Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409839	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sidney Health Center	216 14th Avenue Sw, Sidney, MT	

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 proficiency testing (PT) records from the Wisconsin State Laboratory of Hygiene (WSLH) and the College of American Pathologists (CAP) and an interview with Technical Supervisor (TS) #1, the laboratory failed to review proficiency testing results not evaluated or scored by the vendor from April 12, 2021, to April 12, 2023. Findings: 1. A review of WSLH 2021 PT results revealed the laboratory failed to evaluate the results not scored by the provider for the following: 2021 Cardiac 3 (NB-11 - NB-15); 2021 Special Chemistry 2 (CS-4 - CS-6) and (SF-4 - SF-6) 2. A review of CAP 2022 PT results revealed the laboratory failed to evaluate the results not scored by the provider for the following: 2022 Hemocytometer Fluid Count HFC-A (HFC-01 - HFC-03); 2022 Crystals CRS-B (BFC-03, BFC-04) and 2022 Bacteriology D-C (D15, D-19). 3. No documentation for WSLH 2021 Coag2, HemReg 2 proficiency was available for review. 4. An interview with TS #1 on April 12, 2023, at 3:43 PM confirmed the laboratory failed to have a mechanism to review PT results not evaluated or scored by the vendor from April 12, 2021, to April 12, 2023.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic

	systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: REPEAT CONDITION CITE Based on a review of chemistry, hematology, and immunohematology records and procedures, the laboratory failed to verify new lots of reagents for Activated Partial Thrombin Time (aPTT) normal reference range (Refer to D5421); failed to provide documentation of tHb calibration every three months and perform calibration verification every six months (Refer to D5535); failed to follow their procedure to perform daily visual inspection checks of blood units during storage (Refer to D5553); failed to perform and document alarm inspection checks at the frequency required by their procedure (Refer to D5555); and failed to perform instrument comparison REPEAT DEFICIENCY CITE (Refer to D5775).
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 review of coagulation records, procedures and interview with Technical Supervisor (TS) #2, the laboratory failed to verify the Activated Partial Thrombin Time (aPTT) normal reference range for the new lots of reagents performed on the Sysmex CA-500 series from April 12, 2021 to April 12, 2023. Findings: 1. A review of "HEM.21 Coagulation Studies" revealed the laboratory failed to follow their procedures and verify new lots of reagents for aPTT as stated, "Yearly Procedures (PT, INR, and PTT): Once a year SHC Lab does a roll over to a new lot of reagents & controls." 2. No rollover studies containing a calculated geometric mean, standard deviation and refence range check for aPTT were available for review. 3. A review of the test volume sheet revealed 333 aPTT tests were performed from January 1, 2022 to December 31, 2022. 4. Interview with the TS #2 on April 12, 2023, at 3:43 PM, confirmed the laboratory failed to verify new lots of reagents for aPTT per laboratory procedure from April 12, 2021 to April 12, 2023.
D5535	ROUTINE CHEMISTRY CFR(s): 493.1267(a)(d) For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on a review of blood gas calibration records, Individualized Quality Control Plan (IQCP), and an interview with Technical Supervisor (TS) #2, the laboratory failed to provide documentation of tHb calibration every three months and perform at least a three-point (a minimal, mid-point, and maximum) calibration verification every six months from April 12, 2021 to April 12, 2023. Findings: 1. A review of patient results report #22SD296C0023 resulted on 10/23/2022 revealed results for Blood Gas Arterial for analytes pH, carbon dioxide partial pressure (pCO2), oxygen partial pressure (pO2), hydrogencarbonate ion (HCO3), Base Excess, and hemoglobin oxygen saturation (O2 SAT). 2. A review of the IQCP lacked instructions to perform calibration verification every six months and revealed the laboratory failed to follow their procedures and perform tHb calibration every three months. 3. A review of calibration verification records lacked one of two studies for the years 2021 and 2022 4. No records of tHb calibrations were available for review at the time of the survey. 5. A review of the test volume sheet revealed 267 patient tests performed for analytes pH, pCO2, pO2, HCO3, Base Excess, and O2 SAT from January 1, 2022, to December 31, 2022 6. Interview with the TS #2 on April 12, 2023, at 3:00 PM, confirmed the laboratory failed perform at least a three-point calibration verification on the OPTI CCA-TS Blood Gas Analyzer every six months and couldn't locate the records for tHb calibrations from April 12, 2021 to April 12, 2023.
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 procedures, records, and interview with Technical Supervisor (TS) #1, the laboratory failed to follow their procedure to perform daily visual inspection checks of blood units during storage from January 01, 2022 to December 31, 2022. Findings: 1. A review of blood bank records lacked daily visual inspection of blood units during storage for 25 days out of 365 for 2022. 2. A review of " Blood Bank Duties" procedure revealed the laboratory failed to document and perform visual inspections as stated, "4. Visually check inventory of units daily for quantity and quality." 3. An interview with TS #1 on April 12, 2023, at 2:30 PM, confirmed the laboratory failed to perform daily visual inspection of stored blood units from January 01, 2022 to December 31, 2022.
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 review of procedures, records of blood bank alarm checks, and interview with the Technical Supervisor (TS) #1, the laboratory failed to follow their procedure to perform and document alarm checks every other month for one of one blood bank refrigerator and freezer from April 12, 2021 to April 12, 2023. Findings: 1. A review of Verifying Blood Bank Alarms Performance procedure revealed the laboratory failed to perform alarm tests as stated, "Complete an Alarm Test every other month." 2. A review of the alarm check logs revealed that the laboratory failed to perform alarm checks for the month of September 2021 and the months of September and November 2022. 3. An interview with TS #1 on April 12, 2023, at 2:30 PM. confirmed the laboratory failed to perform alarm checks at the frequency dictated by their procedure from April 12, 2021 to April 12, 2023.
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: REPEAT DEFICIENCY CITE Based on record review of instrument comparison documentation, procedure, and interview with Technical Supervisor (TS) #1, the laboratory failed to perform instrument comparison between the Ortho Vison and Ortho Workstation, the Sysmex XN-2000 Hematology System two analytical modules, and the two Siemens Dimension EXL chemistry instruments for overlapping analytes every six months from January 01, 2022, to April 12, of 2023. Findings: 1. Review of laboratory instrument comparison documentation lacked a second comparison studies for the year 2022 and one for the year 2023 between the Ortho Vison and Ortho Workstation, the Sysmex XN-2000 Hematology System two analytical modules, and the two Siemens Dimension EXL chemistry instruments for overlapping analytes. 2. Review of Lab-Hem-063 revealed the laboratory staff failed to follow their procedure as stated, "Twice per year, perform and evaluate a patient or proficiency sample(s) on each side of the XN-2000 to verify the two sides (instruments) results are performing equivalently." 3. Interview with TS #1 on April 12, 2023, at 4:30 PM, confirmed the laboratory failed to perform instrument comparison to evaluate and define the relationship between test results using different methodologies or instruments every six months from January 01, 2022, to April 12, of 2023
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

