Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0879806	04/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Group	595 Main Street, Meadville, MS	

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) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 review of the laboratory procedure manual and the XN-330 hematology analyzer Troubleshooting Manual, the laboratory failed to establish a written procedure for the performance of complete blood count (CBC) testing and interpretation of results when patient results are flagged with an asterisk (*) by the Sysmex XN-330 hematology analyzer. Findings include: Review of the XN-330 hematology analyzer Troubleshooting Manual revealed the IP (Interpretive Program) Messages section states, "With respect to the following IP messages, when a sample judgment is Positive (abnormal sample), the analysis results are regarded as having

	low reliability due to the abnormality and "*" is displayed to the right of the data." Review of the laboratory procedure manual revealed no written procedure for the performance of CBC testing and interpretation of results when patient results are flagged with an asterisk (*).
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on an interview on 4/19/22 at 3:00 p.m. with Testing Personnel #1 listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and review of the Sysmex XN-330 Automated Hematology Analyzer Basic Operation Manual and Troubleshooting Manual, the procedures for performing complete blood count (CBC) testing on the Sysmex XN-330 hematology analyzer were not approved and signed by the laboratory director. Findings include: In an interview on 4/19/22 at 3:00 p.m., Testing Personnel #1 stated the Sysmex XN-330 Automated Hematology Analyzer Basic Operation Manual and Troubleshooting Manual were used as the procedures for performing CBC testing. Review of these manuals revealed no documentation that they were approved and signed by the laboratory director. The laboratory began patient CBC testing with the Sysmex XN-330 hematology analyzer on 9/22/20.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for Sysmex XN-L Check hematology controls, observation of opened vials of controls - Lot #20701401 (Low), #20701402 (Normal), #20701403 (High) - stored in the laboratory refrigerator on 4/19/22 at 2:45 p.m., and interview with Testing Personnel #1 listed on the CMS 209 personnel form on 4/19/22 at 2:45 p.m., the laboratory failed to follow manufacturer's instructions for open-vial stability for Sysmex XN-L Check hematology controls from 4/4/22 through 4/19/22. Findings include: Manufacturer's instructions for Sysmex XN-L Check hematology controls state, "Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2 - 8 degrees Celsius after being re-capped." Observation of opened vials of controls - Lot #20701401 (Low), #20701402 (Normal), #20701403 (High) - stored in the laboratory refrigerator on 4/19/22 at 2:45 p.m. revealed no open date visible on the vials. Interview with Testing Personnel #1 on 4/19/22 at 2:45 p.m. revealed these vials of control were opened on 3/18/22, according to documentation on quality control (QC) records. The vials of control were used for twelve testing days, from 4/4/22 through 4/19/22, past the open-vial stability date of 4/2/22.

D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the verification of performance specifications for the Sysmex XN-330 hematology analyzer performed at installation in August 2020 and lack of documentation of review of these records, the technical consultant failed to ensure that the verification procedures used were adequate to determine the accuracy, precision, and reportable range of the Sysmex XN-330 hematology analyzer, which was put in use for patient complete blood count (CBC) testing on 9-22-20. Findings include: Review of the verification of performance specifications for the Sysmex XN-330 hematology analyzer revealed a reportable range study, carryover study, precision, and method comparison with the Horiba ABX Micros 60 hematology analyzer were performed in August 2020. However, there was no documentation of review of these records by the technical consultant to ensure these verification procedures were adequate to determine the accuracy, precision, and reportable range of the Sysmex XN-330 hematology analyzer before the system was put in use for patient CBC testing on 9-22-20.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form, personnel records since the last survey on 9/1/20, and confirmation by Testing Personnel #1, the technical consultant failed to evaluate the competency of Testing Personnel #2, #3, and #4 to ensure their competency to perform test procedures and report test results promptly, accurately and proficiently. Findings include: Review of personnel records since the last survey on 9 /1/20 revealed Testing Personnel #2 had an initial evaluation on 12/11/20; Testing Personnel #3 had an initial evaluation on 10/18/21; and Testing Personnel #4 had an initial evaluation on 4/14/22. These initial evaluations were performed by an individual other than a qualified technical consultant. Testing Personnel #1 confirmed Testing Personnel #2, #3, and #4 performed moderate-complexity complete blood count (CBC) testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form, personnel records since the last survey on 9/1/20, and confirmation by Testing Personnel #1, the technical consultant failed to evaluate and document the performance of Testing Personnel #2 and #3, responsible for moderate complexity testing, at least semiannually during the first year these individuals tested patient specimens. Findings include: Review of personnel records since the last survey on 9/1/20 revealed Testing Personnel #2 began testing patient specimens in December 2020 and had a semiannual evaluation on 6/11/21; Testing Personnel #3 began testing patient specimens in October 2021 and had a semiannual evaluation on 4/7/22. These semiannual evaluations were performed by an individual other than a qualified technical consultant. Testing Personnel #1 confirmed Testing Personnel #2 and #3 performed moderate-complexity complete blood count (CBC) testing.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form, personnel records since the last survey on 9/1/20, and confirmation by Testing Personnel #1, the technical consultant failed to evaluate and document the performance of Testing Personnel #2, responsible for moderate complexity testing, at least annually, after the first year. Findings include: Review of personnel records since the last survey on 9/1/20 revealed Testing Personnel #2 began testing patient specimens in December 2020, and an annual evaluation of Testing Personnel #2 was performed on 12/16/21 by an individual other than a qualified technical consultant. Testing Personnel #1 confirmed Testing Personnel #2 performed moderate-complexity complete blood count (CBC) testing.