Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0518495	02/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Spanish Peaks Regional Health Center	23500 Us Hwy 160, Walsenburg, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, proficiency testing (PT) records review, and an interview with the general supervisor (GS), the laboratory failed to establish a written policy or procedure for, and failed to evaluate PT results that were not evaluated or scored by the PT provider since the laboratory's last survey on 6/21/2019. The laboratory performs approximately 133,927 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed the laboratory failed to establish a written policy or procedure for evaluating PT scores that were not evaluated or scored by the PT provider since the last survey was conducted on 6/21/2019. 2. A review of the laboratory's PT records revealed the laboratory did not evaluate the accuracy of any analyte for which the PT provider did not evaluate or score since the last survey was conducted on 6/21/2019. 3. An interview with the GS on February 13, 2024, at approximately 11:15 AM, confirmed that the laboratory failed to establish a written policy or procedure for, and evaluate any PT scores that the PT provider did not evaluate or score since the laboratory's last survey was conducted on 6/21/25019.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the procedure manual and an interview with the general supervisor (GS), the laboratory failed to include all test procedure requirements for microbiology, diagnostic immunology, chemistry, hematology, and immunohematology assays since the laboratory's last survey on 6/21/2019. Findings Include: 1. A review of the laboratory's procedure manual for microbiology, diagnostic immunology, chemistry, hematology, and immunohematology assays revealed the procedures failed to provide step-by-step instructions for test performance, specimen requirements and retention, calibration and calibration verification requirements, reportable ranges, limitations of the test, quality control requirements, criteria to determine acceptable control results and patient results, corrective actions for when there are problems with the test system, reporting patient results, and down-time procedures when the systems are inoperable. The laboratory performs approximately 133,927 tests annually. 2. An interview with the GS on February 13, 2024 at approximately 11:45 AM, confirmed that the laboratory failed to have complete procedures for the laboratory test systems.
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, and an interview with the general supervisor (GS), the laboratory failed to document acceptable physical characteristics of media received from the manufacturer since December 2023. The laboratory performs approximately 10,003 microbiology tests annually. Findings include: 1. Based on a records review, the laboratory failed to document physical characteristics of media received from the

	manufacturer since December 2023. The laboratory performs approximately 10,003 microbiology tests annually. 2. Based on an interview with the GS on February 13, 2024, at approximately 12:45 PM, confirmed that the laboratory failed to document acceptable physical characteristics of media received from the manufacturer since December 2023.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 a 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, or perform an at least quarterly alarm check for their temperature monitoring system attached to their blood product storage refrigerator since the last survey was conducted on 6/21/2019. The laboratory conducts approximately 448 immunohematology tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, revealed the laboratory failed to establish a policy or procedure for, or perform an at least quarterly alarm check for their temperature monitoring system attached to their blood product storage refrigerator since the last survey was conducted on 6/21/2019. 2. Based on an interview with the GS on February 13, 2024, at approximately 12:15 PM, confirmed that the laboratory had failed to perform at least quarterly alarm checks of the temperature monitoring system attached to their blood product storage refrigerator.