



Quality Division Use Only

Quality Tracking #:	<input type="text" value="2020-060"/>	Classification:	<input type="text" value="Incident"/>
Non-Conformance Level:	<input type="text" value="N/A"/>	Section:	<input type="text" value="Toxicology"/>
Date of Discovery:	<input type="text" value="07/16/20"/>	Date of Incident:	<input type="text" value="07/06/20"/>

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2020-03117	028050120

Description of Non-conformance:

A blood vial with a replacement top was analyzed prior to consulting section management as required by the Toxicology SOP. This verification is required to ensure the sample matrix is appropriate for the required testing. The Toxicology Manager retroactively approved and determined that the testing for this evidence sample had been appropriate (i.e. the section can perform analysis on the sample).

Additional Information/Follow-Up:

The Toxicology section procedure requires analysts to consult with section management in instances when samples are submitted in tubes with tops of certain colors to determine if the matrix contents are appropriate for the requested testing. For example, when a blood sample is collected in a serum separator tube, this type of tube contains a clot-activating gel that separates serum from other components present in the blood sample. In this instance, only the serum could be tested. When reporting the ethanol concentration, the analyst would need to convert the serum concentration into whole blood concentration using a conversion factor described in the section procedure.

The intent of this verification requirement is to ensure the analyst is aware and paying attention to different color top tubes and applying the appropriate conversion factors when determining results. In most instances, the section proceeds and analyzes samples submitted in atypical tubes if they are the only sample available in the case. The Toxicology section has not rejected the analysis of samples submitted in atypical tubes in the last five years.



Actions Taken:

The Toxicology Manager retroactively approved and determined that the testing for this evidence sample had been appropriate. She also added the following comment to the "Toxicology BAC Batch Materials" page: "Approval for analyzing case sample 2020-03117 Item 001-01 was granted on 07/16/2020 after completion of the analysis on 07/06/2020. See quality report 2020-060 for details." The 07/16/2020 email communication with the section manager was also uploaded to the case record on 08/14/2020.

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: 08/14/20

Division Director: Amy Castillo

Date: 08/27/20

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: 08/27/20