Quality Division Use Only

Quality Tracking #:	2017-009	**Date Quality Division Notified:**	2/20/2017
Non-Conformance Level:	III	**Date Submitted to Management for Review:**	3/28/2017
Date Submitted to Quality for Review:	5/10/2017	**Dated Closed:**	5/11/2017

Date of Discovery:	2/23/2017	**Division:**	Comparative & Analytical Division
Date of Incident:	8/12/2016	**Section:**	Toxicology

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
N/A	N/A

Description of Discrepancy/Non-conformance. Do not include analysts' names unless otherwise instructed by the Section Manager or Division Director(s):

On August 12, 2016, an analyst incorrectly prepared the Urine Negative Stock Solution (Lot # 081216U-St-N) for benzoylecgonine. Subsequently, this stock solution was used to make the negative control solutions prepared on August 12, 2016 and December 12, 2016 (Lot #081216U-MXN and 121216U-MXN). The final concentration of benzoylecgonine was prepared at 100 ng/mL instead of 75 ng/mL, which violated the Toxicology standard operating procedure (SOP v2.5 and v2.6). This miscalculation occurred because the analyst prepared the stock solution using the Negative Control Supplemental Worksheet, which contained an incorrect concentration for benzoylecgonine.

Associated Batches: 20161130U_ASG, 20161209U_ASG, 20170119U_ASG 20160921U_AAJ & 20160922U_AAJ, 20161006U_AAJ & 20161028U_AAJ, 20161101U_AAJ, 20161129U_AAJ, and 20170111U_AAJ.

Actions Taken:

The Toxicology Supervisor and analyst discovered the error on February 17, 2017. The Toxicology Manager determined that, although the benzoylecgonine concentration in the stock solution and subsequent negative controls was different from the concentration listed in SOP v2.5 and v2.6 and the 2015 urine validation, using the negative control at a higher concentration still followed the Scientific Working Group for Forensic Toxicology guidelines that

state a negative control must be no less than 50% of the calibrator. Therefore having the negative control at 100 ng/mL instead of 75 ng/mL is scientifically acceptable for use in casework.

Analytical results issued using these solutions were not impacted because:

• Immunoassay results depend upon the concentration of the calibrator, which was correctly prepared at 150 ng/mL as stated in the SOP.

• The 100 ng/mL concentration is closer to the 150 ng/mL calibrator concentration, allowing for a tighter evaluation of the calibrator performance.

• All positive drug screening results are subjected to confirmatory analysis.

This corrective action is being issued solely to document the violation of the SOP. To prevent a similar nonconformance from occurring in the future, the section no longer uses the supplemental worksheet. SOP v2.8 (effective March 01, 2017) was revised to eliminate the need for the worksheet. The Working Stock/Standard Preparation Log (LAB-27) for preparing immunoassay standards, sub-stocks, calibrator, and control solutions lists individual drug concentrations rather than denoting them simply as "mixed concentration" solutions. By listing individual drug concentrations, the laboratory form will serve as an additional check to verify drug concentrations with the SOP for both the preparer and reviewer.

The concentration of the benzoylecgonine on the Immunoassay Batch Report of urine batches involved was corrected to reflect the true concentration of the negative control. The benzoylecgonine concentration on the Urine Method Verification for Qualitative Test Methods issued on September 8, 2016 (pages 7 and 19) and the Urine Method Verification for Qualitative Test Methods issued on December 21, 2016 (page 7) was also corrected to reflect the true concentration of the negative control.

The following comment will be added to the urine batches and the urine verifications pending approval of this corrective action report, "The urine negative control (Lot # 081216U-MXN or 121216U-MXN) was made with a benzoylecgonine concentration of 100 ng/mL instead of 75 ng/mL. Refer to Corrective Action 2017-009 for additional information."

Summary of Root Cause Analysis:

This nonconformance occurred because the Toxicology SOP was not clear and concise, leading to confusion in how to prepare stock solutions. Rather than revise the SOP, the section created the Negative Control Supplemental Worksheet. This worksheet, rather than the SOP, was used as a reference when making the stock solution referenced in this corrective action report. The worksheet, which contained a typographical error in the concentration of the stock solution, was not a controlled document and was not compared to the SOP before being used in the laboratory.

The Toxicology SOP has since been revised and the Supplement Worksheet is no longer used by the section.

Additional Information/Follow-Up:
Toxicology SOP version 2.8 was revised to eliminate the use of the supplemental worksheet. All solutions are now prepared following instructions in the SOP.

Section Manager: Dayong Lee **Date:** 5/10/2017

Division Director: Irma Rios **Date:** 5/10/2017

Quality Director: Lori Wilson **Date:** 5/11/2017