Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0518422	01/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Prowers Medical Center	401 Kendall Dr, Lamar, CO	

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 a review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to establish a written policy or procedure to ensure the storage conditions of blood products are appropriate to prevent deterioration of the products during a failure of the laboratory's monitored refrigerator since the laboratory's last survey was conducted on 11/10/2020. The laboratory performs approximately 1,023 immunohematology tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a written policy or procedure to document and monitor the temperature of blood products to prevent the deterioration of blood products in case of a failure of their monitored refrigerator since the last survey was conducted on 11/10/2020. 2. An interview with the GS on January 16, 2024, at approximately 1:00 PM, confirmed that the laboratory failed to establish a written policy or procedure to document and monitor the temperature of blood products to prevent the deterioration of blood products in case of a failure of their monitored refrigerator.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual, and an interview with General Supervisor (GS), the laboratory failed to assess the competency of, or establish a written policy or procedure for assessing the competency of personnel in the positions of Clinical Consultant (CC), Technical Supervisor (TS), and General Supervisor (GS) since the laboratory's last survey was conducted on 11/10/2020. The laboratory conducts a total of approximately 169,640 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that the laboratory failed to assess the competency of, or establish a written policy or procedure for assessing the competency for the CC, the TS, or for the GS listed on CMS Form-209 since the last survey was conducted on 11/10/2020. 2. Based on an interview with the GS on January 4, 2024, at approximately 11:30 AM, confirmed that the laboratory failed to assess the competency of or establish a written policy or procedure for assessing the competency of personnel in the positions of CC, TS, and GS.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to have written procedures available to, and followed by laboratory personnel for routine chemistry, endocrinology, and toxicology tests on the Ortho VITROS analyzer, the detection of fetal fibronectin, and issuing and returning blood products since the last survey was performed on 11/10/2020. The laboratory conducts a total of approximately 115,431 chemistry tests, and 1,023 immunohematology tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that the laboratory failed to have a written procedures available to and followed by laboratory personnel for routine chemistry, endocrinology, and toxicology tests on the Ortho VITROS analyzer, the detection of fetal fibronectin, and issuing and returning blood products since the last survey was performed on 11/10/2020. 2. An interview with the general supervisor (GS) on January 16, 2024, at approximately 11:45 AM, confirmed that the laboratory failed to have written procedures available to and followed by laboratory personnel for routine chemistry, endocrinology, and toxicology tests on the Ortho VITROS analyzer, the detection of fetal fibronectin, and issuing and returning blood products since the last survey was performed on 11/10/2020.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on observation, and an interview with the general supervisor (GS), the laboratory failed to follow the temperature storage requirements set by the manufacturer for Taxo A susceptibility discs, Bacitracin susceptibility discs, and Taxo P susceptibility discs. The laboratory performs approximately 3,569 microbiology tests annually. Findings include: 1. Based on an observation on January 16, 2024, at approximately 12:15 PM, revealed 1 box of Taxo A susceptibility discs (Lot #: 3062072 expires: 9/30/24), 2 boxes of Bacitracin susceptibility discs (Lot #s: 3129525, 3010997 expires[respectively]: 5/31/26, 1/31/26) and one box of Taxo P susceptibility discs (Lot #: 1333605 expires: 12/31/25) in a -20 degrees centigrade freezer, above the manufacturers storage requirement of -80 degrees centigrade. The laboratory performs approximately 3,569 microbiology tests annually. 2. Based on an interview with the GS on January 16, 2024, at approximately 12:45 PM, confirmed that the laboratory failed to follow the temperature storage requirements set by the manufacturer for 1 box of Taxo A susceptibility discs (Lot #: 3062072 expires: 9/30 /24), 2 boxes of Bacitracin susceptibility discs (Lot #s: 3129525, 3010997 expires [respectively]: 5/31/26, 1/31/26) and one box of Taxo P susceptibility discs (Lot #: 1333605 expires: 12/31/25) by storing the discs in a -20 degrees centigrade freezer, above the manufacturers storage requirement of -80 degrees centigrade.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on records review, a review of the laboratory's policies and procedures manual, and an interview with the general supervisor (GS), the laboratory failed to demonstrate the ability of thioglycolate broth to support growth by using at least one organism, and failed to have a policy or procedure in place to document physical characteristics of media received from the manufacturer since the last survey was conducted on 11/10/2020. The laboratory performs approximately 3,569 microbiology tests annually. Findings include: 1. Based on a records review, the laboratory failed to document the ability of thioglycolate broth to support growth by using at least one organism since the last survey was conducted on 11/10/2020. The laboratory performs approximately 3,569 microbiology tests annually. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to have a policy or procedure in place to document physical characteristics of media received from the manufacturer since the last survey was conducted on 11/10/2020. The laboratory performs approximately 3,569 microbiology tests annually. 3. Based on an interview with the GS on January 16, 2024, at approximately 12:50 PM, confirmed that the laboratory failed to demonstrate the ability of thioglycolate broth to support growth by using at least one organism, and failed to have a policy or procedure in place to document physical characteristics of media received from the manufacturer since the

	last survey was conducted on 11/10/2020. The laboratory performs approximately 3,569 microbiology tests annually.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual, and an interview with the General Supervisor (GS), the laboratory failed to establish a policy or procedure for determining the criteria for whether returned blood is suitable for reissue, and for the visual inspection of red blood cells during storage and immediately before distribution since the last survey was conducted on 11/10/2020. The laboratory performs approximately 1,023 immunohematology tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure for determining the criteria for whether returned blood is suitable for reissue since the last survey was conducted on 11/10/2020. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure for the visual inspection of red blood cells during storage and immediately before distribution since the last survey was conducted on 11/10/2020. 3. The laboratory performs approximately 1,023 immunohematology tests annually. 4. Based on an interview with the GS on January 16, 2024, at approximately 12:05 PM, confirmed that the laboratory failed to establish a policy or procedure for determining the criteria for whether returned blood is suitable for reissue, and for the visual inspection of red blood cells during storage and immediately before distribution.