Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D1088815	06/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Providence Med Group - Grant Creek Family Practice	3075 North Reserve, Suite Q, Missoula, 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
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 the patient test results report, procedures, and an interview with the technical consultant (TC) #1, the laboratory failed to include in their procedure manual the step-by-step performance of the procedure for manual differentials including calculated results and the course of action to take if the test system becomes inoperable from June 30, 2023, to June 30, 2025. Findings: 1. A review of patient (234230024GG) complete blood count with differential and manual differential

	results report listed absolute values for Segmented Neutrophils, Band form neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, and Metamyelocytes. 2. The procedures failed to include a step-by-step performance of the manual differential procedure including the equations used in the laboratory information system (LIS) to calculate the absolute values listed in the patient results report and what to do if the system becomes inoperable. 3. An interview with TC #1 on June 30, 2025, at 12:40 PM confirmed the manual differential absolute values were calculated by their laboratory information system and staff would not be able to manually calculate these values if the laboratory information system was inoperable. 4. An interview with TC #1 on June 30, 2025, at 12:36 PM confirmed the laboratory failed to include in their procedure manual the step-by-step performance of the procedure for manual differentials including calculated results and the course of action to take if the test system becomes inoperable from June 30, 2023, to June 30, 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, procedure manual, and an interview with technical consultant (TC) #1, the laboratory failed to define and perform a function check protocol to verify the accuracy of two centrifuges from June 30, 2023, to June 30, 2025. Findings: 1. Observed on June 30, 2025, at 12:01 PM two Hettich EBA 21 centrifuges in the laboratory. A review of the maintenance records revealed no record of the tachometer readings or timer checks to verify the accuracy of the two centrifuges. 2. A review of the Test Volume Report revealed 930 microscopic urinalyses were performed using the centrifuge as part of the procedure from June 30, 2023, to June 30, 2025. (12 months). 3. A review of laboratory procedures revealed the laboratory failed to establish a procedure that defines the function checks on each piece of equipment or instrument it uses, including those that are peripherally involved in patient testing. 4. An interview with TC #1 on June 30, 2025, at 12:15 PM confirmed the laboratory failed to define and perform a function check protocol to verify the accuracy of two centrifuges from June 30, 2023, to June 30, 2025.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with technical consultant (TC) #1, the laboratory failed to establish a written policy and procedure for its quality assurance

	program including a mechanism to verify the accuracy of its calculated data from June 30, 2023, to June 30, 2025. Findings: 1. No verification studies of the laboratory information system's calculated test results were available for review. Cross Reference (D5403) 2. No policy or procedure for a quality assurance program to address a mechanism to monitor, assess and, when indicated, correct problems identified was available for review. 3. An interview with TC #1 on June 30, 2025, at 12:36 PM confirmed the lack of policy and procedure for its quality assurance program including a mechanism to verify the accuracy of its calculated data from June 30, 2023, to June 30, 2025.