Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2017911	08/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Back To Life Medical Group, Llc	557 Riverstone Parkway, Suite 140, Canton, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) initial survey was completed on August 21, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. An immediate jeopardy situation was identified due to the laboratory's inability to demonstrate compliance in the speciality of Toxicology for a moderate complexity laboratory. Specifically, the labs inability to validate the analytical system prior to patient testing that began 1/15/19 and the lab director's inability to provide overall management and direction in accordance with 493.1407. The following deficiencies were cited:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of lab documents provided and staff interview, the lab failed to verify the accuracy of the test or procedure twice annually for all assays performed by the lab on the Indiko Plus analyzer. Findings include: 1. Review of Proficiency Testing (PT) binder and enrollment letter (dated 8/12/19) revealed the lack of participation in PT or verification of accuracy twice annually to date. 2. Interview on 8 /21/19 with staff #1 (CMS 209 form) on the phone at approximately 11:00 AM confirmed the lack of participation in PT or verification of accuracy twice annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that

	provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records provided and interviews with the Lab Director (LD) and testing personnel (TP) the lab failed to validate the overall quality of the analytical system used for urine drug testing before performing patient analysis in accordance with 493.1289 resulting in Immediate Jeopardy (IJ). This Condition level deficiency contributed to the Immediate Jeopardy. Findings include: For details refer to: D5401, D5411, D5421
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the lab procedure manual (SOP) and staff interview, the lab failed to have written procedures for all assays performed by the lab on the Indiko Plus analyzer. Findings include: 1. Review of SOP revealed the lack of procedure for the THC (tetrahydrocannabinol) and EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine) assays. 2. Interview on 8/21/19 with staff #1 (CMS 209 form) on the phone at approximately 11:15 AM confirmed the lack of the aforementioned procedure assays.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the lab procedure manual (SOP) and staff interview, the lab failed to have package inserts/ manufacturer procedures for all assays performed by the lab on the Indiko Plus analyzer. Findings include: 1. Review of SOP revealed the lack of package inserts/manufacturer procedures for the THC (tetrahydrocannabinol) and EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine) assays. 2. Interview on 8 /21/19 with staff #1 (CMS 209 form) on the phone at approximately 11:15 AM confirmed the lack of the aforementioned assay package inserts/ manufacturer procedures.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records provided and interview with the Lab Director (LD), the lab failed to validate the overall quality of the analytical system used for urine drug testing before performing patient analysis Findings include: 1. Review of calibration and EP Evaluator documents presented revealed the lab failed to validate the overall quality of the Indiko Plus analyzer by performing accuracy, precision, linearity, sensitivity, specificity, and reference intervals on the analyzer at the facility's lab location. 2. Interview on 8/21/19 with staff #1 (CMS 209 form) on the phone at approximately 4:45 PM confirmed the lab documentation did not indicate the analyzer was validated at the facility's lab location.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of temperature/relative humidity (RH) records and staff interview, the lab failed to document corrective actions when RH exceeded acceptable limits. Findings include: 1. Review of temperature/relative humidity (RH) records revealed the RH was out of range without corrective actions documented 6 of 64 days during the period of January 2019 to August 21, 2019. 2. Interview with testing personnel #2 (CMS 209 form) on 8/21/19 at 4:20 PM in the front provider's office, confirmed the corrective actions were not documented.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	Based on document reviews and staff interviews, the lab failed to monitor pH per the manufacturer/ procedure manual (SOP). Findings include: 1. Review of the SOP, QC, and patient log sheets, revealed that the lab failed to follow the procedure for pH on samples. 2. Interviews with TP #1 (on the telephone) and #2 (CMS 209 form) on 8/21 /19 in the front provider's office at approximately 12:15 PM, confirmed that the pH was not monitored.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records provided, the lab director (LD) failed to provide overall management and direction in accordance with 493.1407. This defeciency contributed to Immediate Jepardy (IJ). Findings include: For details refer to: D5217, D5401, D5411, D5421, D5781, D5791, D6013, D6032
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of documents provided and staff interview, the laboratory director (LD) failed to ensure that the test system, Indinko Plus, was properly validated in the facility's lab. Findings include: 1. Review of calibration and EP Evaluator documents revealed the test performance of the Indiko Plus analyzer was not validated in the facility's lab. 2. Interview on 8/21/19 with staff #1 (CMS 209 form) on the phone at approximately 4:45 PM confirmed the lab documentation did not indicate the analyzer was validated in the facility's lab location.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen

	processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify, in writing the duties and responsibilities of each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of laboratory testing. Findings include: 1. SOP review revealed the LD failed to specify, in writing ,the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing including the LD, clinical consultant, technical consultant, or testing personnel. 2. A phone interview with Staff #1 (CMS 209), on 8/21/19, at approximately 4:45 p.m., confirmed the SOP did not contain a policy and procedure for duties and responsibilities.