Quality Division Use Only

Quality Tracking #:	2021-003	**Classification:**	Incident
Non-Conformance Level:	N/A	**Section:**	Biology/DNA
Date of Discovery:	07/16/20	**Date of Incident:**	07/13/20

Forensic Case Number(s), if applicable:	Agency Case Number(s), if applicable:
2020-01847 **2020-00361**	**015999420** **001876220**

Description of Non-conformance:

A differential extraction reagent blank exhibited low level allelic activity. While the source of the allelic activity cannot be conclusively determined, there is one sample within the extraction set that cannot be excluded as the possible source.

Additional Information/Follow-Up:

While reviewing the data for the worklist an analyst noticed allelic activity in reagent blank RB1_QC20-0202 SF-F1 and notified forensic biology management via email. The technical leader advised the analyst to re-inject, but upon re-injection the allelic activity was still present. The technician supervisor then submitted a re-amplification request, and after re-amplification the allelic activity was still present, and a contamination workflow was initiated.

Upon interview, the extracting analyst handled the samples in the order specified in the worksheet, where the reagent blank is always handled after the associated samples. While the analyst doesn't have specific recollection of this extraction, it is her stated practice to document anything out of the ordinary on the worksheet. This specific worksheet did not have any issues or events documented.

The technician that conducted the quantification and the amplification is no longer employed at HFSC and is therefore not available for interview. The technician that conducted the verification of the "Quant Checklist" was interviewed and noted that he only conducted the verification and could not recall this specific instance. He mentioned that when he performs the quantification process, he would write a note in the documents, if warranted, indicating what he observed and, depending on the severity of the observation, he would notify the technician supervisor.

Although reprocessing did not indicate the potential contamination happened at the injection step, the technician that loaded the plate was interviewed. She did not have a recollection of this specific set of samples but indicated that if anything was out of the ordinary in any run, she would document this in the "Notes" section of the Amplification and Load Checklist and/or at the end of the "GF Tecan Amplification Setup Worksheet". Also, depending on the severity of what occurred, she would notify the technician supervisor and if the issue was instrument related, she would notify the operations coordinator.

The technical leader reviewed the data and determined that RB1_QC20-0202 SF-F1 contained 2 peaks below analytical threshold (at TPOX and D22) and 2 peaks above analytical threshold (at D10 and D2). The low-level activity is consistent with a sample in the same extraction set (2020-01847_2.1.1 SF) but because the activity in the reagent blank is low-level it is difficult to determine with certainty if this sample is the source of the contamination.

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 2020-01847, permission to consume was requested from the associated attorney but no response was received. Fraction 1 for items 2.1.1, 2.2.1, 2.3.1, 2.4.1, and 2.6.1.1 were reported with the following statement: The reagent blank associated with these items did not meet quality assurance standards. No results will be reported for these items. Retesting will require the consumption of these items, please contact the analyst for more information. See Quality Report 2021-003.
For case 2020-00361, based on her review of the data for item 1.3.1 fraction 1, the technical leader does not recommend re-processing at this time, but this sample can be reprocessed if requested. Fraction 1 item 1.3.1 was reported with the following statement: The reagent blank associated with this item did not meet quality assurance standards. No results will be reported for this item. Retesting will require the consumption of this item, please contact the analyst for more information. See Quality Report 2021-003.

	Courtney Head		09/01/22
Section Manager:		**Date:**	
Division Director:	Amy Castillo	**Date:**	09/06/22

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

Technical Leader:	Cheron Maxwell	**Date:**	08/16/2022
CODIS Administrator:	Jennifer Clay	**Date:**	09/01/2022

Quality Director:	Erika Ziemak	**Date Closed:**	09/08/22