



Quality Division Use Only

Quality Tracking #:	<input type="text" value="2018-066"/>	Classification:	<input type="text" value="Incident"/>
Non-Conformance Level:	<input type="text" value="N/A"/>	Section:	<input type="text" value="Biology/DNA"/>
Date of Discovery:	<input type="text" value="07/26/18"/>	Date of Incident:	<input type="text" value="07/26/18"/>

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2017-23471 2016-05907	158796517 045884916

Description of Non-conformance:

The laboratory has interpreted 4-person mixtures but our validation did not extend itself to these mixture types. This was a nonconformance during the 2018 ANAB Accreditation Assessment. At the time of this assessment, the laboratory had an open nonconformance involving the interpretation of a 4-person mixture that was reported to have a distinguishable major contributor. The interpretation was approved by a Forensic Biology supervisor in accordance with the laboratory's SOP. However, when the interpretation was reviewed by the Technical Leader, the mixture was determined to be more indistinguishable than previously reported (see Quality workflow 2018-050/ID# 28239).

Actions Taken:

The Forensic Biology laboratory has validated the interpretation of 4-person mixtures to allow for the interpretation of the major contributor's DNA profile in cases where the mixture meets specific criteria and revised its SOP to forbid the interpretation of 4-person mixtures that do not meet these criteria. While the consensus is that 4-person mixtures are not commonly received by the laboratory, it is not possible to support this statement with metrics because the laboratory does not currently have a method by which to track these types of samples within the Porter Lee Laboratory Information Management System (LIMS). The laboratory commits to issuing amended reports and/or removing any potential profiles from CODIS that are not supported by validation data, if discovered by any means. Amended reports will be issued with the following statement: "A mixture of DNA from at least four contributors, at least 2 of whom are male, was obtained from this item. This mixture is not suitable for comparison due to an excessive number of contributors. See Incident Report 2018-066. Upon request, this complex mixture may be considered a candidate for reinterpretation once further validation is complete." Additionally, the laboratory recognizes that in scenarios where approval is needed from the technical leader, manager or a supervisor, this approval is only being documented on paper within the case file. A Qualtrax workflow was created in order for section management to document future approvals in a manner that is transparent and trackable.



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

Additional Information/Follow-Up:

The DNA Interpretation SOP was revised to the following: "A mixture assumed to be of four contributors must have a major (single contributor) at all loci or the approval of the Technical Leader, the Forensic Biology Manager, or the DNA Interpretation Supervisor. Due to the uncertainty introduced in complex mixtures from allele sharing/stacking, major/minor deconvolutions shall adhere to the 60% PHR of a single-source profile and the 25% PHR criteria of a major/minor deconvolution, without the subtraction of possible stutter, at a minimum of sixteen of the twenty-one STR loci."

Section Manager: Courtney Head

Date: 09/11/18

Division Director: Amy Castillo

Date: 09/11/18

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

Technical Leader: Robin Guidry

Date: 09/11/2018

CODIS Administrator: Jennifer Clay

Date: 09/11/2018

Quality Director: Lori Wilson

Date Closed: 09/11/18