

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D2136287	<b>(X3) Date Survey Completed</b>  04/12/2024
<b>Name of Provider or Supplier</b>  Living Well Behavioral Health, Inc	<b>Street Address, City, State</b>  502 Mcknight Drive, Suite 201, 202, Knightdale, NC	
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>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based upon the review of a patient test report, review of a package insert for DP (Diagnostic Products) quality control materials and review of 2023 quality control data, the laboratory does not perform both a positive and negative quality control for urine amphetamine and urine cocaine (2 of 5 qualitative toxicology analytes performed on the Biolis immunoassay instrument) each day of patient testing. Findings: Review of a patient test report (08291996MC) revealed the following: 1. The laboratory utilizes a cut off value of 500 ng/mL for amphetamine. 2. The laboratory utilizes a cut off value of 150 ng/mL for cocaine. Review of the package insert for DP quality control materials revealed the following: 1. The concentrations of the two levels of quality control for urine amphetamine are 750 ng/mL and 1000 ng/mL. 2. The concentrations of the two levels of quality control for urine cocaine are 225 ng/mL and 375 ng/mL. Review of 2023 quality control data for urine amphetamine and urine cocaine revealed the following: 1. The laboratory performs two levels of quality control on each analyte each day of patient testing. 2. Both levels of quality control performed above the cut off value of each analyte and were acceptable as positive quality controls. 3. The laboratory does not perform a negative quality control that falls below the cut off value of urine amphetamine or urine cocaine each day of patient testing.</p>