Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0862429	05/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Family Medical, Pc	1407 Baddour Pkwy, Lebanon, TN	

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
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 review of the laboratory's quality assurance plan, review of the laboratory's quality assurance records, and interview with the quality manager, the laboratory failed to follow their quality assurance policy in 2020, 2021 and 2022. The findings include: 1. Review of the laboratory's quality assessment plan revealed the following: a) Patient Test Management section states laboratory manager will observe if specimens are properly collected, labeled, processed, and results recorded accurately semi-annually. b) Comparison of Test Results section states laboratory will send split specimens to outside facilities for further verification of accuracy quarterly. 2. Review of the laboratory's Annual Quality Assurance Summary records revealed the following: a) Patient test management review was recorded 0 of 2 times in 2022. b) Comparison of test result was recorded 2 of 4 times in 2022 (May and August), 2 of 4 times in 2021 (June and October), and 3 of 4 times in 2020 (February, May, and September). 3. Interview on 05/10/23 at 11:15 am with the laboratory quality and office managers defined semi-annual to mean twice per year and quarterly as four times per year. 4. Interview on 05/10/23 at 1:30 pm with the laboratory quality manager and office manager confirmed the laboratory failed to follow it's own quality assessment plan when it did not perform patient test management reviews twice in 2022 and comparison of test results 4 times in 2020, 2021, and 2022.
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 observation of the laboratory, review of manufacturer's user manual, reagent package instructions, lack of documentation and interviews with the quality and office managers, the laboratory failed to monitor the ambient temperature and relative humidity in the area where the complete blood count (CBC) instrument was being used for patient testing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 05/10/23 at 8:15 am revealed the following: a) Horiba ABX Micros 60 CBC instrument (serial #402CS93724) and for performing patient CBC testing. b) ABX Minoclair, Miniclean, Alphalyse, and Minidil LMG reagents used by the Horiba ABX Micros 60 stored in ambient conditions beneath the analyzer. 2. Review of the Horiba Micros 60 CS/CT User Manual's section titled "3.4 Humidity and Temperature conditions" revealed an operating ambient temperature range of 18 - 32 degrees Celsius (C) and a relative humidity range of up to 95%. 3. Review of the ABX Minoclair, Miniclean, Alphalyse, and Minidil LMG reagent package instructions revealed storage range for each reagent is between 18 - 25 degrees Celsius (C). 4. There were no environmental records for monitoring of ambient temperature and relative humidity for surveyor review. 5. Interviews with the quality and office managers on 05/10/23 at 1:30 pm confirmed the laboratory failed to monitor the ambient temperature and relative humidity in the area where the Horiba ABX Micros 60 CBC instrument was used for patient testing in 2021, 2022, and 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer instructions for use, and interviews with the quality and office managers, the laboratory failed to label three of three controls observed on the date of the survey (05/10/23) with corrected expiration date after the controls were opened. The findings include: 1. Observation of the laboratory on 05/10/23 at 8:15 am revealed three levels of Minotrol 16 Tri-Level controls (Kit: MX441) in use for performing quality control on the Horiba ABX Micros 60 complete blood count (CBC) instrument. All three in-use controls were labeled with an open date (05/04/23) but no corrected expiration date. 2. Review of the Minotrol 16 Tri-Level controls manufacturer package inserts revealed CBC controls for the Horiba ABX Micros 60 are to be stored at 2-8 degrees Celsius (C) and are stable for 16 days after opening. 3. Interviews with with the quality and office

	managers on 05/10/23 at 1:30 pm confirmed the laboratory controls in use had expiration dates that changed after opening and the laboratory failed to label the controls with the corrected expiration dates on the date of the survey for three of three controls observed.