Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0702573	11/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Associates	42320 Hwy 195, Haleyville, AL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Laboratory Director (LD), the laboratory failed to ensure the LD signed the attestation statements for four of twelve events from 2023 through 2024. The findings include: 1. A review of the API PT records revealed no signature by the Laboratory Director (or designee) on attestation statements for the following surveys: a) 2023 Hematology 2nd Event, b) 2023 Hematology 3rd Event, c) 2023 Chemistry 3rd Event. d) 2024 Chemistry 3rd Event. 2. During the exit interview on 11/5/2024, at 4:20 PM, the LD confirmed the above findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: 51319 Based on the review of the American Proficiency Institute Proficiency Testing

	(PT) records, the laboratory failed to provide signed PT attestations forms, failed to ensure the preservation of CBC sample integrity, failed to ensure submission of PT results before the due dates, and failed to review and document corrective actions for all unsuccessful PT events. Refer to D2009, D5203, D5215, D5221.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of the Sysmex XP 300 Hematology Quality Control (QC) logs, a review of the Complete Blood Count (CBC) patient testing logs, a review of the Quality Assurance (QA) checklist, and an interview with the Laboratory Director (LD), the laboratory failed to ensure the preservation of CBC sample integrity when samples were tested outside parameter stabilities. This was noted for CBC samples that were collected 2 days out of 31 days in October 2023 and not tested until five to six days later; 22 patients were affected. Findings include: 1. A review of the 2023 Hematology QC records and a review of the CBC patient testing records revealed the laboratory collected CBC samples from 22 patients on October 5, 2023 and October 6. 2023, however, these samples were not tested until October 10, 2023. The laboratory's Monthly QA Checklist indicated; a. Positive identification and optimum integrity of specimens were maintained under General Laboratory System. b. Patient specimens were collected and handled according to our protocol and were acceptable for testing under Pre-Analytical System. 2. A further review of Becton Dickinson Vacutainer EDTA tubes for the CBC sample acceptability revealed manufacturer demonstrated CBC tube-testing-stabilities to be within 48 hours when collected samples are stored at room temperature for 24 hours plus at 2-8 degrees Celsius for 24 hours. 3. LD confirmed these findings during the exit conference on 11-05-2024 at 4:20 PM.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, corrective action document, and an interview with the Laboratory Director (LD), the laboratory failed to ensure PT results were submitted before the postmark due date. This was noted for one of five events reviewed in 2023. The findings include: 1. A review of the API PT records revealed a score of 0% and "Failure to participate" on 2024 Complete Blood Count (CBC) Hematology Event 1 with a deadline date of 3/27/2024. 2. A further review of the corrective action document revealed, "Laboratory did not submit results, self-evaluation performed and

	all within range." 3. During the exit interview on 11/5/2024, at 4:20 PM, the LD confirmed the above findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Laboratory Director (LD), the laboratory failed to document review of returned PT results for four of eight events reviewed in 2022 through 2023. The findings include: 1. A review of the API PT records revealed no documentation of a review from the Laboratory Director, or designee, for the following surveys: a) 2022 Chemistry 3rd Event. b) 2023 Hematology 3rd Event. c) 2023 Chemistry 1st Event. d) 2023 Chemistry 3rd Event. 2. During the exit interview on 11/5/2024, at 4:20 PM, the LD confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: 51319 Based on the reviews of the Immunoassay and Hematology patient testing logs, the Room Temperature and Humidity logs, the Quality Control logs, the Analyzer maintenance logs, and the the laboratory policies and procedure manual, the laboratory failed to monitor and assess the overall quality of its pre-analytical and analytical systems and be able to provide appropriate corrective actions when problems are identified. Refer to D5413, D5417, D5447, D5429.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the Room Temperature (RT) and Humidity record, Sysmex XP-300 analyzer manual, and an interview with Laboratory Director (LD), the laboratory

