Quality Division Use Only

Quality Tracking #:	2020-108	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Biology/DNA
Date of Discovery:	12/16/20	**Date of Incident:**	10/15/20

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2019-18403	**146540219**

Description of Non-conformance:

A reagent blank was amplified at a lower volume than two of the samples in the amplification set (item 1.2.1 "portion of outer labia majora swabs – fraction 1" and item 1.3.1 "portion of inner labia majora/labia minora swabs – fraction 1"). The data from the two samples was initially reported due to a miscommunication between the case analyst and the Technical Leader.

Additional Information/Follow-Up:

The original electropherogram for the reagent blank RB1_QC20-0113SF_F1 exhibited low level allelic activity. The reagent blank was reinjected and yielded similar results. The reagent blank was then re-amplified in accordance with standard operating procedures. The analyst performing the re-amplification noted on the "Request for Amplification" worksheet that only 11.6uL of the reagent blank extract were remaining and proceeded with the re-amplification procedure using the remaining 11.6uL to perform the re-amplification. After the re-amplification procedure was finished, the Technical Leader reviewed the resulting reagent blank data, using only the electropherograms in order to determine if the reagent blank and its associated samples were approved for interpretation and reporting purposes. During her review, the Technical Leader did not have all of the supporting documentation/worksheets for the re-amplification in her possession and therefore was not aware that only 11.6uL of the reagent blank were used to perform the re-amplification procedure. After the Technical Leader reviewed the re-amplification data she documented her approval of the data for interpretation and reporting purposes on the electropherogram. Her documentation included the statement "This reagent blank and its associated sample may be used for interpretation". The report writer for case 2019-18403 interpreted this statement to mean that all associated data was approved for interpretation and reporting purposes, including the items 1.2.1 and 1.3.1 from 2019-18403 that were amplified using more than 11.6uL, and the data was reported.

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:
While reviewing the electropherogram data associated with the re-amplification of the reagent blank, the Technician Supervisor read the note on the re-amplification worksheet and sought clarification. It was unclear to the Technician Supervisor if the note indicated that 11.6uL were used in the re-amplification or if 11.6uL were remaining after the re-amplification. The analyst who performed the re-amplification clarified that his note indicated that 11.6uL were used during the re-amplification. The Technician Supervisor then realized two of the associated samples from case 2019-18403 were amplified using more than 11.6uL and notified both the Technical Leader and the Quality Division. The analyst who performed the re-amplification, the Technician Supervisor, the case analyst, a quality specialist and the Technical Leader met to discuss this incident and how to prevent recurrence. The Technician Supervisor presented information at the January 7, 2021 technician meeting regarding the best practices when conducting re-injections and re-amplifications including, but not limited to, notifying the case analyst when there is less than 15uL remaining in a reagent blank prior to performing the re-amplification procedure. In addition, the Technical Leader will now review all supporting documentation/worksheets associated with a reagent blank as part of her approval process. This will help prevent oversight of additional information that is important to the case. In addition, the Technician Supervisor and technicians will be including a link to the technician documentation/worksheets with requests for Technical Leader review so that its readily accessible. Once the miscommunication between what the case analyst interpreted the statement to mean and what the Technical Leader had intended was identified, the report was amended to rescind the interpretation of the two samples that were amplified using more than 11.6uL. The report was issued with the following statement and the case analyst emailed the investigator in the case to inform him of the reason for the report amendment: Laboratory Report #1 dated October 15, 2020 has been amended to omit the reported results of Item 1.2.1 (Fraction 1) and Item 1.3.1 (Fraction 1). The original laboratory report is available at the Houston Forensic Science Center upon request. In addition, the following statement was included for both items 1.2.1 and 1.3.1: Data for these items did not meet quality assurance standards and therefore will not be reported. See Quality Report #2020-108 for more information.

Section Manager: Courtney Head **Date:** 12/29/21

Division Director: Amy Castillo **Date:** 12/29/21

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

Technical Leader: Cheron Maxwell **Date:** 11/29/2021

CODIS Administrator: Jennifer Clay **Date:** 12/17/2021

Quality Director: Erika Ziemak **Date Closed:** 12/30/21