Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2141611	07/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
First Choice Immediate Care	197 Will Walker Road, Columbia, KY	

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
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview on 07/08/2020, the laboratory failed to include two levels of control material on five days of patient testing from 05/13/2020 through 06/25/2020 on the Abbott iStat chemistry instrument. The findings include: 1. Review of test report on 05/13/2020, revealed Chem8+ results were reported on Patient #1. Review of quality control results revealed only Control 1 was tested. 2. Review of test report on 05/14/2020, revealed Chem8+ results were reported on Patient #2. Review of quality control results revealed only Control 1 was tested. 3. Review of test report on 05/28/2020, revealed Chem8+ results were reported on Patient #3. Review of quality control results revealed only Control 1 was tested. 4. Review of test reports on 06/18/2020, revealed Chem8+ results were reported on Patient #4 and Patient #5. Review of quality control results revealed only Control 1 was tested. 5. Review of test report on 06/25/2020, revealed Chem8+ results were reported on Patient #6. Review of quality control results revealed only Control 1 was tested. Testing personnel revealed in an interview at 11:30 AM on 07/08/202, the laboratory failed to include two levels of control material each day of patient testing.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of proficiency testing results from American Proficiency Institute testing program and staff interview on 07/08/2020, it was determined the laboratory director failed to ensure the laboratory was enrolled in Chemistry proficiency testing program for the testing of analytes (sodium, potassium, chloride, total carbon dioxide, ionized calcium, glucose, blood urea nitrogen, creatinine, hematocrit) on the Abbott iStat Chem8+ cartridge. The findings include: 1. Record review revealed patient test results from the iStat Chem8+ chemistry cartridge were first reported on 05/13/2020. 2. There was no evidence of confirmation of enrollment in chemistry proficiency testing with the proficiency testing program in 2020. Testing personnel revealed in an interview at 10:45 AM on 07/07/2020, the laboratory director failed to ensure the laboratory was enrolled in the chemistry proficiency testing program.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel files and staff interview on 07/08/2020, the technical consultant failed to perform and document a semiannual competency assessment on seven of nine testing personnel responsible for moderate complex testing. The findings include: 1. Review of the personnel file revealed Testing Personnel #1 through Testing Personnel #7 began laboratory testing 10/10/2019. There was no evidence of a semiannual competency assessment. Testing personnel revealed in an interview at 9:30 AM on 07/08/2020, the Technical Consultant failed to ensure the laboratory had a system in place to ensure competency assessments were performed and documented at least semiannually during the first year for personnel responsible for moderate complex testing.