Quality Division Use Only

Quality Tracking #:	2018-039	**Classification:**	Corrective Action
Non-Conformance Level:	Class II	**Section:**	Toxicology
Date of Discovery:	06/22/18	**Date of Incident:**	06/22/18

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2018-07696	064486918

Description of Non-conformance:

During technical review, the administrative review button was accidentally selected in the Laboratory Information Management System (LIMS) releasing the report before the technical review was electronically captured. The report was immediately reset and the technical review button in LIMS was selected before the case moved on to the administrative review. However, during administrative review, the Toxicology Manager noticed the ion ratio for the phencyclidine internal standard did not meet acceptance criteria. This discrepancy should have been caught when the assigned analyst was compiling and reviewing the batch data, during the technical review of the batch, drafting of the analytical report, and the technical review of the report.

Actions Taken:

The report was not released on 6/22/2018 because the case needed to be reanalyzed for phencyclidine. The phencyclidine reanalysis was completed with an analytical result of 52 +/- 9 ng/mL and the ion ratio for the internal standard met the acceptance criteria. This result fell within the previously reported result of 58 +/- 10 ng/mL. The analytical report was issued with the acceptable results that met all acceptance criteria with the following comments, "Laboratory Information Management System did not capture the date of the technical review on Report 2. HFSC has corrected the administrative error. However, during the administrative review of this case, it was noticed the results did not meet all necessary acceptance criteria. The case sample was reanalyzed and all acceptance criteria were met. Those analytical results are disclosed on this report. For more information regarding this please see quality report 2018-039 pending as of August 9, 2018. Please refer to this report for more details."

Summary of Root Cause Analysis:

Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

This nonconformance occurred because both the analyst and the technical reviewer expedited their review process for this case in an attempt to close out the report before the Toxicology Manager was out of the office for two weeks.

Additional Information/Follow-Up:

The administrative review process caught that the ion ratio did not meet the acceptance criteria for this drug. But because the report was released by accident, this had to be documented through the quality division workflow even though the review process discovered this.

Section Manager: Dayong Lee **Date:** 08/14/18

Division Director: Amy Castillo **Date:** 08/16/18

Incidents or Corrective Actions that involve the Biology/DNA section are reviewed by the Technical Leader and CODIS Administrator.

Technical Leader: N/A **Date:** N/A

CODIS Administrator: N/A **Date:** N/A

Quality Director: Lori Wilson **Date Closed:** 08/16/18