Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0055977	11/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Haxtun Hospital District	235 W Fletcher St, Haxtun, 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
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 interviews with the laboratory director (LD), and testing personnel (TP) #1, 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 Consultant (TC), and General Supervisor (GS) since the laboratory's last survey on 7 /28/2021. The laboratory conducts a total of approximately 36,710 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 two out of two of the clinical consultants (CC), two out of two of the technical supervisors (TS) listed on the CMS-209 Form, or for the general supervisor (GS) whose position was not filled at time of survey. The laboratory conducts a total of approximately 36,710 tests annually. 2. Based on an interview with the LD and TP #1, on November 1, 2023, at approximately 12:30 PM, and 1:00 PM, respectively, 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, TC, and GS.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on an onsite records review, and interview with Testing Personnel (TP) #1, the laboratory director failed to review and evaluate results obtained on American Proficiency Institute (API) proficiency testing (PT) performed in the laboratory. Findings include: 1. Based on an onsite records review, the laboratory director failed to review or evaluate results obtained on API PT performed by the laboratory for the following events: 2023, Chemistry Core, Event 2 2023, Chemistry Miscellaneous, Event 2 2023, Hematology/Coagulation, Event 1 2023, Hematology/Coagulation, Event 2 2023, Microbiology, Event 1 2023, Microbiology, Event 2 2023, Immunology /Immunohematology, Event 1 2023, Immunology/Immunohematology, Event 2 2022, Chemistry Core, Event 3 2022, Hematology/Coagulation, Event 2 2022, Hematology /Coagulation, Event 3 2022, Immunology/Immunohematology, Event 2 2022, Immunology/Immunohematology, Event 3 2. Based on an interview with TP #1, on November 1, 2023 at approximately 1:00 PM, confirmed that the laboratory director did not review or evaluate results obtained on API PT for the following events: 2023, Chemistry Core, Event 2 2023, Chemistry Miscellaneous, Event 2 2023, Hematology /Coagulation, Event 1 2023, Hematology/Coagulation, Event 2 2023, Microbiology, Event 1 2023, Microbiology, Event 2 2023, Immunology/Immunohematology, Event 1 2023, Immunology/Immunohematology, Event 2 2022, Chemistry Core, Event 3 2022, Hematology/Coagulation, Event 2 2022, Hematology/Coagulation, Event 3 2022, Immunology/Immunohematology, Event 2 2022, Immunology /Immunohematology, Event 3
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 interviews with the laboratory director (LD), and testing personnel (TP) #1, the laboratory director failed to ensure that the laboratory's policies and procedures manual for quality assurance, blood bank, chemistry, toxicology, hematology, and microbiology had been approved, signed, and dated by the current LD before use since the laboratory's last survey on 7/28/2021. The laboratory conducts a total of approximately 36,710 tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual for quality assurance, blood bank, chemistry, toxicology, hematology, and microbiology revealed that Clinical Consultant (CC) #2 had approved, signed, and dated the laboratory's policies and procedures prior to their use in the laboratory. 2. Based on an interview with the LD and TP #1, on November 1, 2023, at approximately 12:30 PM, and 1:00 PM, respectively, confirmed that CC #2 approved, signed, and dated the laboratory's policies and procedures manual for quality assurance, blood bank, chemistry, toxicology, hematology, and microbiology, and was not approved, signed, or dated by the LD prior to their use in the laboratory.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an onsite records review of the laboratory's individualized quality control plan (IQCP) risk assessment (RA) for Siemens Dimension EXL 200, Abbott i-STAT, Alere D-Dimer, Siemens DCA Vantage, and MedTOX ER platforms, and an interview with the laboratory director (LD) and testing personnel (TP) #1, revealed that the laboratory director did not reevaluate the RA to account for personnel changes in the laboratory since the laboratory was last surveyed on 7/28/2021. The laboratory performs approximately 36,710 tests annually. Findings include: 1. Based on an onsite records review of the laboratory's IQCP RA, it was revealed that the laboratory director did not perform a reevaluation of the RA for the above-named test systems to account for changes in personnel performing testing. 2. Based on an interview with the LD, and TP #1 on November 1, 2023, at approximately 12:15 PM, confirmed that the RA has not been reevaluated for the above-named test systems to account for changes in laboratory personnel.
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 (TP) #1, the laboratory failed to compare, or establish a policy or procedure to compare their Beckman Coulter DxH 520 Hematology analyzers at least semiannually since the laboratory's last survey on 7/28/2021. The laboratory conducts approximately 8,500 hematology tests annually. Findings include: 1. Based on an onsite records review, the laboratory failed to compare two out of two Beckman Coulter DxH 520 Hematology analyzers at least semiannually. 2. 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 Beckman Coulter DxH 520 Hematology analyzers at least semiannually. 3. Based on an interview with TP #1 on November 1, 2023, at approximately 2:30 PM, confirmed that the laboratory failed to compare and establish a policy or procedure to compare two out of two Beckman Coulter DxH 520 Hematology analyzers at least semiannually.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459

	The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory failed to hire a qualified General Supervisor to provide day-to-day supervision of the laboratory, of testing personnel, and reporting of test results since the last survey of the laboratory was conducted on 7 /28/2021 (Refer to D6142).
D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on an onsite review of CMS Form-209 provided and signed by the Laboratory Director (LD), an interview with testing personnel (TP) #1, and the LD, the laboratory failed to hire a General Supervisor (GS) who provides day-to-day supervision of testing personnel and reporting of test results since the last survey of the laboratory was conducted on 7/28/2021. The laboratory performs approximately 36,710 tests annually. Findings include: 1. Based on an onsite review of CMS Form-209 provided and signed by the LD, the laboratory failed to hire one or more GS who provides day-to-day supervision of testing personnel and reporting of test results. 2. An interview with TP #1 and the LD on November 1, 2023 at approximately 12:00 PM, confirmed that the laboratory failed to hire one or more GS who provides day-to-day supervision of testing personnel and reporting of test results.