

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0862429	(X3) Date Survey Completed 07/21/2026
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
D0000	During a recertification survey performed on July 21, 2026, the laboratory was found out of compliance with the following condition: D6063 - 42 C.F.R. 493.1421 Condition: Laboratory Testing Personnel
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Citation 1 Based on a review of the laboratory's "Personnel" policy and staff interview, the laboratory failed to ensure the procedure for competency assessment of testing personnel included the monitoring of recording and reporting of test results and did not define what documentation would be reviewed. The findings included: 1. A review of the laboratory's "Personnel" policy revealed that competency of all testing personnel would include "Direct observation of instrument maintenance and patient testing, Review of documentation, Proficiency testing performance, and other methods, including evaluation of problem-solving skills." The policy failed to include monitoring of recording and reporting of test results. The policy included review of documentation, but did not define what documentation would be reviewed. 2. Testing person four confirmed the findings during an interview on 07/21/2026 at 12:00 p.m. Citation 2 Based on laboratory observation, review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), the laboratory's "Personnel" policy, the laboratory's personnel records, lack of documentation, and staff interview, the laboratory failed to follow its written policies and procedures to assess employee competency for the moderately complex test CBC w/Diff in 2025 and 2026. The findings included: 1. Observation of the laboratory on July 21, 2026, at 9:05 a.m. revealed the Medonic M Series, serial number 62294,

moderately complex test system, in use for patient testing for CBC w/Diff. 2. A review of the laboratory's Form CMS-209 revealed the laboratory employed seventeen testing personnel at the time of the survey. 3. A review of the laboratory's "Personnel" policy revealed that competency of all testing personnel would be completed "prior to testing patient specimens" and "semi-annually for the first year and annually thereafter. " 4. A review of the laboratory's personnel records revealed the laboratory lacked documentation of the following: a. Semi-annual competency assessment during the first year for two of seventeen current testing personnel: TP fourteen (doh: 04/17/2025) and TP fifteen (doh: 07/07/2025). b. Annual competency for fifteen of seventeen current testing personnel in 2025: i. TP two (doh: 01/16/2023) ii. TP three (doh: 06/09/2006) iii. TP four (doh: 09/08/2014) iv. TP five (doh: 02/06/2023) v. TP six (doh: 03/16/2015) vi. TP seven (doh: 04/17/2017) vii. TP eight (doh: 06/06/2022) viii. TP nine (doh: 03/31/2024) ix. TP ten (doh: 01/11/2023) x. TP eleven (doh: 12/20/2019) xi. TP twelve (doh: 11/23/2009) xii. TP thirteen (doh: 09/25/2017) xiii. TP fourteen (doh: 04/17/2025) xiv. TP fifteen (doh: 07/07/2025) xv. TP sixteen (doh: 10/13/2022) 5. 2026 annual competencies had not been performed for 15 of 15 established testing personnel on the survey date. 6. Testing person four confirmed the findings during an interview on 7/21/2026 at 12:00 p.m. Citation 3 Based on a review of the laboratory's "Personnel" policy, personnel records, lack of documentation, and staff interview, the laboratory failed to follow the procedure for competency assessment of testing personnel that included the six required competency elements for three of three competency assessments performed in 2025. The findings included: 1. A review of the laboratory's "Personnel" policy revealed that competency of all testing personnel would include "Direct observation of instrument maintenance and patient testing, Review of documentation, Proficiency testing performance, and other methods, including evaluation of problem-solving skills." 2. A review of testing personnel competency assessment forms revealed that three of three 2025 competency assessment documents were signed by the laboratory director, with no documented assessment of the required competency elements for initial competency for TP fourteen dated 06/24/2025, the six-month competency assessments for TP one dated 03/06/2025, and TP fifteen dated 09/25/25. 3. Testing person four confirmed the findings during an interview on 07/21/2026, at 12:00 p.m.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), the laboratory's personnel records, and staff interview, the laboratory failed to provide educational documentation that qualified testing person ten (one of seventeen current testing personnel) to perform moderately complex testing for Complete Blood Count with Automated White Cell Differential (CBC w/Diff). Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the Form CMS-209, the laboratory's personnel records, and staff interview, the laboratory failed to provide educational documentation that qualified testing person ten (one of seventeen current testing personnel) to perform moderately complex testing for CBC w/Diff. The findings included: 1. A review of the Form CMS-209 revealed seventeen current testing personnel. 2. A review of testing personnel records revealed no educational documentation that qualified testing person (TP) ten to perform moderately complex patient testing for CBC w/Diff. The listed hire date (doh) was 01/11/2023. 3. Testing person four confirmed the findings during an interview on 07/21/2026 at 12:00 p.m.