



Quality Division Use Only

Quality Tracking #:	2020-031	Classification:	Corrective Action
Non-Conformance Level:	Class II	Section:	Biology/DNA
Date of Discovery:	04/22/20	Date of Incident:	10/17/17

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2015-16944 2016-20493 2017-01250 2017-10242 2017-14331 2017-16173 2017-17655 2017-22711 2018-09438 2016-00678 2016-05850 2017-15017 2017-17851 2017-19615 2017-23167 2017-23705 2018-07147 2018-07863 2016-18965 2016-20520 2017-12619 2017-13543 2017-15019 2017-17803 2017-19613 2017-20523 2018-05338 2018-07438 2016-20852	159054615 136234916 001372817 065666517 092910617 112027617 118622317 136677017 080591018 005507116 042619416 099220317 114282017 128381217 149968017 161106217 058801818 066024418 123570516 136511416 080048817 088175117 099031317 092731317 129909717 136642417 041520018 061443718 124649616

Description of Non-conformance:

As part of the investigation into an incorrect deduction made by a DNA report writer as part of Quality Corrective Action Report 2018-085 and the final report being issued by the Texas Forensic Science Commission in July 2018 that addressed complaint 17.04 in which the panel reported observations of inadequacies in the HFSC training program and recommended HFSC “review a representative sample of DNA mixture casework for newly qualified analysts to ensure protocols are being applied appropriately”, the Forensic Biology section committed to reviewing previously reported mixture deductions from all DNA report writers. Quality Report 2020-031 is being used to document the review of cases completed by one DNA report writer who was first authorized as an interpreting analyst in 2013.

Additional Information/Follow-Up:

As the lab transitioned from the Identifiler Plus amplification kit to the Globalfiler amplification kit in January 2017, it was apparent through validation data that the peak height balance between heterozygous peaks was not consistent with the validated percentages previously seen with Identifiler Plus data. The observed artifacts were also elevated more frequently in validation data generated with the Globalfiler amplification kit. This empirical data was discussed during the training process of shifting to a new amplification kit (Identifiler Plus to Globalfiler); however, it became apparent once more casework data was generated that additional discussions and training would need to be implemented regarding deductions. As a result, the Forensic Biology section strengthened the SOP with regard to deductions. The Forensic Biology section also developed additional training and created practice sets and a competency test to demonstrate compliance. The review of this DNA report writer spanned casework containing deductions written between May 2016 (the date when deductions were permitted by the DNA Interpretation SOP) and December 2018. The query showed that 844 reports had been issued by this DNA report writer between May 2016 and December 2018. A process of elimination was used to narrow down the list of cases that contained deductions. Each report was reviewed for the word “deduced”, because analysts used a specific report statement that included this word only when a deduction was made. If the word “deduced” did not



