

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2132779	(X3) Date Survey Completed 03/13/2018
Name of Provider or Supplier Ascendant Behavioral Health, Llc	Street Address, City, State 4179 Riverboat Road, Suite 220, Salt Lake City, UT	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on verification studies review and interview with staff, the laboratory failed to verify test accuracy for 1 of 13 toxicology tests performed (Buprenorphine) on the Synermed IR-500. The laboratory began performing toxicology testing in 07/2017 and had tested approximately 65 patient samples from July 2017 to March 2018. Findings include: 1. The laboratory verification documentation included one positive and one negative control sample tested 20 times each on 2 consecutive days. 2. Buprenorphine verification data documents 13 of the 20 positive control tests on day 2 fell below the positive cut-off value of 5ng/mL. 3. Staff confirmed on 03/13/2018 at approximately 10:00 a.m., Buprenorphine accuracy documentation on day 2 failed to demonstrate they could produce accurate positive test results.</p>