

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2079100	(X3) Date Survey Completed 12/17/2018
Name of Provider or Supplier Lifeback Llc	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Competency Assessment (CA) records, review of the procedure manual and interview with the Testing Personnel (TP), the laboratory failed to perform a CA on one out of one testing personnel in the calendar year 2017. The TP confirmed on 12/17/18 at 2:05 pm that the CA procedure was not followed.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel(TP), the laboratory failed to review and evaluate Urine Drug Screen PT results obtained from the American Academy of Family Physicians (AAFP) in the second quarter of 2017 and 2018. The TP confirmed on 12/19/18 at 1:30 pm that the laboratory did not review and evaluate all PT results.</p>