Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0518342	01/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Weisbrod Memorial Hospital	1208 Luther St, Eads, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. 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 #1 (GS #1), and technical supervisor #3 (TS #3) the laboratory director (LD) failed to ensure that all the laboratory's policies and procedures manual for chemistry, hematology, and microbiology had been approved, signed, and dated by the current LD before use since the laboratory's last survey on 5 /18/2021. The laboratory conducts a total of approximately 32,289 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual for chemistry, hematology, and microbiology revealed that the current LD had not approved, signed, or dated all the laboratory's policies and procedures prior to their use in the laboratory. 2. Based on an interview with GS #1 on January 18, 2024, at approximately 10:30 AM, confirmed that the current LD had not reviewed, signed, and dated all the laboratory's policies and procedures manual for chemistry, hematology, and microbiology prior to their use in the laboratory. 3. Based on an interview with TS #3 on January 18, 2024, at approximately 10:30 AM, confirmed that the current LD had not reviewed, signed, and dated all the laboratory's policies and procedures manual for chemistry, hematology, and microbiology prior to their use in the laboratory.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, an interview with general supervisor #1 (GS #1), and technical supervisor #3 (TS #3), the laboratory failed to include the effective dates of approved policies and procedures used by the laboratory for testing since the laboratory's last survey was conducted on 5 /18/21. The laboratory performs approximately 32,289 tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to include the effective dates of approved policies and procedures used by the laboratory for testing since the last survey was conducted on 5/18/21. 2. Based on an interview with GS #1, on January 18, 2024, at approximately 10:30 AM, confirmed that the laboratory failed to include the effective dates of their approved policies and procedures manual used by the laboratory for testing since the last survey was conducted on 5/18/21. 3. Based on an interview with TS #3, on January 18, 2024, at approximately 10:30 AM, confirmed that the laboratory failed to include the effective dates of their approved policies and procedures manual used by the laboratory for testing since the last survey was conducted on 5/18/21.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and an interview with general supervisor #1 (GS#1), the laboratory failed to replace the Potassium Hydroxide (KOH) reagent after it had exceeded the expiration date and approximately 5 KOH preparations had been performed using this reagent. Findings include: 1. An observation of the laboratory's reagents on January 18, 2024, at approximately 12:30 PM, revealed one bottle of KOH reagent, lot number: B05E014M, expired on: 10/31/23. 2. An interview with GS#1 on January 18, 2024, at approximately 12:30 PM, confirmed that the KOH reagent had expired and had been used for KOH preparation for approximately 5 patients.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a records review, and an interview with general supervisor #1 (GS #1), and technical supervisor #3 (TS #3), the laboratory failed to verify manufacturer's

	performance specifications of instrumentation following the movement of the laboratory from one physical location to another on or about 12/18/21. The laboratory conducts a total of approximately 32,289 tests annually. Findings include: 1. Based on a records review, it was revealed that the laboratory failed to verify the performance specifications set by the instrument's manufacturers for their Cepheid Genexpert, Ortho Vitros, Abbott ID NOW, Werfen Hemochron, Alere Triage, and Optimed Blood Gas instruments since the laboratory moved physical locations on or about 12 /18/21. 2. Based on an interview with GS #1, on January 18, 2024, at approximately 11:30 AM, confirmed that the laboratory failed to verify the performance specifications set by the instrument's manufacturers for their Cepheid Genexpert, Ortho Vitros, Abbott ID NOW, Werfen Hemochron, Alere Triage, and Optimed Blood Gas instruments since the laboratory moved physical locations on or about 12 /18/21. 3. Based on an interview with TS #3, on January 18, 2024, at approximately 11:30 AM, confirmed that the laboratory failed to verify the performance specifications set by the instrument's manufacturers for their Cepheid Genexpert, Ortho Vitros, Abbott ID NOW, Werfen Hemochron, Alere Triage, and Optimed Blood Gas instruments since the laboratory moved physical locations on or about 12 /18/21.
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 a records review, a review of the laboratory's policies and procedures manual, and an interview with general supervisor #1 (GS #1), and technical supervisor #3 (TS #3)), the laboratory failed to evaluate, or establish a policy or procedure that evaluates at least semi-annually molecular test results obtained using the Cepheid Genexpert and Biomerieux Biofire instruments since the last survey was performed on 5/18/21. The laboratory conducts approximately 1,084 microbiology tests annually. Findings include: 1. Based on a records review, the laboratory failed to evaluate at least semi-annually SARS CoV-2/Flu A&B/RSV test results obtained using the Cepheid Genexpert and Biomerieux Biofire instruments since the last survey was performed on 5/18/21. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure that evaluates at least semi-annually SARS CoV-2/Flu A&B/RSV test results obtained from the Cepheid Genexpert and Biomerieux Biofire instruments since the last survey was performed on 5/18/21. 3. Based on an interview with GS #1, on January 18, 2024, at approximately 11:00 AM, confirmed that the laboratory failed to evaluate, or establish a policy or procedure that evaluates SARS CoV-2/Flu A&B/RSV results at least semi-annually since the last survey was performed on 5/18/21. 4. Based on an interview with TS #3, on January 18, 2024, at approximately 11:00 AM, confirmed that the laboratory failed to evaluate, or establish a policy or procedure that evaluates SARS CoV-2/Flu A&B/RSV results at least semi-annually since the last survey was performed on 5/18/21.