

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2130105	(X3) Date Survey Completed 03/19/2020
Name of Provider or Supplier Integritox Laboratories, Llc	Street Address, City, State 3151 Airway Ave Ste I-2, Costa Mesa, 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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Levey Jennings (LJ) quality control (QC) records, and interview with the laboratory testing personnel and the laboratory director, it was determined that the laboratory failed to take actions when monitoring over the cumulative QC date between 01/21/2020 and 01/30/2020 LJ chart for the analyte including, but are not limited to the followings: Alpha -OH alprazolam (AH), Alprazolam (AL), 7-Aminoflunitrazepam (AF), and 7-Aminoclonazepam (AC). The laboratory failed to document all corrective action activities and procedures performed. The findings included: a. The laboratory performed high complexity testing of LC/MS/MS drug testing for qualitative confirmation of the drugs detected in the specimen and reported with its quantitative concentration. b. Review of LJ charts from 01/21/202 thru 01/30/2020 for quality control run data for AH, AL, AF, and AC, there are items to indicate how the QC performances under columns of "QC Status" and "Failed Rule". c. All QC for the 4 drugs mentioned above (b), resulted in 2 out of 4 QC ran on 01/21/2020 greater than -3SD. d. QC run on 01/21/2020 @ 11:55:03 resulted as follows: Drug Lo Range Hi Range AH 0 18.3 -33.3 211.5 98.9-157</p>

AL - 7.92-17.4 87.3 199-296 AF 14.1 14.7 -20.2 112 131-181 AC 49.5 51-73 461 558-713 e. QC Status between 01/21/2020 and 01/30/2020 for the 4 drugs mentioned in (b) showed "Warning" f. Failed Rule between 01/21/2020 and 01/30/2020 for the 4 drugs mentioned in (b) showed "1-2S" g. The laboratory and the laboratory director affirmed (03/19/2020 @ 01:15 PM) that the laboratory must update their QC policies and procedures.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 Levey Jennings (LJ) quality control records, and interview with the laboratory testing eprsonnel and the laboratory director, it was determined that the laboratory director failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. Review of the laboratory's LJ charts between 01/21/2020 and 01/30/2020 for the following drugs QC including but are not limited to AH, AL, AF, and AC falled outside of the acceptable ranges, see D-5441