Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 06D0516905	**(X3) Date Survey Completed** 01/23/2024
Name of Provider or Supplier Yuma District Hospital	**Street Address, City, State** 1000 W 8th Ave, Yuma, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) records review, and an interview with the facility's CEO (not included on CMS-209), the laboratory failed to enroll in an approved PT program for Gram stain testing performed in the specialty of microbiology since the laboratory's last survey was completed on 5/11/21. The laboratory performs approximately 143 microbiology cultures annually. Findings include: 1. Based on a review of the laboratory's PT records revealed the laboratory was not participating in PT testing for Gram staining in the specialty of microbiology since the last survey was conducted on 5/11/21. 2. An interview with the facility's CEO (not included on CMS-209) on January 19, 2024, at approximately 11:15 AM, confirmed that the laboratory failed to enroll in PT for Gram staining in the specialty of microbiology since the last survey was conducted on 5/11/21.
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 the facility's CEO (not included on CMS-209) 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 on 5/11 /21. The laboratory performs approximately 145,330 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 completed on 5/11/21. The laboratory performs approximately 145,330 tests annually. 2. Based on an interview with the GS on January 19, 2024, at approximately 11:45 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.
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 facility's CEO (not included on CMS-209), 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 5/11/21. The laboratory performs approximately 145,330 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 5/11/21. 2. A review of the laboratory's PT records reveled 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 5/11/21. 3. An interview with the facility's CEO (not on CMS-209), on January 19, 2024, at approximately 11:30 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 5 /11/21.
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 review of the laboratory's policies and procedures manual, and an interview with the facility's CEO (not included on CMS-209), the laboratory failed to include in their policies and procedures manual criteria for acceptable slide staining in microbiology and hematology; step-by-step instructions, including calculations when required while performing testing in chemistry, hematology, microbiology, and immunohematology; and control procedures since the laboratory's last survey was completed on 5/11/21. The laboratory conducts a total of approximately 145,330 tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to include in their policy and procedure manual criteria for acceptable stain quality when performing Gram stains in the specialty of microbiology, and manual differentials in the specialty of hematology since the last survey was performed on 5/11/21. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to include step-by-step instructions, including calculations when required, of how to perform testing in the specialties of chemistry, hematology, microbiology, and immunohematology since the last survey was conducted on 5/11/21. 3. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a written policy for, or document quality control requirements for the Gram stain in the specialty of microbiology at least weekly, or for manual differentials in the specialty of hematology with each use since the last survey was conducted on 5/11/21. 4. An interview with the facility's CEO (not included on CMS-209), on January 19, 2024, at approximately 1:30 PM, confirmed that the laboratory failed to include in their policies and procedures manual criteria for acceptable stain quality when performing Gram stains in the specialty of microbiology, and manual differentials in the specialty of hematology; failed to include step-by-step instructions, including calculations when required, of how to perform testing in the specialties of chemistry, hematology, microbiology, and immunohematology; and failed to establish a written policy for, or document quality control requirements for the Gram stain in the specialty of microbiology, or manual differentials in the specialty of hematology.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not

	provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's immunohematology policies and procedures manual, the laboratory's chemistry policies and procedures manual, and an interview with the laboratory's CEO (not on CMS-209), the laboratory failed to include corrective actions to take, reference ranges, panic or alert values, steps to take to enter results into the patient's record or actions to take when the test system is out of service for manufacturer's package inserts being used as procedures in the specialties of immunohematology and chemistry since the laboratory's last survey was completed on 5/11/21. The laboratory performs approximately 95,000 chemistry and approximately 200 immunohematology tests annually. Findings include: 1. Based on a review of the laboratory's immunohematology policies and procedures manual, revealed the laboratory was using the Ortho MTS manufacturer's package insert as their procedure for immunohematology testing but failed to include corrective actions to take, reference ranges, panic or alert values, steps to take to enter results into the patient's record or actions to take when the test system is out of service since the laboratory's last survey was completed on 5/11/21. 2. Based on a review of the laboratory's chemistry policies and procedures manual, revealed the laboratory was using the Siemens Dimension EXL manufacturer's package insert as their procedure for chemistry testing but failed to include corrective actions to take, reference ranges, panic or alert values, steps to take to enter results into the patient's record or actions to take when the test system is out of service since the laboratory's last survey was completed on 5/11/21. 3. The laboratory performs approximately 95,000 chemistry tests, and 200 immunohematology tests annually. 4. Based on an interview with the laboratory's CEO (not included on CMS-209) on January 23, 2024 at approximately 11:00 AM, confirmed the laboratory failed to include corrective actions to take, reference ranges, panic or alert values, steps to take to enter results into the patient's record or actions to take when the test system is out of service for the package inserts being used as procedures in the specialties of chemistry and immunohematology.
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 the facility's CEO (not included on CMS-209), the laboratory director (LD) failed to ensure that the laboratory's policies and procedures manual for quality assurance, chemistry, hematology, immunohematology, and microbiology had been approved, signed, and dated by the current LD before use since the laboratory's last survey on 5/11/21. The laboratory conducts approximately 145,330 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual for quality assurance, chemistry, hematology, immunohematology, and microbiology revealed that the current LD had not approved, signed, or dated the laboratory's policies and procedures prior to their use in the laboratory. 2. Based on an interview with the GS on January 19, 2024, at approximately 2:00 PM, confirmed that the

