Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409839	08/25/2021
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, patient results report with corresponding case slides and interview with the Histotechnician (HT)#1 (not listed on the CMS-209 Laboratory Personnel Report), the laboratory failed to establish and follow written policies and procedures for specimen and quality control (QC) slide labeling. Findings include: 1. No pathology slide labeling policies and procedures were available for review. 2. Review of patient file 19Y00242S report, patient specimen slide and quality control (QC) slide, revealed the following: a. Patient specimen slide label lacked second identifier and date processed b. Patient report indicates specimen ID A; source as Stomach, no source was labeled on the specimen slide. 3. Review of patient file 20Y00598S report, patient specimen slide and quality control (QC) slide revealed the following: a. QC slide "B-H" lacked date processed. b. Report indicates specimen ID B; source as Esophagus which is crossed out and handwritten "stomach" which is inconsistent with the patient slide labeled "B1-1 Gastric Biopsy". c. Addendum report for change of specimen source from Esophagus to Stomach was not available for review 4. Interview with HT#1 on August 24, 2021 at 9:20 AM, stated collection date is not always the same as the processing date 5. Interview with HT#1 on August 24, 2021 at 9:25 AM, confirmed the lack of consistent labeling for specimen slides and quality control slides.

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: Based on review of hematology, pathology and urinalysis procedures, the laboratory failed to record pathology reagent lot number and expiration dates (see D5415), failed to maintain Tissue tek cryostat (see D5435), failed to perform stain quality checks for microscopic urinalysis (see D5473), and failed to perform intstrument comparison of hematology analytes (see D5775).
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review and interview with the Histotechnician (HT)#1 (not listed on the CMS-209 Laboratory Personnel Report), the Pathology section failed to document reagent lot numbers and expiration dates for years 2019 and 2020. Findings: 1. Review of Pathology's Daily/Weekly/Monthly Maintenance Records for 2019 and 2020, lacked entry of reagent lot numbers and expiration dates. 2. Interview on August 24, 2021 at 9:30 AM with the HT #1, confirmed reagent lot numbers and expiration dates were not documented for years 2019 and 2020.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of maintenance documentation, observation of cryostat, and interview with the Histotechnician (HT)#1 (not listed on the CMS-209 Laboratory

	Personnel Report), the laboratory failed to certify the Tissue tek cryostat for years 2019 and 2020. Findings: 1. No Tissue Tek cryostat maintenance documentation was available for review for years 2019 and 2020. 2. Observation of the Tissue tek cryostat available for use showed the certification sticker was performed in 2018. 3. Interview on August 26, 2021 at 9:40 AM with HT #1, confirmed the laboratory failed to have the Tissue tek cryostat certified for years 2019 and 2020.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Technical Supervisor (TS)#1, the laboratory failed to document the intended staining characteristics for each day microscopic urinalysis slides were stained with KOVA Stain for years 2019 and 2020. Findings include: 1. Review of laboratory records revealed the laboratory failed to document KOVA Stain lot number, expiration date and the staining quality of microscopic urinalysis slides for each day of testing for years 2019 and 2020. 2. Interview on August 24, 2021 at 8:45 AM with TS #1, confirmed the laboratory failed to document staining quality for microscopic urinalysis slides stained with KOVA Stain.
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 record review of instrument comparison documentation and interview with Technical Supervisor (TS) #1, the laboratory failed to perform instrument comparison for analyzers, Sysmex XN-2000 Hematology System two analytical modules for overlapping analytes two times a year for 2020. Findings: 1. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for analyzers, Sysmex XN-2000 Hematology System two analytical modules for complete blood counts in year 2020. 2. Interview with TS #1 on August 25, 2021 at 10:10 AM confirmed the laboratory failed to perform twice a year instrument comparison.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are

	established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to ensure the quality assessment programs were established and maintained to identify failures in pathology specimen slide labeling (see D5311), failed to monitor and evalute the overall quality of the analytic systems (see D5400), failed to record pathology reagent lot number and expiration dates (see D5415), failed to maintain verification of cryostat (see D5435), failed to perform stain quality checks for microscopic urinalysis (see D5473), and failed to perform hematology comparison of test results (see D5775) for years 2019 and 2020.