Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2099823	12/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical Associates West	26279 Hwy 195, Double Springs, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to maintain copies of all relevant records for Proficiency Testing events. This was noted for 2 out of 5 events reviewed from the date of the last survey, 12/28/2021, to the date of the current survey, 12/06/2023. The findings include: 1. A review of PT records revealed no evidence of signed attestation statements, program report forms, or instrument print outs for 2023 Hematology Event 1 and 2023 Hematology Event 2. 2. During an interview on 12/6/2023 at 11:00 AM, Testing Personnel #1 confirmed the above findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231

	through 493.1236. This STANDARD is not met as evidenced by: Based on a review of Policies and Procedures and an interview with Testing Personnel #1, the laboratory failed to establish a written policy for an ongoing Quality Assessment mechanism. This was noted from the date of the last survey, 12/28/2012, to the date of the current survey, 12/6/2023. The findings include: 1. A review of Policies and Procedures revealed no evidence of a Quality Assessment policy. 2. During an interview on 12/06/2023 at 2:00 PM, Testing Personnel #1 confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 Policies and Procedures, Sysmex XP-300 Hematology Quality Control (QC) records, and an interview with Testing Personnel #1, the laboratory failed to follow policies approved and set forth by the Laboratory Director. The findings include: 1. A review of Policies and Procedures revealed the following text under "A,B,C's of QC", "...At the end of each lot of quality control material the Levy Jennings Graph Chart and all the values will be printed and placed in the same binder...". 2. A review of Hematology QC revealed only daily instrument print outs and background checks were being retained. No evidence of Levy Jennings charts were available for review at the time of survey. 3. During an interview on 12/06/2023 at 11:00 AM, the Surveyor inquired about the laboratory monitoring Levy Jennings charts over a period of time. Testing Personnel #1 replied, "I have not been shown that".
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of Policies and Procedures, Sysmex XP-300 calibration records, and an interview with Testing Personnel #1, the laboratory failed to perform

	calibration at least every six months. This was noted for two out of two calibration opportunities in the year 2023. The findings include: 1. A review of Policies and Procedures revealed the following under the procedure for Sysmex, "...Calibration verification is performed according to the laboratory Standard Operating Procedure and accreditation agency requirements...". 2. A review of Sysmex calibration records revealed the following: a) Calibration performed 2/10/2022. Calibration Certificate expired 8/09/2022. b) Calibration performed 8/09/2022. Calibration Certificate expired 2/05/2023. c) No evidence of documented calibration in 2023. 3. During an interview on 12/6/2023 at 2:00 PM, Testing Personnel #1 confirmed the above findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of Personnel records and an interview with Testing Personnel #1, the Laboratory Director failed to ensure all testing personnel had appropriate education documented prior to patient testing. This was noted for one out of two testing personnel from the date of the last survey, 12/28/2021, to the date of the current survey, 12/6/2023. The findings include: 1. A review of Personnel records revealed Testing Personnel #1 to have a phlebotomy certificate on file. No evidence of any official diplomas or transcripts were available for review day of survey. 2. During an interview on 12/6/2023 at 2:00 PM, Testing Personnel #1 confirmed the above findings.
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 a review of Personnel records and an interview with Testing Personnel #2, the Technical Consultant failed to assess competency annually for Testing Personnel performing non waived patient testing. This was noted for one out of one Testing Personnel previously qualified at the date of the last survey, 12/28/2021. The findings include: 1. A review of Personnel records revealed no evidence of annual competency assessments in 2022 or 2023 for Testing Personnel #2. 2. During an interview on 12/6 /2023 at 2:00 PM, Testing Personnel #2 provided the surveyor with Clinical Consultant and Technical Consultant competency assessment forms for themselves. Neither form assessed competency for Sysmex XP-300.