Incident / Corrective Action Plan Form
Toxicology: Blood Drug Analysis Findings

Incident/Corrective Action Number: 2023-02

Date of Discovery: May 11, 2023/Updated - October 2, 2023

Incident Date(s): Multiple

Section: Toxicology

Reported By: Laboratory Director

Classification: Incident

Incident Type: Procedural

Description of Non-Conformity:
The District Attorney's (DA) office requested the case file, reviewable data, and all standard operating procedures (SOPs) related to BCCL-19-0451. The Laboratory Director started gathering the data and noticed an issue with the blood drug report upon review. According to the report and supporting data, only one analytical test was used to call each positive result. Other Laboratory personnel were consulted and came to the same conclusion that only one test was used to call a positive identification. Upon further investigation, it appeared that the analyst at the time not only did not include any disclaimers or footnotes required in the SOPs regarding the screening exam, but also did not conduct any further examinations to support any findings.

> TOX-A-02-01 Screening of Blood Specimens by EMIT
> *8.2.6 EMIT only reports (no GC/MS confirmation) will have the disclaimer "A positive screen indicates the possible presence of the drug or its metabolites by drug class" or similar.*
> *8.2.7 In the circumstances in which GC/MS confirmation was not possible an explanatory footnote should appear on the report to clarify the reason confirmation(s) were not possible. The examiner has discretion as to exact wording of the footnote; examples include "insufficient sample for confirmation", "EMIT screen of specimen is positive; however unable to confirm by GC/MS" or similar wording.*

TOX-B-01-03 ABN

9.2 If sufficient data supports identification of an analyte, it shall be qualitatively reported.

TOX-A-04-01 GC/MS Screening for Drugs

7.1.4 Evaluate mass spectral data. A drug or drug metabolite is qualitatively identified if both:

7.1.4.1 The mass spectrum matches the pattern of the reference standard or library. (If the spectrum printed by the target software doesn't match due to extra or missing ions, evaluate manually to print the best possible spectrum.)

7.1.4.2 The retention time matches the retention time of the reference standard within ± 2% (If the retention times do not match, evaluate the relative time compared to the internal standard)

8.1 Drugs are reported as "Drug name detected"

9.1 Some drugs do not extract with a method used or do not chromatograph with the GC/MS conditions used. These will not be detected or cannot be eliminated as possibly being present. If such drugs are possible from case information, a specific method to enable detection should be performed.

Root Cause Analysis:
The root cause investigation was brief since the Toxicologist who performed the analysis has since retired, and everyone else in the section had previously departed from the Laboratory. Laboratory management were not able to question the analyst's or reviewer's lines of thinking in order to understand how such values came to be reported. However, it was definitely noted that less than good scientific practice was being utilized.

Level of Non-Conformity: N/A

Level of Non-Conformity Determination and its Impact on Casework:
This incident report only serves to document the findings of irregularities with the Laboratory blood drug analysis. The Laboratory withdrew its scope of accreditation in Toxicology in March 2022 based on the investigation of a 2021 nonconformance in blood alcohol analysis. This investigation lead to the conclusions that all testing in toxicology should be withdrawn. While the blood alcohol issues were readily addressed, the blood drug issues drifted into the background. This finding brings the blood drug issues to the forefront.

Preventive Action(s):

1. Contact the DA's office to inform them of the issues with past blood drug analysis.

2. Request guidance from the Texas Forensic Science Commission regarding how to proceed since we are no longer accredited in Toxicology. Depending on recommendation, possibly:
    a. Look back at previous cases to determine if other cases were affected
    b. Notify our accrediting body (ANAB) since the Laboratory was accredited during the time of analysis
3. Implement OSAC guidelines when re-building and re-writing Toxicology standard operating procedures in the future.
4. This revised CAP reflects the use of the new CAP form that was updated after the Laboratory's 2023 ANAB assessment. The new CAP form better highlights the root cause analysis and impact on casework of the nonconformance.

Proposed Corrective Action(s): N/A

Timeframe for Corrective Action(s): Unknown due to personnel constraints

Lab Quality Manager — 20 Nov. 2023 — Date

Laboratory Director — 11 Oct 2023 — Date