Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2020484	04/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Family Care Clinic, Llc	306 N Chancery Street, Mcminnville, 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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: ========== Based on a review of one final patient test report, the Centers for Medicare and Medicaid Services (CMS)-116 form, and an interview with the technical consultant and testing personnel, the laboratory failed to have the correct address on one of one final laboratory patient test report. The findings include: 1. A review of patient 28682 final test report dated 2/6/2024 revealed the following name and address: Family Care Clinic, 231 Northgate Drive, Suite 102, McMinnville, TN 37110. 2. A review of the CMS-116 form revealed the following laboratory name and address: Family Care Clinic, 306 North Chancery Street, McMinnville, TN 37110. 3. In an interview on 4/17/2024 at 11:45 a.m., the technical consultant and testing personnel confirmed the laboratory failed to have the correct address on one of one final laboratory patient test report. ==========
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 observation of the laboratory, a review of the laboratory procedure manual and one instrument printout, one final patient test report, and an interview with the technical consultant and one testing personnel, the laboratory failed to ensure the defined reference ranges in the procedure manual were provided to its clients on one of one final patient test report. The findings include: 1. Observation of the laboratory on 4/17/2024 at 08:15 a.m. revealed the Medonic M-series hematology analyzer (SN- 49420) in use for complete blood count (CBC) testing to include white blood count (WBC), red blood count (RBC), hemoglobin (HGB), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), random distribution width percent (RDW%), and platelet count (PLT). 2. A review of the laboratory procedure manual and instrument printout revealed the following defined reference ranges: WBC 3.5-10 (10^9/L) RBC 3.5-5.5 (10^12/L) HGB 11.5-16.5 (g/dL) HCT 35-55 % MCV 75-100 (fl) MCH 25-35 (pg) MCHC 31-38 (g/dL) RDW% 11-16 % PLT 100-400 (10^9/L) 3. A review of one final patient test report revealed the following reported reference ranges: WBC 3.8-10.8 (10^9/L) RBC 3.90-5.20 (10^12/L) HGB 12.0-15.6 (g/dL) HCT 35.0-46.0 % MCV 80.0-100.0 (fl) MCH 27.0-33.0 (pg) MCHC 32.0-36.0 (g/dL) RDW% 9.0-15.0 % PLT 130-400 (10^9/L) 4. In an interview on 4/17/2024 at 11:45 a.m., the technical consultant and one testing personnel confirmed the laboratory failed to ensure the defined reference ranges found in the procedure manual were provided to its clients on one of one final patient test report. ==========