Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0042135	(X3) Date Survey Completed 08/21/2025
Name of Provider or Supplier Msu Student Health Services	**Street Address, City, State** 950 W Grant Street, Montana State Univ Bozema, 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 MSU Student Health Partners on August 21, 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.
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, laboratory policy and procedure, and an interview with Technical Supervisor (TS) #1, the laboratory failed to assess the competency of the technical supervisor and general supervisor listed on the CMS-209 Laboratory Personnel Report based on their position responsibilities, and failed to follow its procedure for conducting annual competency assessments for one of four testing personnel (TP) from August 21, 2023, to August 21, 2025. Findings: 1. A review of the CMS-209 Form revealed that one individual was listed as both the technical supervisor and the general supervisor. No competency assessments based on the responsibilities of these positions were available for review from August 21, 2023, to August 21, 2025. 2. A review of the "QA Program: Laboratory" policy and procedure revealed that the laboratory failed to follow its procedure for conducting an annual competency assessment for TP #4 using the six required elements for years 2024 and 2025. 3. An interview with TS #1 on August 21, 2025, at 9:20 AM confirmed that the laboratory failed to assess the competency of the technical supervisor and general

	supervisor based on their respective position responsibilities, and failed to follow its procedure for conducting annual competency assessments for one of four testing personnel from August 21, 2023, to August 21, 2025.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) proficiency testing records and an interview with technical supervisor (TS) #1, the laboratory failed to verify the accuracy of "Not Graded" scores for eleven of eleven proficiency testing (PT) events from August 21, 2023, to August 21, 2025. Findings: 1. A review of proficiency testing records lacked documentation that the laboratory verified the accuracy of the "Not Graded" scores for the following PT events: API 2023 Hematology/Coagulation 3rd Event - Vaginal Wet Preparation (KOH) and Educational Blood Cell Identification API 2024 Chemistry Core 1st Event - Bilirubin, Total API 2024 Microbiology 1st Event - Gram Stain Morphology and Urine Culture Susceptibility Interpretation API 2024 Microbiology 2nd Event - Gram Stain and Urine Culture Susceptibility Interpretation API 2024 Microbiology 3rd Event - Gram Stain API 2024 Hematology/Coagulation 1st Event - Educational Blood Cell Identification API 2024 Hematology/Coagulation 2nd Event - Vaginal Wet Preparation (KOH) and Educational Blood Cell Identification API 2024 Hematology/Coagulation 3rd Event - Educational Blood Cell Identification API 2025 Hematology/Coagulation 1st Event - Educational Blood Cell Identification API 2025 Chemistry Core 2nd Event - Bilirubin, Total API 2025 Microbiology 2nd Event - Gram Stain Morphology 2. An interview with TS #1 on August 21, 2025, at 10:10 AM confirmed the laboratory failed to verify the accuracy of "Not Graded" scores for eleven PT events listed above from August 21, 2023, to August 21, 2025.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 a review of patient test reports, verification records, and an interview with Technical Supervisor (TS) #1, the laboratory failed to verify that complete blood count (CBC) with automated 6-part differential reference ranges (normal values) used for reporting patient test results were appropriate for the laboratory's patient population from August 21, 2023, through August 21, 2025. Findings: 1. A review of CBC with automated 6-part differential patient results reports for Sample IDs 189401

	and 198093 listed reference intervals (normal values) for the following analytes: White Blood Cell count (WBC), Red Blood Cell count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Platelet count (PLT), Red Cell Distribution Width (RDW), Mean Platelet Volume (MPV), Absolute Neutrophil Count (NEUT#) and Neutrophil Percentage (NEUT%), Absolute Immature Granulocyte Count (IG#), Absolute Lymphocyte Count (LYMPH#) and Lymphocyte Percentage (LYMPH%), Absolute Monocyte Count (MONO#) and Monocyte Percentage (MONO%), Absolute Eosinophil Count (EO#) and Eosinophil Percentage (EO%), and Absolute Basophil Count (BASO#) and Basophil Percentage (BASO%). The CBC patient results reports failed to include a reference range for Immature Granulocyte Percentage (IG%), a reportable analyte on the Sysmex XN-430. 2. The laboratory failed to provide documentation verifying that the reference intervals (normal values) listed in patients' CBC result reports were appropriate for its patient population for analytes performed on the Sysmex XN-430 hematology analyzer. 3. An interview with the TS #1 on August 21, 2025, at 2:20 PM, stated they were unaware of the origin of the reference ranges listed in the patients CBC results reports and confirmed the laboratory failed to verify the CBC reference ranges (normal values) were appropriate for its patient population from August 21, 2023, to August 21, 2025.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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 observation, review of maintenance records, policy and procedures, and an interview with technical supervisor (TS) #1, the laboratory failed to define and perform a function check protocol to verify the accuracy of two centrifuges and one microscope used in patient testing from August 21, 2023, to August 21, 2025. Findings: 1. On August 21, 2025, at 11:45 AM, two centrifuges and one microscope were observed in the laboratory. Maintenance records lacked documentation of the tachometer readings and timer checks for the centrifuges to verify accuracy, and there was no documentation describing what function check was performed for the microscope. 2. A review of the Test Volume Report showed that 480 microscopic urinalyses were performed in the past 12 months using the centrifuge and microscope as part of the testing process. 3. A review of the laboratory's policy and procedure revealed that no function check protocol had been established for the two centrifuges and the microscope. 4. An interview with TS #1 on August 21, 2025, at 12:15 PM confirmed the laboratory failed to define and perform a function check protocol to verify the accuracy of two centrifuges and one microscope from August 21, 2023, to August 21, 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 calibration records, laboratory policy and procedure, and an interview with Technical Supervisor (TS) #1, the laboratory failed to follow its procedure to perform one of two calibration verifications every six months for sodium, potassium, and chloride testing performed on the Siemens Dimension EXL 200 chemistry analyzer during the calendar year 2024. Findings: 1. A review of calibration records for sodium, potassium, and chloride testing performed on the Siemens Dimension EXL 200 chemistry analyzer lacked one of two calibration verifications studies for calendar year 2024. 2. A review of the "QA Program: Laboratory" policy and procedure revealed the laboratory failed to follow their procedure to perform calibration verifications every 6 months. 3. An interview with TS #1 on August 20, 2025, at 2:44 PM confirmed the laboratory failed to follow their procedure to perform one of two calibration verifications every six months for sodium, potassium, and chloride testing performed on the Siemens Dimension EXL 200 chemistry analyzer during the calendar year 2024.