Quality Division Use Only

Quality Tracking #:	2020-062	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Toxicology
Date of Discovery:	07/30/20	**Date of Incident:**	07/29/20

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2020-09936 2020-09934 2020-05211 2020-05182 2020-05181 2020-05180 2020-05177	096574620 096583520 050287220 049907420 049901820 049761720 049463720

Description of Non-conformance:

A blood alcohol quality control failed to meet acceptance criteria. During blood alcohol analysis every 10 case samples must be bracketed by alternating low (BQC1) and high (BQC2) quality controls that meet acceptance criteria.

Additional Information/Follow-Up:

The Toxicology section procedure requires that every 10 case samples to be bracketed by alternating low (BQC1) and high (BQC2) blood quality controls. The target concentration values for BQC1 is 0.0754 g/100mL and BQC2 is 0.2024 g/100mL. If acceptance criteria are not met for the quality controls, the positive cases samples between those two quality controls must be reanalyzed. Upon further investigation, it was determined that the analyst had mistakenly aliquoted BQC1 into the BQC2 vial due to the resulting concentration values.

The involved analyst was interviewed, and she explained that quality control aliquot labels are handwritten. In addition, the analyst also handwrites the quality control information into the headspace vials when they are prepared/used for analysis. Since this is handwritten on headspace vials, the analyst confused her handwritten number 1 with the number 2 and mistakenly aliquoted this control sample. This situation could not happen with casework because all transfer containers and their corresponding headspace vial labels are electronically printed, and the samples are prepared and labeled in the same order as they are analyzed. In addition, one of the reasons all case samples are analyzed in duplicate is as a quality control measure to prevent and detect if case samples were mistakenly switched in the sample preparation stage.

Actions Taken:
The positive cases were reanalyzed, and the new results showed that they were within 5% or less of the original results from the first run, showing that both runs were consistent. **In order to prevent this from reoccurring, the analyst will be more cognizant and will clearly label headspace vials by handwriting the number 1 as a single vertical line so it's not confused with the number 2. In addition, a color-coding label system for blood quality controls was implemented. Each quality control has now an assigned color label that acts as an additional visual cue for the analyst. This color-coding system was discussed on August 12, 2020 at the Toxicology section meeting.**

Summary of Root Cause Analysis: Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.
N/A

Section Manager: Dayong Lee **Date:** 09/21/20

Division Director: Amy Castillo **Date:** 09/24/20

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: Erika Ziemak **Date Closed:** 09/25/20