Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0409361	08/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Stillwater Billings Clinic	710 N 11th Street, Columbus, 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
D0000	An announced CLIA recertification survey was conducted at Stillwater Billings Clinic on August 20, 2025, by the Montana CLIA Program. The laboratory was evaluated for compliance with the CLIA requirements under 42 CFR Part 493. Specific deficiencies were identified during the survey.
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 (PT) records from the American Proficiency Institute (API) and an interview with the technical supervisor (TS) #1, the laboratory failed to perform one of the two required biannual verifications in 2023 and did not perform any biannual verifications from January 1, 2024, through August 20, 2025, for urine protein confirmation using Exton's reagent test. Findings: 1. A review of API PT records for urine protein confirmation using Exton's reagent test revealed that the laboratory failed to perform one of the two required biannual verifications in 2023 and did not perform any biannual verifications from January 1, 2024, through August 20, 2025. 2. An interview conducted on August 20, 2025, at 10:30 AM with TS #1 confirmed that the laboratory failed to perform one of the two required biannual verifications in 2023 and did not perform any biannual verifications from January 1, 2024, through August 20, 2025, for urine protein confirmation using Exton's reagent test.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by

	the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, laboratory policies and procedures, and an interview with Technical Supervisor (TS) #1, the laboratory failed to establish a policy and procedure for the review of historical blood bank patient data to determine previously identified antibodies and other serological anomalies, and a policy and procedure for the verification of performance specifications for new analytes, methods, or instruments from August 20, 2023, to August 20, 2025. Findings: 1. The laboratory lacked a policy and procedure for the review of historical blood bank patient data to determine previously identified antibodies and other serological anomalies. 2. The laboratory lacked a policy and procedure for the verification of performance specifications for new analytes, methods, or instruments. 3. An interview with TS #1 on August 20, 2025, at 1:00 PM confirmed that the laboratory did not have a policy and procedure for the review of historical blood bank patient data to determine previously identified antibodies and other serological anomalies or for the verification of performance specifications for new analytes, methods, or instruments from August 20, 2023, to August 20, 2025.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 a review of records, laboratory policies and procedures, and an interview with Technical Supervisor (TS) #1, the laboratory failed to establish a policy and procedure for calibration verification of sodium (Na), potassium (K), chloride (Cl), and triglycerides performed on the chemistry analyzer; a step-by-step procedure for calculating estimated glomerular filtration rate (eGFR), low-density lipoprotein (LDL), and mean glucose; and a step-by-step procedure for performing blood bank quality control from August 20, 2023, to August 20, 2025. Findings: 1. The laboratory

	lacked a calibration verification procedure for the analytes Na, K, Cl, and triglycerides performed on the Siemens Dimension EXL 200 chemistry analyzer that defines the number, type, and concentration of materials used, the method of evaluation, and the criteria for acceptable limits based on the instrument's verified performance specifications. (Cross-reference: D5439) 2. The laboratory lacked a step-by-step procedure to perform eGFR, LDL, and mean glucose calculations, including the equations used, interpretation of results, and annual verification of calculated values. 3. The laboratory lacked a step-by-step procedure to perform blood bank quality control, including the type, identity, number, and frequency of controls; criteria for acceptability; and corrective actions to take when quality control results fail. 4. An interview with TS #1 on August 20, 2025, at 3:30 PM confirmed that the laboratory failed to establish a policy and procedure for calibration verification for the analytes Na, K, Cl, and triglycerides performed on the Siemens Dimension EXL 200 chemistry analyzer; a step-by-step procedure to perform eGFR, LDL, and mean glucose calculations; and a step-by-step procedure to perform blood bank quality control from August 20, 2023, to August 20, 2025.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the chemistry analyzer calibration records, laboratory policies and procedures, and an interview with Technical Supervisor (TS) #1, the laboratory failed to perform at least a three-point calibration to cover the analytical measurement range for triglycerides every six months, and failed to evaluate the linearity of the calibration verification data for sodium (Na), potassium (K), chloride (Cl) from August 20, 2023, to August 20, 2025. Findings: 1. The laboratory failed to perform at least a three-point calibration to cover the analytical measurement range (AMR) for triglycerides performed on the Siemens Dimension EXL 200 chemistry analyzer every six months from August 20, 2023, to August 20, 2025. 2. The laboratory failed to evaluate the linearity of the calibration verification data for Na, K, and Cl from August 20, 2023, to August 20, 2025. 3. An interview with Technical Supervisor (TS) #1 on August 20, 2025, at 11:15 AM, confirmed that the laboratory failed to perform

	at least a three-point calibration verification to cover the AMR for triglycerides every six months, and failed to evaluate the linearity of the calibration verification data for Na, K, and Cl from August 20, 2023, to August 20, 2025.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on record review, laboratory policies and procedures, and an interview with Technical Supervisor (TS) #1, the laboratory failed to establish a quality assessment program (QAP) policy and procedure for the analytic system that defines an ongoing mechanism to monitor, assess, and, when indicated, correct problems from August 20, 2023, to August 20, 2025. Findings: 1. The laboratory failed to provide a written QAP policy and procedure that defines an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the analytic systems from August 20, 2023, to August 20, 2025. 2. An interview with TS #1 on August 20, 2025, at 4:00 PM confirmed that the laboratory failed to establish a quality assessment program policy and procedure from August 20, 2023, to August 20, 2025.