Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2061968	02/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Care Plus Family Medical	8914 U S Hwy 431, Albertville, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, a review of policies and procedures, including the IQCP (Individualized Quality Control Plan) for microalbumin and creatinine, a review of 2016-2018 quality control records for Chemistry, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform the quality control testing for the microalbumin and creatinine, as established in the quality control plan of the IQCP. This affected January of 2017, one month in the year. The findings include: 1. During the entrance tour of the laboratory on 2/21/19 at 8:40 AM, the laboratory supervisor (also TP #1) stated microalbumin and creatinine were performed on the Siemens DCA Vantage and were considered moderate complexity tests. 2. The quality control plan of the IQCP for microalbumin (ualb) and creatinine indicated the following: QC: two levels (low and high) are run with each new lot of reagent and to train and confirm performance of new analysts, or when results do not match patient's clinical condition; one level of control, either a low or high, is performed on each box of reagents within the same lot number; two levels of control are performed once monthly whether the same or different lot number, or as an added quality assurance. 3. A review of the quality control records revealed only one level was tested in January of 2017. 4. At 12:38 PM on 2/21/19, the

	surveyor and TP #1 reviewed the quality control records for ualb and creatinine. TP #1 confirmed that only one level of quality control was tested in January, 2017; although the IQCP indicated two levels would be tested once per month. 5. The surveyor discussed the above noted findings with TP #1 again during the exit summation on 2/21/19 at 2:00 PM.
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 the personnel and training records and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure two testing personnel of moderate complexity testing presented with the appropriate educational credentials, prior to testing patient specimens and reporting the results. This affected two of seven listed testing personnel on the CMS form #209 (Laboratory Personnel Report). The findings include: 1. A review of the personnel records revealed certifications for TP #6 (Medical Assistant) and #7 (Licensed Practical Nurse). Note: The minimum requirement for personnel of moderate complexity testing is a high school diploma. A science-based degree may be used as educational credential. 2. Further review of the training records revealed both testing personnel had been trained on moderate complexity testing: TP #6 was trained and oriented in the laboratory on 2/4/19 and #7, on 1/21/19. 3. In an interview on 2/21/19 at 12:38 PM, TP #1 (also the Laboratory Supervisor) confirmed the two testing personnel performed moderate complexity testing. TP #1 also reviewed the personnel records and noted only certifications of the employees had been obtained. 4. During the exit summation on 2/21/19 at 2:00 PM, the surveyor stated to TP #1 the laboratory could fax the educational documents to the State Agency by 5:00 Friday, February 22. The educational document for TP #6 was received by the State Agency via fax on 2/22/19. No additional documentation of education was received for TP #7.