

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0907431	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Nextgen Laboratories	Street Address, City, State 4229 Birch St Ste 130, Newport Beach, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the technical consultants, it was determined that the laboratory failed to verify, at least twice annually, the accuracy of the test or procedures the laboratory performed. The findings included: a . The laboratory used Beckman AU 480 to perform urine drug screen including but are not limited to urine pH, an adulterant. b. The laboratory used Shimadzu LC/MS/MS 8060 to confirm the drugs detected and provided with concentrations in random urine collection. c. The laboratory reported in approximately 70 drug analyte including parent drugs with its metabolites for the patient urine samples. d. In order to meet the requirement of evaluation of proficiency testing performance for the tests not included in the subpart I of 42 CFR part 493, the laboratory elected to enroll "Forensic Urine Drug Test Conf (UDC)", a proficiency testing program offered by CAP (College of American Pathologists) PT provider. e. The laboratory reported 7 unacceptable results out of 10 PT samples for urine pH in the UDC-B 2018 PT event, namely UDC-11 , UDC-12, UDC-13, UDC-14, UDC-16, UDC-19 and UDC-20 were unacceptable, which were unsatisfactory performance for the event. f. The laboratory attained 1 unacceptable concentration result and the other was NR* out of 2 PT samples (UDC-24 and UDC-30) for Benzoylcegonine 150 in UDC-C 2018 PT event, which was unsatisfactory performance. g. The laboratory received a [42] code = No credit assigned due to absence of response for Benzoylcegonine in UDC-C 2018 PT event unacceptable concentration result out of 2 PT samples for in UDC-C 2018 PT event, which was unsatisfactory performance. h. The laboratory reported and obtained results for UDC-16, UDC-24 and UDC-30 as follows: Analyte Result Range Grade Metamphetamine Quant UDC-16 502 661 -</p>

1030 unacceptable Benzoylcegonine 150 UDC-24 321 324 - 483 unacceptable UDC-30 NR* [42] NR* = Not Reported/No Result [42] = No credit assigned due to absence of response. i. The laboratory performed in approximately 421 and 695 patient samples for urine drug screens and confirmation tests, respectively per month.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's evaluation of proficiency testing (PT) performances and the PT result reports, and interview with the technical consultants, it was determined that the laboratory director failed to assure the quality of laboratory services provided and to identify failure in quality as they occur. The findings included: See D-5217