

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2017911	<b>(X3) Date Survey Completed</b>  03/29/2023
<b>Name of Provider or Supplier</b>  Back To Life Medical Group, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 29, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D2111</b>	<p><b>TOXICOLOGY</b> CFR(s): 493.845(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologist (CAP) proficiency testing (PT) documents and testing personnel interview, the lab failed to participate in PT 2 of 3 events of 2022. Findings: 1. Review of the CAP PT documents available revealed the lab failed to participate in the 2022 events #1 and #2. 2. Interview with testing personnel #1 (CMS 209) on 3/29/23 in the office of the practice manager at 11:35 am confirmed the aforementioned findings.</p>
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure</p>

positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:

Based on observation during the lab tour, policy and procedure (SOP) review, and testing personnel interview, the laboratory failed to follow the labeling of specimens per the procedure titled "SAMPLE accessioning and follow up LOGIN in HORIZON LIS". Findings: 1. Observation during the tour of the laboratory at 10:17 am, revealed 2 of 2 urine specimens were labeled on the urine cup lid not the sample cup as outlined in the above mentioned procedure. 2. Review of the "SAMPLE accessioning and follow up LOGIN in HORIZON LIS" procedure revealed on page 3 of 4 "each specimen must have 2 unique identifiers on the specimen cup that matches the paperwork". 3. Interview with testing personnel #1 (CMS 209) on 3/29/23 at 10:19 am in the lab confirmed the aforementioned findings.

**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 review of testing personnel (TP) documents and an interview with the testing personnel, the lab director (LD) failed to document initial training on 1 of 1 TP for the Indiko Plus analyzer used for toxicology testing. Findings: 1. Review of TP documents revealed the LD failed to ensure 1 of 1 TP had documented initial training for the Indiko Plus analyzer used for toxicology testing. 2. Interview with the TP in the practice manager's office on 3/29/23 at 10:30 am confirmed the aforementioned finding.

**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 lab director (LD) interview, the laboratory director failed to specify, in writing the duties and responsibilities of each required Clinical Laboratory Improvement Amendments (CLIA) position. Findings : 1. SOP review revealed the LD failed to specify in writing the duties and responsibilities of the Technical Consultant (TC), the Clinical Consultant (CC), and the LD. 2. Interview with the LD (CMS 209) in the practice manager's office at 10:30 am confirmed the SOP did not contain a duties and responsibilities policy and procedure for the aforementioned positions.