appear in the report, the case was eliminated from the list of cases to review. Of these 844 issued reports, 52 contained deductions. Once the list was narrowed down to cases with deductions, the list was further reduced by eliminating cases where the deduced profile appeared in multiple samples, because it was reasoned to be of low risk since a different profile (single source or major component) had been entered into CODIS, or the case was pending review for Quality Corrective Action Report #2018-IA-09, as this would also encompass a review of deductions, leaving 28 potential cases available for review. The Forensic Biology Assistant Technical Leader (ATL) initially reviewed the deductions in nine of the 28 potential cases available for review: 2015-16944, 2016-20493, 2017-01250, 2017-10242, 2017-14331, 2017-16173, 2017-17655, 2017-22711, and 2018-09438. These cases were randomly chosen from the following time periods to obtain a representative sample of deductions: May and November 2016; August and November 2017; and May, August, and October 2018. These cases included both Identifiler Plus and Globalfiler data. The ATL independently interpreted each DNA profile in which a deduction was originally made. The ATL then compared her deduction to the original deduction. In addition, the ATL created a rating system that ranked the risk of missing a CODIS association based on any differences between her interpretation and the original deduction/CODIS entry. Differences in interpretation (or the lack of) were rated as follows: 0-no risk, 1-low risk, 2-medium risk, and 3-high risk of not obtaining a potential CODIS association. The nine cases reviewed were rated as follows: 0-no risk (2016-20493, 2017-01250, 2017-14331, 2017-17655, 2017-22711, and 2018-09438); 1-low risk (2015-16944); 2-medium risk (2017-10242); and 3-high risk (2017-16173). The cases rated low to high risk were given to the DNA Interpretation Supervisor at the time, for an additional level of review to ascertain if the concerns raised by the ATL were reasonable and if an amended report and/or CODIS entry modification was justified. Although the cases were provided to the DNA Interpretation Supervisor at that time for review that supervisor is no longer employed at HFSC and there is no documentation that a review occurred. When a new DNA Interpretation Supervisor was selected, the cases were then provided to her for review. Based on the risk ratings, the Technical Leader at the time made the decision to review the remaining cases with deductions. The ATL reviewed the deductions in the remaining 19 cases which also included both Identifiler Plus and Globalfiler data. The same process was used to assess the deductions. The following cases reviewed were rated as 0-no risk: 2016-18965, 2016-20520, 2017-12619, 2017-13543, 2017-15019, 2017-17803, 2017-19613, 2017-20523, 2018-05338, and 2018-07438. The following cases were rated as 1-low risk to 3-high risk: 2017-17851 (low), 2017-19615 (low), 2017-23705 (low), 2016-00678 (high), 2016-05850 (high), 2017-15017 (high), 2018-07147 (high), and 2018-07863 (high). These cases were provided to the current DNA Interpretation Supervisor. Case 2017-23167 was rated as low risk by the ATL but once reviewed by the DNA Interpretation Supervisor and Forensic Biology Manager, the decision was made to not amend the original deduction. Additionally, case 2017-10242 (reviewed in the first wave of cases) was rated as medium by the ATL but was ultimately reviewed/modified as part of Quality Corrective Action Report #2018-IA-09. DNA Interpretation Supervisor agreed with all the ATL's risk assessments. The review of these 28 cases revealed a heavy reliance on allelic balance for deducing. The report writer did not consistently consider the additive effects of stutter in the peak heights of alleles identified in stutter positions. The report writer also was using estimated contributor ratios and evaluating the profile as a whole when deducing rather than applying the stochastic threshold at each locus and considering dropout when the RFUs for an observed allele were lower than the stochastic threshold. The SOP used at the time of this incident was not clear and allowed for analyst discretion. No further training was recommended specifically for this report writer, as all analysts have had additional training and an accompanying quiz.



Summary of Root Cause Analysis:

Note: Incidents are documented for tracking purposes and trend analysis. Root Cause Analysis is not required for incidents.

When the Forensic Biology section first implemented mixture deductions, the SOP provided guidelines, but no formal competency test was provided. Therefore, although the expectation was for staff to adhere to the guidelines, there was no mechanism in place to demonstrate a clear understanding of said guidelines. The SOP deduction guidelines have since been enhanced to provide more restrictions and decrease reliance upon analyst discretion when interpreting and deducing mixtures. All interpreting analysts (including this specific DNA report writer) have now been given an opportunity to demonstrate their ability to conservatively deduce.

Actions Taken:

As part of the Forensic Biology section's course of action to address deductions, the DNA report writers were involved in numerous conversations and refresher trainings associated with performing more conservative deductions. In March 2021, the Forensic Biology Manager and DNA Interpretation Supervisor met with this DNA report writer to discuss next steps. It was decided that all cases reviewed were to be re-interpreted using STRmix and a new report issued with the STRmix interpretation conclusions. Case 2017-16173 had already been reset in LIMS, prior to the decision to reinterpret the cases using STRmix therefore, an amended report was issued for case 2017-16173 but a subsequent report was then also issued regarding the reinterpretation of item 2.11.1.1 using STRmix. For case 2017-16173, the report was amended on July 26, 2021, with the following statement: The following DNA results and interpretations for Item 2.11.1.1 (Portion of stain from panties - Sperm Fraction) will supersede any previously reported DNA results to reflect current interpretation and statistical guidelines. See Quality Report #2020-031 for additional information. This case was the only case in which re-interpretation occurred without using STRmix as this was the first case that was discussed in reference to this nonconformance. A summary spreadsheet (see below) was created to record what changes, if any, occurred due to the reamplification with Globalfiler chemistry and/or the use of STRmix in 10 cases. The original CODIS specimen category was changed in 5 cases, obligate alleles were added in 5 cases, additional loci were added in 4 cases, and one profile was removed from CODIS. The number of contributors also changed in 3 cases. As of August 1, 2022, there has been no new viable CODIS activity since the CODIS entries in these cases were modified. In addition to the review of cases for this Quality corrective action report, the Forensic Biology section has several other quality measures in place with regard to historical deductions. Over 1,200 DNA profiles were reviewed and modified if applicable as part of Quality Corrective Action 2018-IA-09. The Forensic Biology section also created a set of pre-comparison review guidelines. These guidelines should be followed when a known reference sample is submitted for DNA comparison and the case includes certain criteria associated with a DNA mixture reported prior to September 10, 2018. Pursuant to Quality Corrective Action 2018-066 (a finding during HFSC's 2018 accreditation assessment) the Forensic Biology section committed to issuing amended reports and/or removing any potential profiles from CODIS that are not supported by validation data, if discovered by any means since they don't have a method by which to specifically track these types of samples within the Porter Lee Laboratory Information Management System (LIMS). Lastly, it is Forensic Biology section practice to review casefiles prior to testimony and make revisions or amendments in order to be aligned with current interpretation guidelines as necessary. Prior to the closing of this workflow the report for case 2016-20852 was amended. As opposed to initiating a separate quality workflow to track this amendment, information about the amendment was included in this quality corrective action workflow since it involved an amended report due to changes to an original interpretation. The



