Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0862429	(X3) Date Survey Completed 07/31/2024
Name of Provider or Supplier Family Medical, Pc	**Street Address, City, State** 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the manufacturer instructions for use (IFU), laboratory policy, lack of documentation, and staff interview, the laboratory failed to follow the manufacturer's instructions for performing quality control on the McKesson Consult Diagnostics 120 Urine Analyzer used for 1562 urine microalbumin and creatinine patient tests from June 2023 to June 2024. The findings include: 1. An observation of the laboratory on 07/31/2024 at 8:30 a.m. revealed that it used a McKesson Consult Diagnostics 120 Urine Analyzer (ID: 197T10083EE) and McKesson Consult Diagnostics Microalbumin/ Creatinine Urine Reagent Strips (Lot: UR84030111) for patient testing. 2. A review of the McKesson Consult Diagnostics Microalbumin/ Creatinine Urine Reagent Strips IFU revealed the following statement: "Test known controls (i.e., McKesson Liquid Urine Controls) in case of any of the following events, following local, state, and/or federal requirements: - A new canister of strips is opened - A new operator uses the analyzer - Test results seem wrong - After performing maintenance or service on the analyzer" 3. A review of the laboratory's policy titled "Urinalysis" revealed the following statement: "Quality Control Procedure: Positive and Negative controls are to be tested anytime a new bottle of reagent strips is opened and with every 20 uses of each control bottle" 4. No documentation of quality control testing for the McKesson Consult Diagnostics Microalbumin/ Creatinine Urine Reagent Strips was available for review. 5. An interview with the laboratory lead tech, technical consultant, and office manager on 07

	/31/2024 at 1:00 p.m. confirmed the laboratory had not performed urine microalbumin and creatinine QC from June 2023 to June 2024, with 1562 urine microalbumin and creatinine patient tests reported.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of laboratory instrumentation records, quality control (QC) records, laboratory policies, and staff interviews, the laboratory failed to retain complete blood count (CBC) QC records for six of the fourteen months reviewed in 2023 and 2024. The findings include: 1. A review of laboratory instrumentation records revealed the laboratory used a Horiba ABX Micros 60 (ID: 402CS93724) for patient CBC testing from their last recertification survey (05/10/2023) to 10/25/2023. 2. The laboratory could not provide CBC QC records for the Horiba ABX Micros analyzer from May to October 2023. 3. A review of the laboratory's "Systems Management" policy revealed the following statement in the "Quality Control Procedures" section under "Documentation": - "All documentation, including unacceptable results and all instrument printouts, is kept for at least two years." 4. An interview with the laboratory lead tech and technical consultant on 07/31/2024 at 12:30 p.m. confirmed that the laboratory did not maintain the Horiba ABX Micros 60 CBC QC records for two years.
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 laboratory observation, review of the manufacturer's operator's manual, patient test records, lack of documentation, and staff interview, the laboratory failed to perform daily maintenance on the Medonic M-Series complete blood count (CBC) instrument for 3 of 4 testing dates reviewed in 2023 and 2024. The findings include: 1. Observation of the laboratory on 07/31/2024 at 8:30 a.m. revealed a Medonic M-Series CBC analyzer (ID: 62294). The technical consultant stated the laboratory began using the Medonic analyzer for patient testing on 10/26/2024. 2. A review of the manufacturer's operator's manual revealed a requirement for daily cleaning of the aspiration and pre-dilute probes, probe rinse cup, and sampling device probe inlet with a disinfecting solution. 3. A random review of patient test records revealed the laboratory performed patient CBC testing on the following dates: - 11/14/2023 (Patient: 67077) - 04/01/2024 (Patient: 43711) - 07/06/2024 (Patient: 74077) - 07/30 /2024 (Patient: 74752) 4. The laboratory did not document daily cleaning for the Medonic analyzer on 11/14/2023, 04/01/2024, and 07/06/2024. 5. An interview with the laboratory lead tech and technical consultant on 07/31/2024 at 12:30 p.m. confirmed the findings.

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory observation, review of laboratory instrumentation records, laboratory policies, quality control (QC) records, and staff interviews, the laboratory failed to monitor complete blood count (CBC) QC performance over time in 2023 and 2024 (14 of 14 months reviewed). The findings include: 1. Observation of the laboratory on 07/31/2024 at 8:30 a.m. revealed a Medonic M-Series CBC analyzer (ID: 62294). The technical consultant stated the laboratory began using the Medonic analyzer for patient testing on 10/26/2024. 2. A review of laboratory instrumentation records revealed the laboratory used a Horiba ABX Micros 60 (ID: 402CS93724) for patient CBC testing from the last survey (05/10/2023) to 10/25/2023. 3. A review of the laboratory's "Systems Management" policy revealed the following statement in the "Quality Control Procedures" section under "Documentation": - "Statistical analysis, including the obtained mean, standard deviation, and coefficient of variation are calculated monthly by the instrument and reviewed by the technical consultant and/or the director." - "Levey-Jennings depicting the day of the month and the obtained result are maintained if plotted by the analyzer. L-J graphs are then reviewed monthly by the technical consultant or the laboratory director." - "All documentation, including unacceptable results and all instrument printouts, is kept for at least two years." 4. The laboratory could not provide Levy-Jennings graphs or other evidence of statistical analysis monitoring of CBC QC by the technical consultant or lab director for either the Horiba ABX Micros (May to October 2023) or Medonic M-Series analyzers (October 2023 to June 2024). 5. An interview with the laboratory lead tech and technical consultant on 07/31/2024 at 12:30 p.m. confirmed the laboratory had not monitored hematology QC performance over time.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's approved normal ranges, patient test records, and staff interviews, the laboratory failed to ensure that the complete blood count (CBC) final patient test reports for 3 of 5 reports reviewed contained the approved reference ranges. The findings include: 1. A review of the laboratory policies revealed

	the following approved reference ranges for White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HgB), Hematocrit (HCT), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Platelets (PLTS), Relative Lymphocytes (LYM), and Relative Granulocytes (GRAN): 6 months - 2 years ; Adult - WBC: 4.1 - 10.9 ; 4.8 - 10.8 - RBC: 4.20 - 6.30 ; 4.20 - 6.10 - HGB: 11 - 13 ; 12 - 18 - HCT: 37 - 51 ; 37 - 58 - MCV: 70 - 86 ; 80 - 100 - MCH: 26.0 - 32.0 ; 27.0 - 31.0 - MCHC: 31 - 34 ; 32 - 36 - PLTS: 140 - 440 ; 130 - 440 - LYM: 10.0 - 58.5 ; 20.5 - 51.1 - GRAN: 37.0 - 92.0 ; 42.2 - 75.2 2. A random review of five patient CBC test reports revealed the following reference ranges listed for patients 74752 (10 months), 74077 (1 year), and 67077 (68 years): - WBC: 3.5 - 10.0 - RBC: 3.50 - 5.50 - HGB: 11.5 - 16.5 - HCT: 35.0 - 55.0 - MCV: 75.0 - 100.0 - MCH: 25.0 - 35.0 - MCHC: 31.0 - 38.0 - PLTS: 100 - 400 - LYM: 15.0 - 50.0 - GRAN: 35.0 - 80.0 3. An interview with the laboratory lead tech and technical consultant on 07/31/2024 at 12:30 p.m. confirmed the reference ranges listed on the final patient test reports for patients 74752, 74077, and 67077 did not match the laboratory's approved reference ranges.