	failed to monitor and document the RT and Humidity each day of patient testing per manufacturer's specifications. The surveyor noted the missing RT and Humidity documentation occurred three months out of twelve in 2022. The findings include: 1) A review of the RT and Humidity records revealed the staff did not monitor and document the RT and Humidity of the laboratory from October through December 2022 when patient testing was performed. 2) A further review of the Sysmex XP-300 analyzer technical specifications revealed the manufacturer's established RT and Humidity limits. 3) During an interview with the LD on 11-05-2024 at 4:20 PM, the surveyor asked if the staff monitored the RT and Humidity. LD confirmed it was not monitored and this was manifested in the lack of documentation.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the Tosoh AIA-900 Immunoassay Quality Control (QC) records and an interview with the Laboratory Director (LD), the laboratory utilized expired QC materials prior to patient testing. The surveyor noted the expired QC was utilized for 8 out of 31 days in October 2024, 6 patients were affected. The findings include: 1. A review of the Tosoh AIA-900 QC logs revealed QC Lots 24901 and 24903 had expired on 09-30-2024. The laboratory utilized the expired QC materials prior to patient testing for eight days in October 2024. 2. The LD confirmed the above findings during the exit interview on 11-5-2024 at 4:20 PM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Tosoh AIA-900 Immunoassay and Sysmex XP 300 Hematology maintenance records, and an interview with the Laboratory Director, the Laboratory failed to document weekly, monthly, and quarterly maintenance on the Tosoh AIA-900 Immunoassay analyzer and monthly and quarterly maintenance on the Sysmex XP-300 Hematology analyzer as per the Quality Assurance checklist. This was noted for maintenance record review in 2023 and 2024. The findings include: 1. A review of the maintenance records revealed: A) The Tosoh AIA-900 Immunoassay analyzer had no evidence of: 1. Documented weekly maintenance for August, September, and October 2023; 2. Documented monthly maintenance for May, June, August through October 2023 and August 2024; 3. Documented quarterly maintenance for 2023. B) The Sysmex XP 300 Hematology analyzer had no evidence of: 1. Documented monthly maintenance for October through December 2023; 2. Documented quarterly maintenance for November 2023. 2. A further review of the

	Quality Assurance Checklist revealed, "Our Analytic System was follow as written: All required instrument maintenance was performed and documented." 3. During the exit interview on 11/5/2024, at 4:20 PM, the LD confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the Tosoh AIA-900 Immunoassay Quality Control (QC) logs, and an interview with the Laboratory Director (LD), the laboratory failed to ensure two levels of QC were performed and documented each day of patient testing. The surveyor noted no QC was performed for 8 out of the 31 days in October 2024, 15 patient testing were performed. The findings include: 1. A review of the Tosoh AIA-900 QC logs revealed the laboratory failed to perform the required QC prior to patient testing for eight days in October 2024. There were 15 patients testing performed during this period. 2. During an interview on 11-05-2024 at 4:20 PM, the LD confirmed these findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on reviews of the Immunoassay and Hematology Proficiency Testing (PT) records, the Quality Control records, the analyzer maintenance logs, room temperature and humidity logs, and the lack of a Quality Assurance Program, the Laboratory Director: 1) failed to ensure monitoring and evaluation of all PT performance; 2) failed to ensure laboratory samples were stored and tested within the manufacturer's acceptable limits; 3) failed to monitor and prevent utilization of testing materials that have exceeded the expiration dates; 4) failed to implement and maintain a QAP to assure the quality of laboratory services provided. The findings include: 1. Refer to D2009, D5215, 5221. 2. Refer to D5203. 3. Refer to D5417. 4. Refer to D5400.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

	This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, a lack of documentation, and an interview with the Laboratory Director (LD), who also serves as the Technical Consultant, the LD failed to ensure the laboratory participated in the 2024 Hematology PT first event.The surveyor noted the failure to participate occurred in one of the six testing events reviewed from the last survey date of 06-29-2022 to the current survey date of 11-05-2024. The findings include: 1. Refer to D5215.