amended report statement for case 2016-20852 included a reference to quality corrective action workflow 2020-031.

Section Manager: Courtney Head **Date:** 08/25/22
Division Director: Amy Castillo **Date:** 09/02/22

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

Technical Leader: Cheron Maxwell **Date:** 08/10/2022
CODIS Administrator: Jennifer Clay **Date:** 08/12/2022
Quality Director: Erika Ziemak **Date Closed:** 09/15/22



Summary Spreadsheet

FCN	Reamplify or Reinterpret	Item#	Original CODIS Specimen Category	Updated CODIS Specimen Category	Notes
2016-05850	original ID+, reamplified w/GF use STRmix	1.4.1-EF		Removed from CODIS	changed to mixture of 3, unable to pull a CODIS profile so original entry was removed from CODIS
2017-23705	reinterpret with STRmix	3.2.1-SF	Forensic Mixture	Forensic Mixture	modification of CODIS entry, obligate (+) added to 4 loci, entry at D2S1338 changed from 21 to 21+,22
2016-00678	original ID+, reamplified w/GF use STRmix	1.3.1-SF	Forensic Unknown	Forensic Mixture	original CODIS entry was Forensic Unknown, after re-amplification CODIS entry modified to Forensic Mixture; however, no alleles from original entry were modified, one new GF locus (D2S441 11+,14)
2016-00678	original ID+, re-amplified w/GF use STRmix	1.9.1-EF	none	none	
2016-00678	original ID+, reamplified w/GF use STRmix	1.17.1-SF	none	none	changed to mixture of 3
2015-16944	original ID+, reamplified w/GF use STRmix	1.6.1.1-EF	Forensic Partial	Forensic Mixture	changed to mixture of 3, CODIS profile modified from Forensic Partial to Forensic Mixture 7 loci from original entry modified
2018-07863	reinterpret with STRmix	1.2.1-SF	Forensic Partial	Forensic Mixture	CODIS entry changed to Forensic Mixture, obligates and/or additional alleles add to 10 loci
2018-07147	reinterpret with STRmix	1.2.1-SF	Forensic Mixture	Forensic Unknown	Original CODIS entry changed from Forensic Mixture to Forensic Unknown
2017-17851	reinterpret with STRmix	1.1.1-EF	none	none	No CODIS entry in original report due to potential biological relationship, same result using STRmix
2017-19615	reinterpret with STRmix	1.11.2.1-EF	none	none	NO CODIS entry in original report due to not enough loci to meet SDIS entry requirement, same result using STRmix
2017-15017	reinterpret with STRmix	2.6.1-EF	SDIS Forensic Partial	SDIS Forensic Mixture	Original CODIS entry was SDIS Forensic Partial, only modification to profile was D8, original entry 11,13 modified to 10,11,12,13+ entry modified to SDIS Forensic Mixture
2017-16173	Report #1 amended; Report #2 reinterpret with STRmix	2.11.1.1-SF	Forensic Unknown	Forensic Mixture	Original CODIS entry changed from Forensic Unknown to Forensic Mixture, changes at 4 loci: TH01 9 to 7,9+; FGA 21,25 to 21+,25; D10 13,14 to 13,14+; D1 13,16.3 to 13+,16.3