	This STANDARD is not met as evidenced by: Based on the review of chemistry, hematology and immunohematology record review, proficiency testing (PT) results, employees' annual competency files, procedures, and an interview with the technical supervisor (TS) #1, the laboratory director failed to employ a sufficient number of personnel to properly supervise the analytic processes of the laboratory from April 12, 2021, to April 12, 2023 Findings: 1. A review of the GEN.13 Competency Program revealed the laboratory director failed to ensure enough staff was available to perform annual competency duties as stated, "The Laboratory Director has delegated the Laboratory General Supervisor or a Technical Supervisor to perform competency". (Cross refer 6120) 2. A review of HEM.21 Coagulation Studies, CHIQCP.4-6: IQCP Opti CCA-TS2, BB.32 Blood Bank Duties, Lab-Hem-063 and BB.30 Verifying Blood Bank Alarms Performance revealed the lack of supervisory oversite to prevent a repeat condition cite and ensure procedures are being performed at the frequency required from April 12, 2021, to April 12, 2023. (Cross refer D5400) 3. A review of 2021 recertification survey's plan of correction response signed by the laboratory director and dated 9/14/2021 revealed the laboratory lacked "director or compliance coordinator or designee" personnel to ensure compliance to perform instrument comparison every six months and prevent a repeat deficiency cite. (Cross refer D5775). 4. An interview with TS #1 on April 13, 2023, at 1:00 PM confirmed the laboratory manager and compliance coordinator left in the year 2022.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of employees' annual competency files for 2021 and 2022, the CMS-209 Laboratory Personnel Report, procedures, and an interview with the technical supervisor (TS) #1, the technical supervisor failed to follow their procedure and perform annual competency assessments for three out of 14 established laboratory testing personnel for 2022 and for the nursing staff performing ROM testing for the year 2021. Findings: 1. No annual competency records were available for review for the nursing staff for the year 2021. 2. A review of 2022 competency records for laboratory staff lacked annual competencies for three out of 14 testing personnel (TS-2, TP-3, and TP-7). 3. A review of the GEN.13 Competency Program revealed the technical supervisors failed to follow their procedures as stated, "Technical staff will be evaluated annually." 4. Interview with the TS #1 on April 12, 2023, at 12:00 PM, confirmed the lack of annual competency assessments for nursing staff in 2021 and three out of 14 laboratory testing personnel in 2022.