	current LD had not reviewed, signed, and dated the laboratory's policies and procedures manual for quality assurance, chemistry, hematology, and microbiology prior to their use in the laboratory.
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 an observation, and an interview with testing personnel #7 (TP7), the laboratory failed to follow the manufacturer's instructions for testing coagulation specimens on the Sysmex CA600 since the last recertification survey on 5/11/21. The laboratory performs approximately 400 coagulation tests annually. Findings include: 1. An observation on January 19, 2024, at approximately 1:00 PM, revealed the laboratory failed to input the current lot number of the Innovin reagent (Lot #564628, expiration date: 08/25/2025) into the Sysmex CA600 coagulation analyzer. 2. Based on an interview with TP7 on January 4, 2024, at approximately 1:10 PM, confirmed that that laboratory failed to input the current lot number of Innovin reagent (see above) into the Sysmex CA600 coagulation analyzer.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 facility's CEO (not on CMS-209), the laboratory failed to establish a complete policy for investigating transfusion reactions that occur within the facility since the last survey was conducted on 5/11/21. The laboratory performs approximately 200 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 complete policy or procedure to investigate transfusion reactions that occur within the facility. The policy and procedure does not include reporting potential or confirmed transfusion reactions to the FDA, does not include steps to take to investigate the reaction in completeness, or if they are reviewed by the transfusion services committee since the laboratory's last survey was completed on 5/11/21. 2. An interview with the facility's CEO (not included on CMS-209), on January 23, 2024 at

	approximately 11:15 AM, confirmed that the laboratory's transfusion reaction policy does not include reporting potential or confirmed transfusion reactions to the FDA, does not include steps to take to investigate the reaction in completeness, and are not reviewed by the transfusion services committee.
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 an onsite records review, a review of the laboratory's policies and procedures manual, and an interview with Testing Personnel #7 (TP7), the laboratory failed to compare, or establish a policy or procedure to compare their Abbott iSTAT analyzers, or to their Siemens Dimension EXL chemistry analyzer, and Sysmex CA600 coagulation analyzer at least semiannually since the laboratory's last survey on 5/11/21. The laboratory conducts approximately 95,00 chemistry tests annually, and approximately 4,000 hematology tests annually. Findings include: 1. Based on an onsite records review, the laboratory failed to compare two out of two Abbott i-STAT analyzers at least semiannually since the laboratory's last survey was completed on 5 /11/21. 2. Based on an onsite records review, the laboratory failed to compare two out of two Abbott i-STAT analyzers at least semiannually to the Sysmex Dimension EXL chemistry analyzer for chemistry testing since the laboratory's last survey was completed on 5/11/21. 3. Based on an onsite records review, the laboratory failed to compare two out of two Abbott i-STAT analyzers at least semiannually to the Sysmex CA600 coagulation analyzer for coagulation testing since the laboratory's last survey was completed on 5/11/21. 4. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure to compare two out of two of their Abbott iSTAT analyzers, or to their Siemens Dimension EXL chemistry analyzer, and Sysmex CA600 coagulation analyzer since the laboratory's last survey was completed on 5/11/21. 5. Based on an interview with TP7 on January 19, 2024, at approximately 1:20 PM, confirmed that the laboratory failed to compare and establish a policy or procedure to compare two out of two of their Abbott iSTAT analyzers, or to their Siemens Dimension EXL chemistry analyzer, and Sysmex CA600 coagulation analyzer.