Quality Division Use Only

Quality Tracking #:	2021-039	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Biology/DNA
Date of Discovery:	06/25/21	**Date of Incident:**	06/24/21

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2021-22995 2021-23788 2021-24728	044432721 051503321 059163621

Description of Non-conformance:

An extraction reagent blank exhibited low level allelic activity and the source of the allelic activity cannot be conclusively determined.

Additional Information/Follow-Up:

While reviewing data for the extraction an analyst noticed allelic activity in RB1_EZ21-0176 and notified the DNA Technical Leader and Technician Supervisor.

The reagent blank RB1_EZ21-0176 was reprocessed to potentially identify the step at which contamination may have occurred. The reagent blank was re-injected and DNA activity was present after re-injection. Subsequently, the reagent blank was re-amplified and DNA activity remained present after re-amplification.

Upon interview, the extracting analyst does not have specific recollection of this extraction, but it is her stated practice to document anything out of the ordinary on the worksheet. This specific extraction worksheet did not have any issues or events documented.

The technician who performed the quantification, amplification, and load procedures was also interviewed. While the analyst does not have specific recollection of this procedure, it is her stated practice to document anything out of the ordinary on the worksheet and notify a supervisor. No issues or events were documented on these specific processing worksheets.

The DNA Technical Leader reviewed the data for RB1-EZ21-0176 and was unable to source the contaminant to the elimination database or samples on the same tray. All associated samples required retesting.

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

Actions Taken:

For case 2021-22995, permission to consume was requested from the associated attorney with no response. The report was issued on January 9, 2023 with the following statement for the involved samples: "The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items & retesting will require consumption. See workflow 2021-039. Contact this analyst for additional information."

For case 2021-23788, permission to consume was requested from the associated attorney with no response. The report was issued on October 21, 2022 with the following statement for the involved samples: "The reagent blank associated with these items was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for these items & retesting will require consumption. See workflow 2021-039. Contact this analyst for additional information."

For case 2021-24728, permission to consume was requested and granted. The report was issued on October 4, 2022 with the following statement for the involved sample: "The reagent blank associated with this item was contaminated; therefore, it did not meet quality assurance standards. No results will be reported for this item. See workflow 2021-039. Contact this analyst for additional information."

Due to the nature of the activity present (determined to be single source profile but additional contributors may be possible) in RB1_EZ21-0176, the inability to source the activity, and the determination that the potential contamination occurred prior to amplification, the DNA Technical Leader decided to contact the extraction tubes vendor to submit the profile into their database. Currently, the database is experiencing information technology issues, but the profile will be submitted once these issues have been resolved. The Quality Division will revisit this issue if warranted.

Section Manager: Courtney Head **Date:** 01/19/23

Division Director: Amy Castillo **Date:** 01/19/23

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

Technical Leader: Cheron Maxwell **Date:** 01/18/2023

CODIS Administrator: Jennifer Clay **Date:** 01/19/2023

Quality Director: Erika Ziemak **Date Closed:** 01/19/23