

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2054760	(X3) Date Survey Completed 01/31/2018
Name of Provider or Supplier Precision Toxicology, Llc	Street Address, City, State 4215 Sorrento Valley Blvd Ste 100, San Diego, CA	
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) results reports, and interview with the laboratory staff, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. The findings included: a. The laboratory performed urine drug screen by Coulter Model AU 680 included urine pH to ensure the urine specimens received from the patient collection were not adulterated. b. In order to verify the accuracy of the urine pH testing and meet the requirement of CLIA requirements, the laboratory elected to enroll UDC PT program offered by CAP (College of American Pathologists). c. The laboratory attained a score of 20% for urine pH testing, i.e. 8 out of 10 PT samples results were unacceptable in UDC-B 2017 PT event, was unsatisfactory analyte performance for the testing event. . d. The laboratory performed urine drug screen in approximately 25,000 urine drug screen samples monthly. e. The laboratory affirmed (01/31/2018 @ 2 PM) affirmed that the laboratory attained a score of 20% for urine pH testing in UDC-B 2017 was unsatisfactory analyte performance for the testing event.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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</p>

director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) results reports, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the proficiency testing samples were tested as required under Subpart H of 42 CFR part 493. The findings included: See D-2087