Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409839	12/17/2024
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
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 a record review of testing personnel files, the CMS-209 Laboratory Personnel Report, procedure, and an interview with the general supervisor (GS) #1, the laboratory lacked annual competency for seven out of 28 testing personnel (TP) and failed to perform five of the six required procedures for 19 out of 28 testing personnel (TP) per their competency assessment form from December 16, 2022, to December 17, 2024. Findings: 1. A review of seven testing personnel files listed on the CMS 209 form (TP-4, TP-10, TP-22, TP-24, TP-25, TP-26, and TP-27) lacked annual competency assessments for years 2023 and 2024. 2. A review of testing personnel (TP) annual competency forms and procedures revealed the laboratory failed to perform "direct observations of test performance, monitoring test results recording and reporting, review of worksheets, quality control (QC), proficiency testing (PT) and maintenance records, direct observation of instrument maintenance, and assessment of test performance (PT/blind samples) records" for 19 testing personnel (TP10-TP28) for the AmniSure Rupture of [fetal] Membranes (ROM) for years 2023 and 2024. 3. An interview on December 17, 2024, at 8:45 a.m. with GS #1 confirmed the laboratory failed to complete five of the six required procedures as part of their competency assessment forms for 19 out of 28 testing personnel and lacked annual competency on seven testing personnel from December 16, 2022, to December 17, 2024.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of proficiency testing records from the American Proficiency Institute (API), biannual verification records, the test volume report, and an interview with general supervisor (GS) #1, the laboratory failed to perform two out of two biannual verifications for ammonia and haptoglobin for the year 2024. Findings: 1. A review of the Test Volume Report revealed 84 ammonia and 174 haptoglobin patient tests were performed from November 30, 2023 to November 30, 2024 (12 months). 2. A review of API records and biannual verification records lacked biannual verification of ammonia and haptoglobin in 2024. 3. Interview on December 17, 2024, at 4:23 p.m. with the GS #1 confirmed the laboratory failed to perform biannual verification of ammonia and haptoglobin in 2024.
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: Repeat Deficiency from August 24, 2021 Based on a record review, procedure, and interview with the technical supervisor (TS) #1, the pathology laboratory failed to document reagent lot numbers, expiration dates, and dates in use from January 1, 2023, to December 17, 2024. Findings: 1. A review of the frozen section policy /procedure listed the following reagents: Scott's tap water, bluing reagent solution, eosin Y stain, alcoholic formalin solution, formaldehyde, hematoxylin, glacial acid, alcohol, and xylene. 2. A review of pathology records lacked documentation of reagent tracking of lot numbers, expiration dates, and dates in use. 3. An interview on December 16, 2024, at 8:35 AM with TS #1 confirmed reagent lot numbers, expiration dates, and dates in use were not documented from January 1, 2023, to December 17, 2024.
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 a review of pathology records, procedures, and an interview with the technical supervisor (TS #1), the pathology laboratory failed to check and document

	the intended staining characteristics for each day Hematoxylin and Eosin (H&E) stain was used from December 16, 2022, to December 17, 2024. Findings: 1. A review of pathology records revealed the laboratory failed to check and document the intended staining characteristics for each day H&E stain was used on 2/21/24, 3/7/24, 3/21/24, 4 /15/24, 6/3/24, 6/26/24, 7/10/24, and 8/22/24. 2. The Frozen Section Policy/Procedure lacked the criteria for acceptable H&E staining characteristics and how to document the quality control checks onsite and remotely for each day H&E stain was used. 3. An interview on December 17, 2024, at 8:40 a.m. with TS #1 confirmed that the laboratory failed to check and document the intended staining characteristics for each day H&E stain was used from December 16, 2022, to December 17, 2024.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a record review, the CMS-209 Laboratory Personnel Report (CLIA) form, personnel files, procedures, and an interview with the technical supervisor (TS) #1 and pathology staff #1 (not listed on the CMS-209 form), the laboratory failed to ensure testing personnel were qualified prior to performing high-complexity gross examination on patient specimens. (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2) (ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b) (4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved

by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on a record review, the CMS-209 Laboratory Personnel Report (CLIA) form, personnel files, procedures, and an interview with the technical supervisor (TS) #1 and pathology staff #1 (not listed on the CMS-209 form), the laboratory failed to ensure two out of two pathology staff had the appropriate educational background prior to performing high complexity gross examination from December 16, 2022, to December 17, 2024. Findings: 1. An interview with pathology staff #2 (1 of 2) (not listed on the CMS-209 form) on December 17, 2024, at 8:10 a.m. confirmed grossing notes documented on the patient "Pathology Remote Frozen Section Form" were performed by the two onsite pathology staff members. 2. A review of the "Frozen Section Policy/Procedure" revealed onsite pathology staff were to weigh, measure, orient, ink, and section surgical specimens and document notes of gross examination. 3. No records of an associate degree or higher in a chemical, physical, biological science, or medical laboratory technology prior to performing high complexity testing were available for the two pathology staff (not listed on the CMS-209 form). 4. A review of nine out of nine patients ' Pathology Remote Frozen Section forms revealed gross examination was performed on 2/21/24, 3/7/24, 3/21/24, 4/15/24, 6/3/24, 6/26/24, 7/10/24, and 8/22/24 by unqualified testing personnel. 4. An interview with technical supervisor #1 on December 17, 2024, at 8:50 a.m. confirmed that the two onsite pathology staff were not qualified to perform high-complexity testing but were overseen remotely during the gross examination by the remote pathologist from December 16, 2022, to December 17, 2024.