Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2079100	08/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lifeback Llc	4 Princess Road, Building 200, Suite 206, Lawrenceville, NJ	

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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Toxicology QC used for Toxicology tests performed on the Beckman Coulter AU480 analyzer from 12/17/18 to the date of the survey. The findings include: 1. UTAK Toxicology Controls had no documented evidence that QC verification was performed. 2. The TP confirmed on 8/31/21 at 10: 00 am that assayed QC material was not verified before putting in use.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken

	when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to take corrective action when one out of two levels of controls were out of range for Benzodiazepine, Opioids, Buprenorphine, Cocaine and Amphetamines tests performed on Beckman Coulter AU480 analyzer from 11/6/20 to 12/11/20 the date of survey. The findings include: 1. UTAK Toxicology Control level 1 Lot number C4613 was out of range as below: a. 11/6/20 and 11/20/20 for Benzodiazepine. b. 11/20/20 for Opioids and Cocaine. c. 11/28/20 for Buprenorphine. d. 12/11/20 for Amphetamines. 2. There was no corrective action documented for the above failures. 3. Approximately 100 patient samples were run and reported. 4. The TP confirmed on 8/31/21 at 11:00 am that no corrective action was taken for out of range QC.