October 26, 2023. 2. An interview with TP #1 on October 26, 2023, at 10:20 AM confirmed the laboratory lacked a procedure to prevent, identify, investigate, and report blood transfusion reactions from October 26, 2021, to October 26, 2023.

D3035

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)(ii)

In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

This STANDARD is not met as evidenced by:
Based on record review, policy and procedure review, and interview with testing personnel (TP #1), the laboratory failed to retain emergency release documents for three of three blood units transfused on December 5, 2022, and failed to provide crossmatch paperwork for one of one blood unit transfused on January 1, 2023. Findings: 1. A review of Critical Access Hospital Ancillary Services Laboratory procedures revealed the laboratory failed to follow their procedure to retain emergency release documents as required: "Have the physician sign the uncrossmatched blood request form, including (this is a must) justification for transfusing uncrossmatched blood." 2. A review of the emergency release records for blood units released on 12/05/23, at 1802 PM, 1925 PM, and 2124 PM revealed that three out of three units (W042322023770, W042322024486, and W042322020598) lacked emergency release documents. 3. A review of the Blood Bank Unit Log lacked a record of crossmatch for unit W042323001286 released on 01/17/2023 for blood transfusion. 4. An interview with TP #1 on October 26, 2023, at 10:30 AM, confirmed the lack of documents for emergency release records for three blood units released on 12/05/2023 at 1802 PM, 1925 PM and 2124 PM and the lack of crossmatch records for one blood unit transfused on 01/17/2023.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on record review and policy and procedure review, the laboratory director failed to have a quality assessment program for the emergency release of blood units to prevent a repeat deficiency from October 26, 2021, to October 26, 2023. Findings: 1. A review of emergency release documents, Blood Bank Unit Log, Blood Bank Monitoring log, and Blood Bank Transfusion Log lacked review by the laboratory director from October 26, 2021, to October 26, 2023, to ensure temperature checks, and visual checks are being performed (Cross refer D3021) and emergency release documents for completion. (Cross refer 3035). 2. A review of policy and procedures revealed the laboratory director failed to establish a quality assurance program for the emergency release of blood units from October 26, 2021, to October 26, 2023. 3. A review CMS-2567 signed by the laboratory director on 01/26/2022 for D3021 revealed the laboratory director failed perform quarterly reviews as stated, "Laboratory director will review temperature logs on quarterly visits and ensure they are performed per policy."

D6074

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(5)

Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory director (LD #1), the testing personnel (TP#1) (one of four) failed to notify the laboratory director regarding the lack of a continual temperature monitored blood bank refrigerator with a functioning alarm system for storage of blood products used for emergency release January 23, 2023, to October 26, 2023. Findings: 1. No corrective action reports or documents of communication with lab director regarding the failure of the blood bank refrigerator or a plan of action for the alternative storage of blood units were available for review from January 23, 2023, to October 26, 2023. 2. A interview with the laboratory director on November 1, 2023, at 2:20 PM, confirmed TP #1 failed to keep them informed of the lack of a continual temperature monitored blood bank refrigerator with a functioning alarm system for storage of blood products used for emergency release from January 23, 2023, to October 26, 2023.